The

Canadian Supplement, 1944, to the British Pharmacopoeia

Being DIVISION III of the
Regulations under the
FOOD AND DRUGS ACT

Made by Order in Council
P.C. 2515, April 11, 1944

DEPARTMENT OF PENSIONS AND NATIONAL HEALTH
OTTAWA

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[2515]

AT THE GOVERNMENT HOUSE AT OTTAWA

TUESDAY, the 11th day of April, 1944.

PRESENT:

HIS EXCELLENCY THE GOVERNOR GENERAL IN COUNCIL

WHEREAS the Minister of Pensions and National Health reports that it is deemed necessary in the public interest that regulations be made prescribing standards of quality and potency and defining official methods for testing of and with respect to drugs named in Part V of Schedule B of the Food and Drugs Act, and, further, that such regulations become Division III of the existing regulations made pursuant to such Act, and that the contents of Division III of such regulations may be known and cited as "The Canadian Supplement to the British Pharmacopoeia";

Now, THEREFORE, His Excellency the Governor General in Council, on the recommendation of the Minister of Pensions and National Health, and under the authority of the Food and Drugs Act, is pleased to amend the regulations under the Food and Drugs Act established by Order in Council P.C. 9056 of October 6, 1942, and they are hereby further amended by adding the following thereto as Division III thereof:

DIVISION III

CANADIAN SUPPLEMENT TO BRITISH PHARMACOPOEIA

The standards of quality and potency of the drugs mentioned in Part V of Schedule B of the Food and Drugs Act and the official methods for testing such drugs shall respectively conform to and be judged by the standards and methods described as follows:—

GENERAL NOTES

(1) Abbreviations

The following abbreviations have been used throughout the text of this Division:

"Gm"	for	gramme
"mgm(s)"	"	milligramme(s)
"mil(s)"	"	millilitre(s)
"N/1"	"	normal volumetric solution
"N/2", "N/10", "N/200", etc.	"	half-, tenth-, two hundredth-normal volumetric solution as the case may be

(2) Temperature

All temperatures are expressed in degrees Centigrade at normal atmospheric pressure (760 millimetres of mercury) unless otherwise stated.

(3) Solubilities and Specific Gravities

Solubilities and specific gravities are to be determined at 25° unless otherwise stated.

(4) Reagents and Solutions

The names of all substances printed in italics in the following monographs refer to materials and solutions used in tests, and are described in Appendices I and II to the British Pharmacopoeia, or may be found in the Appendices to this Division of the Regulations.

(5) Tests for Identity

Qualitative tests for basic and acid radicles, not specifically described in the text, may be found in Appendix V to the British Pharmacopoeia.

(6) Quantitative Tests for Lead and Arsenic

These tests are described in Appendices VI and VII to the British Pharmacopoeia.

(7) Limit Tests

The limit tests referred to in the following monographs are described in Appendix VIII to the British Pharmacopoeia.

(8) Physical and Chemical Constants

The methods of determination are described in Appendices IV, X, and XI to the British Pharmacopoeia.

(9) Test for Absence of Cottonseed Oil

This test is described on page 575 of the British Pharmacopoeia.

(10) Determination of Ash and of Alcohol-Soluble Extractive

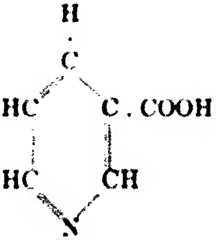
The methods are described in Appendix XII to the British Pharmacopoeia.

ACIDUM NICOTINICUM

(Acid. Nicotin.)

Nicotinic Acid

Synonym.—NIACIN



$C_6H_5NO_2$ Mol. Wt. 123·0

Nicotinic Acid shall be pyridine-β-carboxylic acid and may be prepared by the oxidation of nicotine with a suitable oxidizing agent. When assayed by the method described herein, it shall contain not less than 99·5 per cent of $C_6H_5NO_2$, calculated with reference to the substance dried over sulphuric acid for 3 hours; and shall conform to the following specification with respect to characters, tests for identity and tests for purity.

Characters.

Description.—Nicotinic Acid occurs as white crystals or as a white crystalline powder. It is odourless or it may have a slight odour. The taste is feebly acid.

Solubility.—Nicotinic Acid dissolves in 60 parts of *water* at 25°; it is freely soluble in boiling *water* and in boiling *alcohol*, and also in aqueous solution of alkali hydroxides and carbonates, but is almost insoluble in *ether*.

Melting point.—The *melting point* of Nicotinic Acid lies between 234° and 237°.

Test for Identity.

Triturate Nicotinic Acid with twice its weight of *dinitrochlorobenzene*. Gently heat 10 mgms. of the mixture until melted and continue heating for a few seconds longer. Cool, and add 3 mils of *alcoholic solution of potassium hydroxide;* a deep red or deep wine-red colour is produced.

Dissolve 50 mgms. of Nicotinic Acid in 20 mils of *water* and neutralize to *litmus paper* with *N/10 sodium hydroxide;* then add 3 mils of *solution of copper sulphate;* a blue precipitate is formed gradually.

Tests for Purity.

Chlorides and sulphates.—One Gm. of Nicotinic Acid complies with the *limit test for chlorides* and with the *limit test for sulphates.*

Lead.—The *lead limit* in Nicotinic Acid is 20 parts per million.

Loss on drying and ash.—Nicotinic Acid loses, when dried over sulphuric acid for 3 hours, not more than 1 per cent of its weight, and leaves, on incineration, not more than 0·05 per cent of ash.

Assay.

Dissolve about 0·3 Gm. of Nicotinic Acid, previously dried over sulphuric acid for 3 hours and accurately weighed, in 50 mils of recently boiled and cooled *water* and titrate with *N/10 sodium hydroxide*, using *solution of phenolphthalein* as indicator. Each mil of *N/10 sodium hydroxide* represents 0·0123 Gm. of $C_6H_5NO_2$.

Storage.

Nicotinic Acid should be kept in well-closed containers.

Doses

— daily —

Metric	Imperial
25 to 100 mgms.	½ to 1½ grains.

ACIDUM PHOSPHORICUM

(Acid. Phosph.)

Phosphoric Acid

H_3PO_4 Mol. Wt. 98.04

Phosphoric Acid shall contain not less than 85 per cent and not more than 88 per cent w/w of H_3PO_4, when assayed by the method described herein: and shall conform to the following specification with respect to characters, test for identity and tests for purity.

Characters.

Description.—Phosphoric Acid is a colourless, odourless liquid of syrupy consistence. It is miscible with water. When heated, it loses water and is converted finally into metaphosphoric acid, which, on cooling, forms a transparent mass.

Test for Identity.

Reaction.—Phosphoric Acid is strongly acid, even when diluted freely. It yields, when neutralized, the reactions characteristic of phosphates.

Tests for Purity.

Specific Gravity.—The *specific gravity* of Phosphoric Acid is about 1·71 at 25°.

Alkali Phosphates.—Transfer 1 mil of Phosphoric Acid to a graduated cylinder, and add 6 mils of *ether* and 2 mils of *alcohol (95 per cent)*; no turbidity appears.

Phosphorous and Hypophosphorous Acid.—Dilute 0·5 mil of Phosphoric Acid with 10 mils of *water*, and warm with 2 mils of *solution of silver nitrate*: the mixture does not become brown.

Chlorides.—Using 1 mil, Phosphoric Acid complies with the *limit test for chlorides.*

Sulphates.—Using 0·5 mil, Phosphoric Acid complies with the *limit test for sulphates.*

Iron.—Using 0·1 mil, Phosphoric Acid complies with the *limit test for iron.*

Arsenic.—The *arsenic limit* in Phosphoric Acid is 5 parts per million.

Lead.—The *lead limit* in Phosphoric Acid is 10 parts per million.

Assay.

Mix about 2 Gm. of Phosphoric Acid, accurately weighed, with a solution of 10 Gm. of *sodium chloride* in 30 mils of *water*, and titrate with *N/1 sodium hydroxide*, using *solution of phenolphthalein* as indicator. Each mil of *N/1 sodium hydroxide* is equivalent to 0·04902 Gm. of H_3PO_4.

Preparation.

Acidum Phosphoricum Dilutum.

ACIDUM PHOSPHORICUM DILUTUM

(Acid. Phosph. Dil.)

Dilute Phosphoric Acid

Dilute Phosphoric Acid shall be prepared from the following ingredients in the amounts specified; it shall contain not less than 9·5 per cent and not more than

10·5 per cent w/w of H_3PO_4 when assayed by the method indicated herein; and shall conform to the following specification with respect to tests for purity.

Phosphoric Acid	116 Gm.	(68 mils)
Distilled Water	884 Gm.	(884 mils)

Tests for Purity.

Specific Gravity.—The *specific gravity* of Dilute Phosphoric Acid is about 1·057 at 25°.

Dilute Phosphoric Acid complies with the Tests for Purity described under "Acidum Phosphoricum", when eight times the quantity is taken for each test.

Assay.

Carry out the Assay as described under "Acidum Phosphoricum", using about 10 Gm. accurately weighed.

Doses

Metric	Imperial
0·3 to 4 mils	5 to 60 minims.

ALCOHOLIA LANAE

(Alcohol. Lan.)

Wool Alcohols

Wool Alcohols shall consist of the fraction of the grease of the wool of sheep containing cholesterol and other alcohols. When assayed by the method described herein, it shall contain not less than 28 per cent of cholesterol and it shall conform to the following specification with respect to characters, test for identity and tests for purity.

Characters.

Description.—Wool Alcohols occur as a golden brown solid, somewhat brittle when cold, but becoming plastic when warm; the odour is faint and the fracture smooth and shiny.

Solubility.—Wool Alcohols are insoluble in *water*, moderately soluble in *alcohol (90 per cent)*, and freely soluble in *ether*, in *chloroform*, and in *light petroleum*; it is completely soluble in 25 parts of boiling *dehydrated alcohol*.

Test for Identity.

Dissolve 0·5 Gm. of Wool Alcohols in 5 mils of *chloroform*, add 1 mil of *acetic anhydride* and 2 drops of *sulphuric acid*; a green colour is produced.

Tests for Purity.

Constants.—The *melting point* of Wool Alcohols is not below 54°; the *acid value*, not more than 3; the *saponification value* (two hours' boiling with the alcoholic solution of *potassium hydroxide*), not more than 12; and the *acetyl value*, not less than 130 and not more than 140.

Free alkali.—Dissolve 2 Gm. of Wool Alcohols in 25 mils of hot *alcohol (90 per cent)* which has been freshly boiled and neutralized while hot after the addition of 2·5 mils of *solution of phenolphthalein*; no red colour is produced.

Loss on drying and ash.—Wool Alcohols lose, when heated at 100° for one hour, not more than 0·5 per cent in weight; and leave, on incineration, not more than 0·3 per cent of ash.

Assay.

Dissolve 0·1 Gm. of Wool Alcohols, accurately weighed, in 12 mils of *alcohol (90 per cent)*, allow to stand at laboratory temperature for twelve hours, filter through a Gooch crucible and wash with 5 mils of *alcohol (90 per cent)*; to the filtrate and washings add 40 mils of a 0·5 per cent w/v solution of *digitonin* in *alcohol (90 per cent)* and warm to 60°. Collect the precipitate in a Gooch crucible, wash with *alcohol (90 per cent)* and dry at 100°. Each Gm. of residue is equivalent to 0·239 Gm. of cholesterol.

ALCOHOL TRIBROMOETHYLICUM

(Alcoh. Tribromoethyl.)

Tribromoethyl Alcohol

Synonym.—TRIBROMETHANOL

$CBr_3.CH_2OH$ Mol. Wt. 282.8

Tribromoethyl Alcohol may be prepared by reduction of tribromoacetaldehyde. When assayed by the method described herein, it contains, when dried over sulphuric acid for 18 hours, not less than 99 per cent of $CBr_3.CH_2OH$, and shall conform to the following specification with respect to characters, test for identity and tests for purity.

Characters.

Description.—Tribromoethyl Alcohol is a white crystalline powder, unstable in air; odour and taste, slightly aromatic.

Solubility.—Tribromoethyl Alcohol is soluble in about 35 parts of water at 25°. It is readily soluble in *light petroleum* and in *amylene hydrate.* An aqueous solution of Tribromoethyl Alcohol is unstable.

Melting point.—The *melting point* of Tribromoethyl Alcohol lies between 79° and 81°.

Test for Identity.

A dilute aqueous solution, after warming with *solution of sodium hydroxide*, and neutralising, yields the *reactions* characteristic of bromides.

Tests for Purity.

Reaction.—A 2 per cent w/v solution of Tribromoethyl Alcohol in warm *water* at about 40° is not acid to *solution of methyl red.*

Dibromoacetaldehyde.—Dissolve about 0·1 Gm. of Tribromoethyl Alcohol in 5 mils of *water* at about 40°, cool, add 1 mil of *solution of phenylhydrazine acetate;* no precipitate forms after standing for thirty minutes.

Readily carbonisable substances.—Dissolve 0·1 Gm. of Tribromoethyl Alcohol in 2 mils of *nitrogen-free sulphuric acid;* the solution is colourless, or at most, faintly brown.

Ionised halogens.—To 10 mils of a 2 per cent w/v solution of Tribromoethyl Alcohol in *water*, prepared at 40° and cooled, add 0·5 mil of *solution of silver nitrate;* no immediate opalescence is produced.

Sulphates.—To 10 mils of a 2 per cent w/v aqueous solution of Tribromoethyl Alcohol add 0·5 mil of *solution of barium chloride* and allow to stand for five minutes; no turbidity is produced.

Heavy metals.—To 10 mils of a 2 per cent w/v aqueous solution of Tribromoethyl Alcohol add 1 drop of *solution of sodium sulphide;* no darkening is produced.

Ash.—Tribromoethyl Alcohol leaves, on incineration, not more than 0·05 per cent of ash.

Assay.

Dissolve about 0·3 Gm. of Tribromoethyl Alcohol, previously dried over *sulphuric acid* for 18 hours and accurately weighed, in 20 mils of *N/1 sodium hydroxide.* Boil for two hours under a reflux condenser. Cool, add 20 mils of *dilute nitric acid* and 50 mils of *N/10 silver nitrate,* and titrate with *N/10 ammonium thiocyanate,* using *solution of ferric am-*

monium sulphate as indicator. Each mil of *N/10 silver nitrate* is equivalent to 0·009426 Gm. of $CBr_3.CH_2OH$.

Storage.

Tribromoethyl Alcohol should be kept in a well-closed container, protected from light.

Doses

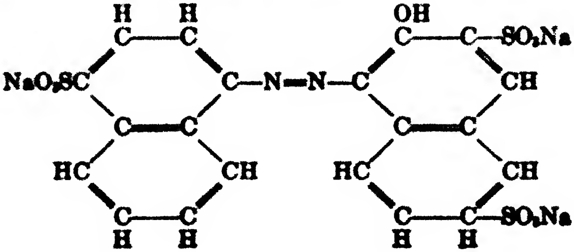
Metric	Imperial
By rectal injection as a basal anaesthetic.	
0·075 to 0·1 Gm. per kilogram of body weight.	½ to ¾ grain per pound of body weight.

AMARANTHUM

(Amaranth)

Amaranth

Synonym.—FD&C, Red No. 2



$C_{20}H_{11}N_2O_{10}S_3Na_3$ Mol. Wt. 604·3

Amaranth [Colour Index (Society of Dyers and Colourists) No. 184] shall be the trisodium salt of 1-(4-sulpho-1-naphthylazo)-2-naphthol-3:6-disulphonic acid, and may be prepared by the coupling of diazotised 1-naphthylamine-4-sulphonic acid with 2-naphthol-6:8-disulphonic acid.

Characters.

Description.—Amaranth occurs as a dark, red-brown powder.

Solubility.—Amaranth is soluble in about 15 parts of *water*, giving a red solution; it is very slightly soluble in *alcohol (95 per cent)*.

Standard.

Amaranth shall be from stocks specially prepared for food purposes, (*see* Section V, Division 1, of these Regulations), and shall not contain more than 10 parts per million of arsenic, calculated as As_2O_3, and, with the exception of iron, shall not contain heavy metals.

AMYLENI HYDRAS

(Amylen. Hydr.)

Amylene Hydrate

Synonym.—TERTIARY AMYL ALCOHOL.

$(CH_3)_2(C_2H_5)C.OH$ Mol. Wt. 88.09

Amylene Hydrate shall be dimethylethylcarbinol, and may be prepared by the hydration of amylene; it shall conform to the following specifications with respect to characters, tests for identity and tests for purity.

Characters.

Description.—Amylene Hydrate occurs as a clear, colourless, volatile liquid at ordinary temperatures; at temperatures below -13° it forms hygroscopic acicular crystals; the taste is pungent and burning; and the odour, characteristic and camphoraceous.

Solubility.—Amylene Hydrate is soluble in 8 parts of *water*, and is miscible with *alcohol (90 per cent)*, with *ether*, with *chloroform*, and with *glycerin*.

Test for Identity.

Heat 2 mils of Amylene Hydrate under a reflux condenser for one hour with 15 mils of *water*, 5 mils of *sulphuric acid* and about 10 Gms. of *potassium dichromate*; distil, and collect the first 2 mils of distillate; 1 mil gives the Test for Identity described under 'Acetonum'. Continue the distillation until most of the water has distilled over, make the distillate alkaline with *test-solution of sodium hydroxide* and evaporate to dryness; the residue, after neutralization, if necessary, yields the reactions characteristic of acetates.

A 10 per cent solution of Amylene Hydrate in *water* mixed quickly with half its volume of *solution of vanillin in sulphuric acid* yields a violet-red colour.

Tests for Purity.

Specific Gravity.—The *specific gravity* of Amylene Hydrate lies between 0·803 and 0·807 at 25°.

Boiling Point.—Not less than 95 per cent v/v of Amylene Hydrate distils between 100° and 104°.

Reaction.—A 10 per cent solution of Amylene Hydrate in *water* is neutral to *solution of litmus.*

Other Amyl Alcohols, Amylene and other organic impurities.—To 1 mil of Amylene Hydrate add 20 mils of *water* and 0·25 mil of *N/10 potassium permanganate;* the pink colour does not entirely disappear within ten minutes.

Aldehyde.—To 1 mil of Amylene Hydrate add 20 mils of *water* and 1 mil of *solution of silver ammonio-nitrate,* and heat in a water bath at 60° for ten minutes; no darkening occurs.

Water.—Mix 10 mils of Amylene Hydrate with 10 mils of *light petroleum* (boiling point, 50° to 60°); no cloudiness is produced.

Residue on evaporation.—Amylene Hydrate leaves, on evaporation and drying at 100°, not more than 0·25 per cent w/v of residue (limit of non-volatile matter).

BENZOINUM

(Benzoin)

Benzoin

Benzoin shall be a balsamic resin, obtained from the incised stem of *Styrax Benzoin* Dryand known in commerce as Sumatra benzoin; or from *Styrax tonkinensis* (Pierre) Craib ex Hartwich or other species of Styrax, known in commerce as Siam Benzoin. It shall contain not less than 19 per cent and not more than 29 per cent, of free balsamic acids, and not less than 30 per cent, and not more than 60 per cent of total balsamic acids, both being calculated with reference to the dry alcohol soluble matter, when assayed by the method indicated herein; and shall conform to the following specifications with respect to characters, test for identity and tests for purity.

Characters.

Description.—Sumatra Benzoin.—Sumatra Benzoin occurs in hard, brittle masses consisting of whitish or reddish tears embedded in a greyish-brown to reddish-brown translucent matrix. The odour is agreeable and balsamic; the taste, slightly acrid.

Siam Benzoin.—Siam Benzoin occurs in pebble-like tears of variable size, compressed, yellowish-brown to rusty brown externally, milky white on fracture, separate or very slightly agglutinated, hard and brittle at ordinary temperatures but softened by heat and becoming plastic on chewing. The odour is agreeable, balsamic, vanilla-like; the taste aromatic and slightly acrid.

Test for Identity.

When slowly heated in a dry test-tube, it melts and evolves irritating whitish fumes, which condense to form a whitish crystalline sublimate in the upper part of the tube. In the case of Sumatra benzoin the sublimate consists of plates and small, rod-like crystals that strongly polarise light. In the case of Siam benzoin the sublimate consists of long rod-shaped crystals which do not strongly polarise light.

Treat about 0·25 Gm. of Benzoin with 5 mils of *ether*, decant 1 mil of *ether* solution into a porcelain dish, and add 2 or 3 drops of *sulphuric acid;* Sumatra benzoin produces a deep reddish-brown colouration of the *sulphuric acid* and Siam benzoin a deep purplish-red colouration.

Tests for Purity.

Constants.—The *acid value* of Benzoin, determined on the alcohol soluble matter from 5 Gm. by the method described under 'Balsamum Tolutanum', varies from 115 to 165; the *ester value* from 47 to 83; the *saponification value*, from 169 to 223; all calculated with reference to the dry alcohol-soluble matter.

Ash.—The ash in Benzoin is not more than 2 per cent.

Extractive.—On *continuous extraction* with *alcohol (90 per cent)*, not less than 75 per cent is dissolved in the case of Sumatra benzoin, and not less than 90 per cent in the case of Siam benzoin.

Loss on drying.—Benzoin loses, when coarsely powdered and dried in vacuo over *sulphuric acid* not more than 10 per cent of its weight in the case of Sumatra benzoin, and not more than 3 per cent of its weight in the case of Siam benzoin.

Assay.

Carry out the *methods for the determination of total balsamic acids and free balsamic acids.*

Preparation.—Tinctura Benzoini Composita.

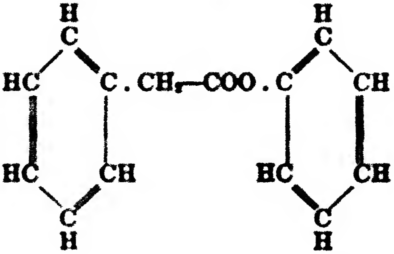
Doses

Metric	Imperial
0·6 to 2 Gm.	10 to 30 grains.

BENZYLIS BENZOAS

(Benzyl. Benz.)

Benzyl Benzoate



$C_{14}H_{12}O_2$ Mol. Wt. 212·1

Benzyl Benzoate may be prepared by the esterification of benzyl alcohol with benzoic acid. When assayed by the method indicated herein, it shall contain not less than 99 per cent of $C_{14}H_{12}O_2$; and shall conform to the following specification with respect to characters, tests for identity and tests for purity.

Characters.

Description.—Benzyl Benzoate occurs as colourless crystals or a colourless oily liquid; its odour is faintly aromatic, its taste, sharp and burning.

Solubility.—Benzyl Benzoate is insoluble in *water*, but it is soluble in *alcohol (90 per cent)*, in *chloroform* and in *ether*; it is insoluble in *glycerin*.

Boiling point.—Benzyl Benzoate boils at about 323°.

Test for Identity.

Boil 2 Gm. of Benzyl Benzoate with 25 mils of *alcoholic solution of potassium hydroxide* for two hours in a flask fitted with a reflux condenser. Remove the alcohol on a water-bath, add 50 mils of *water* to the liquid remaining in the flask, and distil until the liquid distilling is no longer turbid.

The liquid remaining in the flask, after neutralising with *dilute hydrochloric acid*, yields with *test-solution of ferric chloride*, a buff-coloured precipitate and, with *hydrochloric acid*, a white crystalline precipitate of benzoic acid.

To the distillate add 2·5 Gm. of *potassium permanganate* and 2 mils of *test-solution of sodium hydroxide*, boil for fifteen minutes in a flask fitted with a reflux condenser, cool, and filter. The filtrate, after neutralizing with *dilute hydrochloric acid*, yields, with *test-solution of ferric chloride*, a buff-coloured precipitate and, with *hydrochloric acid*, a white crystalline precipitate of benzoic acid.

Tests for Purity.

Constants.—The *specific gravity* of Benzyl Benzoate at 25° varies from 1·063 to 1·120; the *freezing-point* is not below 18·5°; and the *refractive index* at 20° varies from 1·568 to 1·570.

Ash.—Benzyl Benzoate leaves on ignition and incineration not more than 0·05 per cent of ash.

Assay.

Carry out the *method for the determination of esters in volatile oils*, continuing the boiling for two hours over a flame. Each mil of *N/2 alcoholic potassium hydroxide* is equivalent to 0·1061 Gm. of $C_{14}H_{12}O_2$.

Use.

For topical application.

BROMETHOL

(Bromethol)

Bromethol

Synonym.—Solution of Tribromoethyl Alcohol.

Bromethol shall be prepared from the following ingredients in the proportions specified.

Tribromoethyl Alcohol	66·7 Gms.
Amylene Hydrate	33·3 Gms.

Dissolve the Tribromoethyl Alcohol in the Amylene Hydrate.

Storage.

Bromethol should be kept in a dry well-closed container, and protected from light and flame. Bromethol is rapidly decomposed by moisture.

Preparation of a Solution for Rectal Injection.

For use by rectal injection.—Bromethol is diluted immediately before administration with 39 times its own volume of *water* at 40°, solution being effected by vigorous agitation. The diluted solution is tested before administration by adding 0·2 mil of solution of congo red to 5 mils of the diluted solution, when the colour of the indicator should remain orange-red; if it changes to purple or blue, the diluted solution is rejected.

Doses

Metric	Imperial
0·075 to 0·1 mil per kilogram of body weight.	$\frac{1}{2}$ to $\frac{3}{4}$ minim per pound of body weight.

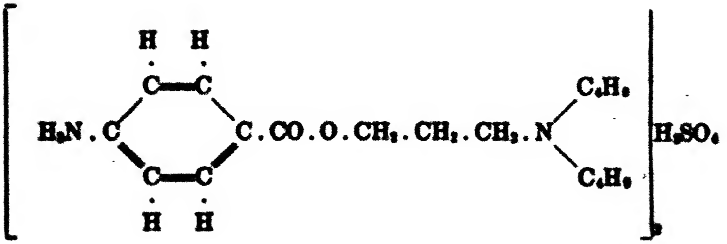
By rectal injection as a basal anaesthetic.

Bromethol contains, in 1 mil, 1 Gm. of Tribromoethyl Alcohol.

BUTACAINAE SULPHAS

(Butacain Sulph.)

Butacaine Sulphate



$(C_{18}H_{30}N_2O_2)_2H_2SO_4$ Mol. Wt. 710·6

Butacaine Sulphate shall be *p*-aminobenyol-γ dibutyl-*n*-amino-propanol sulphate and may be prepared by the condensation of *p*-aminobenzoic acid and dibutyl-*n*-aminopropyl chloride, and subsequent neutralization with sulphuric acid. It shall conform to the following specification with respect to characters, tests for identity and tests for purity.

Characters.

Description.—Butacaine Sulphate occurs as a white, crystalline, odourless powder; it produces numbness when placed on the tongue.

Solubility.—Butacaine Sulphate is soluble in less than 1 part of *water*, and in 1 part of warm *alcohol* at 25°; it is sparingly soluble in *chloroform*, and insoluble in *ether*.

Melting point.—The *melting point* of Butacaine Sulphate lies between 100° and 103°.

Tests for Identity.

An aqueous solution of Butacaine Sulphate yields, on addition of *test-solution of sodium hydroxide*, a colourless oily deposit; and, on addition of *solution of sodium bicarbonate*, a white precipitate.

Dissolve 0·1 Gm. in 5 mils of *water*, and add 2 drops each of *hydrochloric acid* and of a 10 per cent aqueous *solution of sodium nitrite* and finally 5 mils of *solution of β-naphthol*; a scarlet red precipitate is produced.

An aqueous solution of Butacaine Sulphate yields a precipitate with *solution of iodine* (distinction from orthocaine), with *solution of potassio-mercuric iodide* (distinction from benzocaine and orthocaine), and with *solution of trinitrophenol* (distinction from phenocaine).

An aqueous solution yields the *reactions* characteristic of sulphates.

Tests for Purity.

Readily carbonisable substances.—Dissolve 0·1 Gm. of Butacaine Sulphate in 2 mils of *sulphuric acid*; the solution is colourless.

Ash.—Butacaine Sulphate leaves, on incineration, not more than 0·1 per cent of ash.

Storage.

Butacaine Sulphate should be kept in a well-closed container, protected from light.

Use.

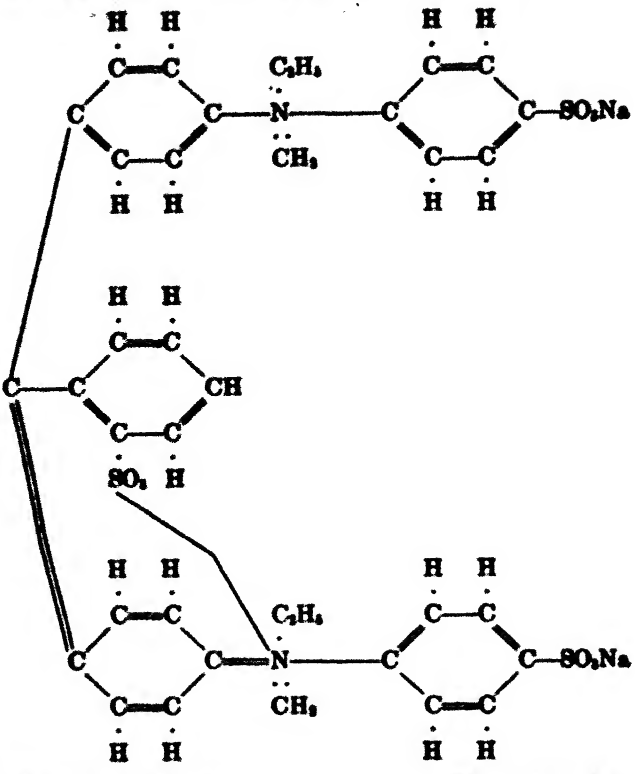
For topical application.

CAERULEUM NITENS

(Caerul. Nit.)

Brilliant Blue

Synonym.—FD&C, BLUE, No. 1.



$C_{37}H_{34}N_2O_9S_3Na_2$ Mol. Wt. 792.5

Brilliant Blue shall be the disodium salt of dibenzyl-diethyl-diamino-triphenylcarbinol trisulphonic acid anhydride and may be prepared by the condensation of benzaldehyde-*o*-sulphonic acid with benzylethylaniline sulphonic acid and oxidation of the product, followed by its conversion into the sodium salt.

Characters.

Description.—Brilliant Blue occurs as a dark, purple, bronzy powder.

Solubility.—Brilliant Blue is soluble in about 7 parts of *water*, giving a greenish-blue solution; it is also soluble in about 65 parts of *alcohol (90 per cent)*.

Standard.

Brilliant Blue shall be from stocks specially prepared for food purposes, (*see* Section V, Division 1, of these Regulations), and it shall not contain more than 10 parts per million of arsenic, calculated as As_2O_3, and, with the exception of iron, shall not contain heavy metals.

CYCLOPROPANUM

(Cycloprop.)

Cyclopropane

$(CH_2)_3$ Mol. Wt. 42.08

Cyclopropane may be prepared by the action of zinc on 1:3 trimethylene dibromide. When assayed by the method described herein, it shall contain not less than 97 per cent v/v of $(CH_2)_3$; and shall conform to the following specifications with respect to characters, tests for identity and purity. For convenience in use it is compressed in metal cylinders.

Characters.

Description.—Cyclopropane occurs as a colourless gas with a characteristic odour at atmospheric pressure; it is inflammable; mixtures with oxygen or air at certain concentrations are explosive. One litre of cyclopropane at normal pressure and 0° weighs 1·879 Gm.

Miscibility and Solubility.—Cyclopropane is miscible in all proportions with *alcohol (90 per cent)*, with *chloroform* and with *ether*. One volume dissolves in about 2·7 volumes of *water* at 15°.

Tests for Identity and Purity.

Boiling point.—Cyclopropane boils at -34·5° at 760 mils pressure.

Foreign Odours.—Transfer to a cylinder cooled in a bath at a temperature not higher than -40° 10 mils of liquid Cyclopropane, pour this in successive small quantities on to a clean filter paper and allow it to evaporate; no foreign odour is detectable at any stage.

Alcohol and Water.—Pass a volume of the gas equivalent to 1,000 mils, measured at normal temperature and pressure, through a weighed tube containing *potassium hydroxide* in small pieces; the increase in weight of the tube does not exceed 9·4 mgms., equivalent to 0·5 per cent w/w of the Cyclopropane used.

Unsaturated Substances.—Pass the gas issuing from the tube in the above test through a suitable spiral scrubber containing 20 mils of solution of *iodine monochloride,* followed by a guard tube containing solution of *potassium iodide;* determine the amount of halogen absorbed by the scrubber and guard tube by titration with *N/10 sodium thiosulphate;* this should show not more than the equivalent of 2·0 per cent w/w of unsaturated substances calculated as propylene.

Bromine containing substances.—Pass a volume of the gas equivalent to 1,000 mils, measured at normal temperature and pressure, in admixture with the necessary amount of air, through a heated quartz tube containing pieces of platinized quartz. Absorb the products of combustion in 100 mils of a 3 per cent solution of *sodium peroxide* contained in equal amounts in two absorption vessels in series. Mix the solutions, boil for five minutes, add 10 mils of *solution of potassium permanganate,* and boil for one minute. Add, if necessary, *solution of potassium permanganate,* drop by drop until a distinct purple tinge persists. Add 6 mils of *solution of hydrogen peroxide* drop by drop, boil for one minute, filter and wash the filter paper with *water.* Add one drop of *solution of methyl red* to the solution, which should be colourless, and make slightly acid with *dilute hydrochloric acid.* Boil to expel carbon dioxide, and neutralize with *N/1 sodium hydroxide.* Add 1 Gm. of *sodium dihydrogen phosphate,* followed by 2 mils of *N/1 sodium hypochlorite,* and boil for one minute. Add 2 mils of a 20 per cent solution of *sodium formate* and boil for one minute, cool, add 10 mils of *dilute sulphuric acid,* 10 mils of solution of *potassium iodide,* and 1 drop of a 10 per cent solution of *ammonium molybdate.* Allow to stand for one minute and titrate with *N/60 sodium thiosulphate.* Repeat the operations without the Cyclopropane. The difference between the two titrations does not exceed 2·2 mils, equivalent to 0·05 per cent w/w of bromine containing substances calculated as propyl bromide.

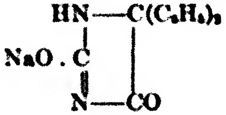
Assay.

Place in a suitable nitrometer, containing mercury, a volume of the material, drawn from the gaseous phase, equivalent to 80-100 mils of the gas measured at normal temperature and pressure. Add 25 mils of *sulphuric acid* and allow to stand for fifteen minutes; not less than 99 per cent v/v is absorbed.

DIPHENYLHYDANTOINUM SOLUBILE

(Diphenylhydant. Sol.)

Soluble Diphenylhydantoin



$C_{15}H_{11}N_2O_2Na$ Mol. Wt. 274·1

Soluble Diphenylhydantoin shall be the monosodium derivative of 5:5 diphenylhydantoin and may be prepared by the action of hypochlorites on diphenylmalonamide, followed by interaction with sodium hydroxide. When assayed by the method described herein, it shall contain not less than 98·5 per cent of $C_{15}H_{11}N_2O_2Na$, calculated with reference to the substance dried at 100° for 4 hours; and shall conform to the following specifications with respect to characters, tests for identity and tests for purity.

Characters.

Description.—Soluble Diphenylhydantoin occurs as a white, microcrystalline, somewhat hygroscopic, odourless powder; it has a slightly bitter taste.

Solubility.—Soluble Diphenylhydantoin is soluble in less than 1 part of *water*, the solution being usually somewhat turbid; it is soluble in *alcohol*, but insoluble in *ether* and in *chloroform*.

Tests for Identity.

To a 5 per cent solution of Soluble Diphenylhydantoin in *water* which is alkaline to *litmus*, add an excess of *dilute hydrochloric acid*; collect the precipitate on a filter, wash with *water*, and dry for 6 hours at 100°. The crystals have a *melting point*, 292° to 299°, with some decomposition.

Evaporate the filtrate from the crystals to dryness; the residue yields the *reactions* characteristic of sodium.

Tests for Purity.

Clarity of solution.—One Gm. of Soluble Diphenylhydantoin dissolved in 20 mils of recently boiled and cooled *water*, requires the addition of not more than 4 mils of *N/10 sodium hydroxide* to produce a bright solution which is colourless.

Sulphates.—Dissolve 0·2 Gm. of Soluble Diphenylhydantoin in 40 mils of *water*, add 1 mil of *hydrochloric acid*, and filter; the filtrate complies with the *limit test for sulphates.*

Chlorides.—Dissolve 0·1 Gm. of Soluble Diphenylhydantoin in 40 mils of *water*, add 1 mil of *nitric acid* and filter; the filtrate complies with the *limit test for chlorides.*

Loss on drying.—Soluble Diphenylhydantoin loses, when dried at 100° for 4 hours, not more than 2·5 per cent of its weight.

Assay.

Dissolve about 0·3 Gm. of Soluble Diphenylhydantoin, previously dried at 100° for 4 hours, and accurately weighed, in 50 mils of *water*, and add 10 mils of *dilute hydrochloric acid.* Extract with four successive portions of 25 mils of absolute ether; evaporate the combined extracts and dry at 100°; 1 Gm. of residue is equivalent to 1·087 Gm. of $C_{15}H_{11}N_2O_2Na$.

Storage.

Soluble Diphenylhydantoin should be kept in a well-closed container.

Doses

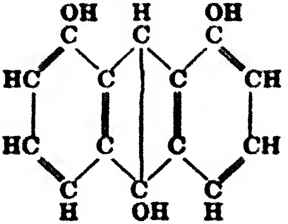
Metric	Imperial
60 to 120 mgms.	1 to 2 grains

DITHRANOL

(Dithranol)

Dithranol

Synonym.—DIOXYANTHRANOL



$C_{14}H_{10}O_3$ Mol. Wt. 226·1

Dithranol shall be 1:8-dihydroxyanthranol, and may be prepared by the reduction of 1:8 dihydroxyanthraquinone. It shall conform to the following specification with respect to characters, tests for identity and tests for purity.

Characters.

Description.—Dithranol occurs as a yellow, odourless and tasteless powder.

Solubility.—Dithranol is insoluble in *water,* and slightly soluble in *alcohol (96 per cent),* and in *ether;* it is soluble in *chloroform,* in *acetone,* in *benzene* and in oils.

Melting point.—The *melting point* of Dithranol lies between 174° and 178°.

Tests for Identity.

Dissolve 5 mgm. of Dithranol in 5 mils of an approximately 4 per cent w/v solution of *sodium hydroxide* in *water;* a clear slightly fluorescent yellow or orange solution is formed which turns red on exposure to air (distinction from 1:2 dihydroxyanthranol).

Tests for Purity.

Dihydroxyanthraquinone.—Dissolve about 1 mgm. of Dithranol in a few drops of *sulphuric acid;* a clear orange coloured solution, with no trace of violet colour, is produced.

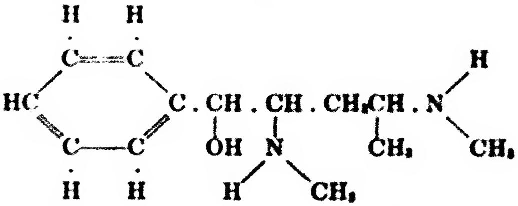
Clarity of solution.—Dissolve 100 mgm. of Dithranol in 5 mils of hot benzene; it is completely soluble, forming a clear yellow or orange solution.

Loss on drying and Ash.—Dithranol loses, when dried at 100°, not more than 1 per cent of its weight, and leaves on incineration, not more than 0·1 per cent of ash.

EPHEDRINA SICCA

(Ephed. Sicc.)

Anhydrous Ephedrine



$C_{10}H_{15}NO$ Mol. Wt. 165·1

Ephedrine shall be *l*-α-hydroxy-β-methyl-amino-propylbenzene, an alkaloid obtained from *Ephedra sinica* Stapf, *Ephedra equisetina* Bunge, and other species of *Ephedra,* or prepared by synthesis. When assayed by the method described herein, it shall contain not less than 98·5 per cent of $C_{10}H_{15}NO$; and shall conform to the following specification with respect to characters, tests for identity and tests for purity.

Characters.

Description.—Anhydrous Ephedrine occurs as a white unctuous, hygroscopic solid; it is odourless, or may have acquired a slight, unpleasant smell. It is gradually decomposed by exposure to light.

Solubility.—Anhydrous Ephedrine is soluble in 20 parts of *water*, readily soluble in *alcohol (95 per cent)*, in *ether* and in *chloroform*. It dissolves in about 20 parts of *glycerin*, in about 25 parts of *olive oil*, and in about 100 parts of *liquid paraffin*.

Melting point.—The *melting point* of Anhydrous Ephedrine lies between 34° and 36°. The melting point of the hydrochloride obtained from the assay lies between 217° and 219°.

Tests for Identity.

An aqueous solution of Anhydrous Ephedrine is strongly alkaline to *solution of litmus*.

Dissolve 10 mgms. of Anhydrous Ephedrine in 1 mil of *water* and 0·2 mil of *dilute hydrochloric acid*, and add 0·1 mil of *solution of copper sulphate*, followed by 1 mil of *test-solution of sodium hydroxide;* the liquid becomes violet; add 1 mil of *ether*, and shake; the ethereal layer is purple, and the aqueous layer is blue.

Dissolve 0·2 Gm. of Anhydrous Ephedrine in 30 mils of *chloroform;* set aside for twelve hours and allow the chloroform to evaporate slowly at laboratory temperature; the crystals of ephedrine hydrochloride which separate have, after drying, *melting point* 217° to 219°, and yield the reactions characteristic of chlorides.

Tests for Purity.

Specific rotation.—The *specific rotation* of the hydrochloride obtained from the assay, in 5 per cent w/v solution of Anhydrous Ephedrine in *water* varies from -33° to -35°.

Chlorides.—Dissolve 0·1 Gm. of Anhydrous Ephedrine in 1 mil of *water* and 1 mil of *dilute nitric acid* and add 0·1 mil of *solution of silver nitrate;* no turbidity is produced.

Sulphates.—Dissolve 0·1 Gm. of Anhydrous Ephedrine in 1 mil of *water* and 1 mil of *dilute hydrochloric acid* and add 0·5 mil of *solution of barium chloride;* no turbidity is produced during ten minutes.

Ash.—Anhydrous Ephedrine leaves, on incineration, not more than 0·1 per cent of ash.

Assay.

Dissolve about 1·5 Gm., accurately weighed, in 5 mils of *alcohol (90 per cent)* in an evaporating dish, add 10 mils of *water* and sufficient *dilute hydrochloric acid* to make the solution distinctly acid to *litmus paper*, evaporate to dryness on a water-bath, dry the residue of ephedrine hydrochloride at 100°, and weigh. One Gm. of ephedrine hydrochloride is equivalent to 0·82 Gm. of $C_{10}H_{15}NO$.

Storage.

Anhydrous Ephedrine should be kept in a well closed container, protected from light, and stored in a cool place.

Doses

Metric	Imperial
15 to 100 mgms.	¼ to 1½ grains

EXTRACTUM CASCARAE SAGRADÆ SICCUM

(Ext. Casc. Sagr. Sicc.)

Dry Extract of Cascara Sagrada

Dry Extract of Cascara Sagrada shall be the dry powder, with addition of starch, obtained by the exhaustion of Cascara Sagrada, and each Gm. shall represent the extractive matter from 3 Gm. of drug. It may be prepared by the following procedure:

Cascara Sagrada, in coarse powder, 900 Gm.
Boiling Water, a sufficient quantity.

Mix the Cascara Sagrada with 4000 mils of Boiling Water, and macerate the mixture during three hours. Then transfer it to a percolator, allow it to drain, and exhaust it completely by percolation, using Boiling Water as the menstruum and collecting about 5000 mils of percolate. Evaporate the percolate to dryness, reduce the extract to a fine powder, and add sufficient starch, dried at 100°, to make the product weigh 300 Gm. Mix the powders thoroughly and pass the Extract through a fine sieve.

Storage.

Dry Extract of Cascara Sagrada should be kept in a small, wide-mouthed, well-closed container, and stored in a cool place.

Doses

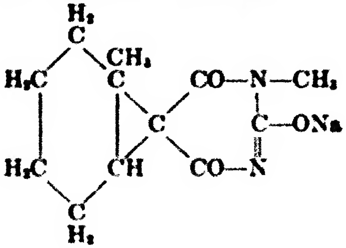
Metric	Imperial
0·12 to 0·5 Gm.	2 to 8 grains.

HEXOBARBITONUM SOLUBILE

(Hexobarbiton. Solub.)

Soluble Hexobarbitone

Synonym.—HEXOBARBITAL SODIUM



$C_{12}H_{15}N_2O_3Na$ Mol. Wt. 258·1

Soluble Hexobarbitone shall be the mono-sodium derivative of 5-Δ′-cyclo-hexenyl-5-methyl-N-methyl barbituric acid and may be prepared by the condensation of methyl-Δ′-cyclo-hexenyl-methyl cyanoacetate with methyl urea, followed by hydrolysis of the product, and subsequent interaction with sodium hydroxide. When assayed by the method described herein, it shall contain not less than 96 per cent of $C_{12}H_{15}N_2O_3Na$; the percentage of sodium shall not be less than 8·86 per cent and not more than 9·0 per cent of the $C_{12}H_{15}N_2O_3Na$. Soluble Hexobarbitone shall also conform to the following specifications with respect to characters, tests for identity and tests for purity.

Characters.

Description.—Soluble Hexobarbitone occurs as a white, odourless, very hygroscopic powder possessing a bitter taste.

Solubility.—Soluble Hexobarbitone dissolves in less than one part of *water*; it also dissolves in *alcohol*, in *methyl alcohol*, and in *acetone*. It is only slightly soluble in *chloroform* and in *ether*; and is insoluble in *benzene*. An aqueous solution absorbs carbon dioxide, causing separation of hexobarbitone in crystals.

Tests for Identity.

Reaction.—A 10 per cent w/v solution of Soluble Hexobarbitone in *water* is strongly alkaline, having a pH about 10·5.

To a 10 per cent w/v solution of Soluble Hexobarbitone in *water* add an excess of *dilute hydrochloric acid;* collect the crystalline precipitate on a filter, wash with *water* and dry at 100°; the crystals have a *melting point,* 143° to 147°, and comply with the following test:

Triturate 0·59 Gm. of Soluble Hexobarbitone with 5 mils of *water* and 0·13 Gm. of *anhydrous sodium carbonate;* add 0·43 Gm. of *nitrobenzyl chloride,* dissolved in 10 mils of *alcohol (95 per cent),* and warm the mixture on a water-bath for thirty minutes. Cool, allow to stand for one hour. Collect the precipitated nitrobenzyl derivative on a filter, wash with 10 mils of *N/1 sodium hydroxide,* then with *water,* drain on porous porcelain, and recrystallize from *light petroleum;* the crystals have a *melting point,* 116° to 117°.

Evaporate the filtrate to dryness; the residue yields the *reactions* characteristic of sodium.

Tests for Purity.

Clarity of solution.—Dissolve 1 Gm. of Soluble Hexobarbitone in 10 mils of freshly-boiled and cooled *water*; it dissolves rapidly and completely, giving a clear, colourless solution which does not show any opalescence after one hour.

Sodium carbonate.—Dissolve 1 Gm. of Soluble Hexobarbitone in 5 mils of *methyl alcohol*; the solution is clear, or only faintly turbid.

Neutral and basic substances.—Dissolve 1 Gm. of Soluble Hexobarbitone in a mixture of 2 mils of *test-solution of sodium hydroxide* and 3 mils of *water,* extract with 25 mils of *ether* and wash the ethereal solution with three separate quantities of 5 mils of water; remove the ether and dry the residue at 100°; the residue weighs not more than 1 mgm.

Assay.

For sodium.—Dissolve about 0·6 Gm. of Soluble Hexobarbitone, accurately weighed, in 20 mils of *water,* add 1 drop of *solution of methyl red* and titrate with *N/10 sulphuric acid* until the yellow colour changes to pink; boil gently for one or two minutes, cool, and if necessary, continue the titration with *N/10 sulphuric acid* until the pink colour is restored. Each mil of *N/10 sulphuric acid* is equivalent to 0·0023 Gm. of Na.

For $C_{12}H_{15}N_2O_3Na$.—To the liquid from the assay for sodium add a further 5 mils of *N/10 sulphuric acid,* and 25 mils of *chloroform;* shake vigorously. Separate the chloroform extract and wash it with 15 mils of *water.* Repeat the extraction of the acid liquid with two further quantities of 15 mils of *chloroform,* and wash each extract with the water used for the first extraction. Remove the chloroform from the mixed chloroform extracts, add 5 mils of *dehydrated alcohol,* evaporate to dryness, and dry the crystalline residue at 100°. One Gm. of residue is equivalent to 1·093 Gm. of $C_{12}H_{15}N_2O_3Na$.

Sterilization of a Solution.

Soluble Hexobarbitone is prepared in solution for injection by dissolving it in the requisite amount of Sterilised Water.

Storage.

Soluble Hexobarbitone should be kept in a well-closed container, preferably sealed by fusion.

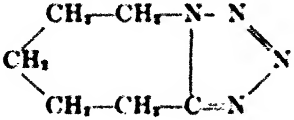
Doses

Metric	Imperial
By intravenous or intramuscular injection	
0·2 to 1 Gm.	3 to 15 grains
By rectal injection	
2 to 4 Gm.	30 to 60 grains

LEPTAZOLUM

(Leptazol)

Leptazol



$C_6H_{10}N_4$ Mol. Wt. 138·1

Leptazol shall be pentamethylenetetrazole, and may be prepared by the interaction in cold benzene solution of hydrazoic acid and cyclohexanone. It shall conform to the following specification with respect to characters, test for identity and tests for purity.

Characters.

Description.—Leptazol occurs in colourless crystals, or as a white, crystalline powder; it is odourless, and possesses a slightly pungent, bitter taste.

Solubility.—Leptazol is freely soluble in *water*, in *alcohol (95 per cent)*, in *ether*, and in *chloroform*.

Melting point.—The *melting point* of Leptazol lies between 57° and 60°.

Test for Identity.

A 10 per cent w/v solution of Leptazol in *water* yields with *test solution of mercuric chloride* a white precipitate, which, after recrystallisation from *water* or *alcohol (95 per cent)*, melts at 177° to 178°.

Tests for Purity.

Reaction.—A 10 per cent solution of Leptazol in *water* is neutral to *solution of litmus.*

Ash.—Leptazol leaves, on incineration, not more than 0·1 per cent of ash.

Doses

Metric	Imperial
50 to 100 mgms.	¾ to 1½ grain

LIQUOR ARSENICALIS

(Liq. Arsen.)

Arsenical Solution

Synonym.—FOWLER'S SOLUTION.

Arsenical Solution shall be prepared from the following ingredients in the amounts specified, and shall contain not less than 0·95 per cent, and not more than 1·05 per cent w/v of As_2O_3.

Arsenic Trioxide, in powder	10 Gm.
Glycerin	100 mils.
Amaranth	20 mgms.
Chloroform Water, sufficient to produce	1000 mils.

Heat the Arsenic Trioxide with the Glycerin at 100° until a clear solution is obtained; cool, add the Chloroform Water and Amaranth. Filter.

Assay.

To 20 mils. of Arsenical Solution add about 3 Gm. of *sodium bicarbonate,* and titrate with *N/10 iodine.* Each mil. of *N/10 iodine* is equivalent to 0·004947 Gm. of As_2O_3.

Doses

Metric	Imperial
0·12 to 0·5 mil.	2 to 8 minims.

Arsenical Solution contains in 0·5 mil. 5 mgms. and in 8 minims about 1/12 grain of Arsenic Trioxide.

LIQUOR HYDROGENII PEROXIDI

(Liq. Hydrog. Perox.)

Solution of Hydrogen Peroxide

In addition to the standard of strength and quality laid down in the British Pharmacopoeia, Solution of Hydrogen Peroxide shall also comply with the following test for purity.

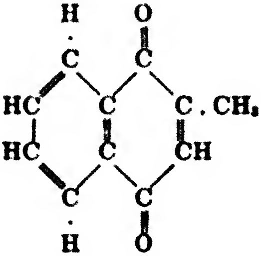
Limit of preservative.—Extract 100 mils with a mixture of 3 volumes of *chloroform* and 2 volumes of *ether* and evaporate the extract to dryness at room temperature; the residue weighs not more than 50 mgms.

MENADIONUM

(Menadion.)

Menadione

Synonym.—MENAPHTHONE.



$C_{11}H_8O_2$ Mol. Wt. 172·1

Menadione shall be 2-methyl-α-naphthaquinone and may be prepared by the oxidation of 2-methylnaphthalene with chromic acid. It shall contain not less than 98·5 per cent of $C_{11}H_8O_2$, calculated with reference to the substance dried in a vacuum desiccator over sulphuric acid for 4 hours, when assayed by the method described herein; and shall conform to the following specification with respect to characters, tests for identity and tests for purity.

Characters.

Description.—Menadione occurs as a bright yellow, crystalline powder, and is almost odourless.

Solubility.—Menadione is practically insoluble in *water*. It is soluble in about 60 parts of *alcohol (95 per cent)*, and in about 10 parts of *benzene*, at 25°. It is moderately soluble in *chloroform*, and in *carbon tetrachloride*, and is soluble in vegetable oils.

Melting point.—The melting point of Menadione lies between 105° and 107°.

Tests for Identity.

Suspend 50 mgm. of Menadione in 5 mils of *water* and add 75 mgm. of *sodium bisulphite*; heat on a water bath, shaking vigorously until the substance is dissolved and the solution is almost colourless. Then add sufficient *water* to produce 50 mils and shake well. To 2 mils of the solution add 2 mils of a mixture of equal volumes of *alcohol (95 per cent)* and *strong solution of ammonia*, shake, and add 2 drops of *ethyl cyano acetate*; a deep purple-blue colour is produced which, on the addition of 1 mil of a 33 per cent w/v solution of sodium hydroxide changes to green and then to yellow.

Tests for Purity.

Loss on drying and ash.—Menadione loses, when dried in a vacuum desiccator over sulphuric acid for 4 hours, not more than 0·3 per cent of its weight; and leaves, on incineration, not more than 0·1 per cent of residue.

Assay.

Weigh accurately about 0·15 Gm. of Menadione, previously dried over *sulphuric acid* in a vacuum desiccator for 4 hours in the dark, and transfer it completely to a 150-mil flask. Add 15 mils of *glacial acetic acid* and 15 mils of *dilute hydrochloric acid*, and rotate the flask until the Menadione is dissolved. Then add about 1 Gm. of *powdered zinc*, close the flask with a stopper bearing a Bunsen valve, and allow to stand in the dark for 30 minutes, with occasional shaking. Rapidly decant the solution through a pledget of cotton into another flask, immediately wash the reduction flask with three 10-mil portions of fresh water, and at once titrate the combined filtrate and washings with *N/10 ceric sulphate*, using 0·1 mil *solution of o-phenanthroline* as the indicator. Perform a blank test with the same reagents and in the same manner, and make any necessary correction. Each mil of *N/10 ceric sulphate* is equivalent to 0·008605 Gm. of $C_{11}H_8O_2$.

Storage.

Menadione should be kept in well-closed containers, protected from light.

Doses

— daily —

Metric	**Imperial**
1-3 mgm.	**1/64-1/20 grain**

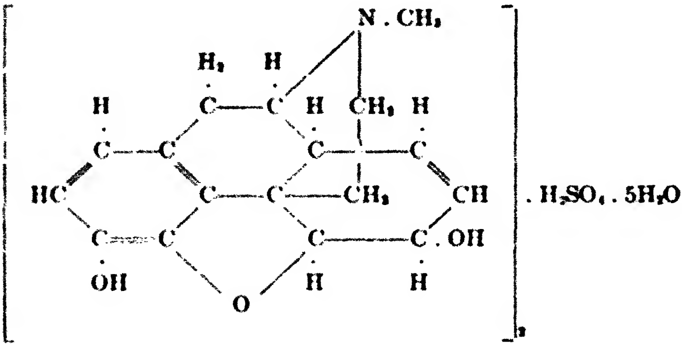
Caution.

Menadione powder is irritating to the respiratory tract, and to the skin, and an alcoholic solution has vesicant properties.

MORPHINAE SULPHAS

(Morph. Sulph.)

Morphine Sulphate



$(C_{17}H_{19}NO_3)_2, H_2SO_4, 5H_2O$ Mol. Wt. 758·5

Morphine Sulphate shall be the sulphate of the alkaloid morphine obtained from opium. When assayed by the method described herein, it shall contain not less than 74·0 per cent and not more than 75·5 per cent of anhydrous morphine, and shall conform to the following specification with respect to characters, tests for identity and tests for purity.

Characters.

Description.—Morphine Sulphate occurs as white, acicular crystals or cubical masses or a white crystalline, odourless powder possessing a bitter taste.

Solubility.—Morphine Sulphate is soluble in 15·5 parts of *water* and in 565 parts of *alcohol (95 per cent)* at 25°; it is insoluble in *ether* and in *chloroform.*

Tests for Identity.

Sprinkle a little Morphine Sulphate, previously powdered, on the surface of a drop of *nitric acid;* an orange-red colour is produced.

Add a little Morphine Sulphate, previously powdered, to 1 mil of *sulphuric acid* containing 1 drop of *solution of formaldehyde;* a purple colour is produced.

To 5 mils of a 2 per cent w/v aqueous solution of Morphine Sulphate add 1 drop of *test-solution of ferric chloride;* a blue colour is produced.

To a 2 per cent w/v aqueous solution of Morphine Sulphate add *solution of potassium ferricyanide,* containing 1 drop per mil of *test-solution of ferric chloride;* an immediate bluish-green colour is produced (distinction from codeine).

To 20 mgms. of Morphine Sulphate, dissolved in 5 mils of *N/10 sulphuric acid,* add 0·5 mil of a saturated *solution of potassium iodate* in *water;* an amber colour is produced, which reaches a maximum in about five minutes; on the addition of 0·5 mil of *strong solution of ammonia* the colour darkens almost to black, (distinction from codeine and diamorphine).

Warm 0·1 Gm. of Morphine Sulphate, dissolved in 2 mils of *sulphuric acid,* on a water-bath for fifteen minutes, cool, and add a few drops of *dilute nitric acid;* a blood-red colour is produced.

Morphine Sulphate yields the *reactions* characteristic of sulphates.

Tests for Purity.

Other alkaloids.—Wash the chloroform solution reserved from the first extraction in the assay, with two successive quantities, each of 5 mils of *water;* evaporate the chloroform solution to dryness on a water-bath; the residue weighs not more than 7·5 mgms.

Readily carbonizable substances.—Dissolve 0·1 Gm. of Morphine Sulphate in 2 mils of *sulphuric acid;* not more than a faint pink colour is produced.

Loss on drying and ash.—Morphine Sulphate, when dried at 120°, loses not more than 12 per cent of its weight, and leaves, on incineration, not more than 0·1 per cent of ash.

Assay.

Transfer about 0·5 Gm. of Morphine Sulphate, accurately weighed, to a separator, add 15 mils of *water,* 5 mils of *N/1 sodium hydroxide* and 10 mils of *chloroform,* shake, allow to separate, and transfer the chloroform solution to another separator. Repeat the extraction with two further quantities, each of 10 mils of *chloroform.* Wash the mixed chloroform solutions with 10 mils of *N/10 sodium hydroxide,* reserve the chloroform solution for the test for limit of other alkaloids, and add the alkaline solution to the first alkaline liquid. Add 20 mils of *alcohol (90 per cent),* 40 mils of a mixture of three volumes of *chloroform* and one volume of *alcohol (90 per cent),* and 1 Gm. of *ammonium sulphate.* Shake well, allow to separate, and reserve the chloroform solution. Repeat the extraction with successive quantities of 30, 20, 20 and 20 mils of the chloroform-alcohol mixture. Wash each chloroform solution successively with two quantities, each of 5 mils, of *water*, avoiding vigorous shaking. Filter the chloroform solutions through a plug of cotton-wool, previously moistened with *chloroform*. Remove the solvent. Add 20 mils of *N/10 sulphuric acid*, boil, cool, and titrate the excess of acid with *N/10 sodium hydroxide*, using *tincture of cochineal* or *solution of methyl red* as indicator. Each mil of *N/10 sulphuric acid* is equivalent to 0·02852 Gm. of anhydrous morphine.

Storage.

Morphine Sulphate should be kept in a well-closed container, protected from light.

Sterilization of a Solution.

A solution of Morphine Sulphate for parenteral injection is sterilised by *heating with a bactericide* or by *filtration*. The containers comply with the *tests for limit of alkalinity of glass*.

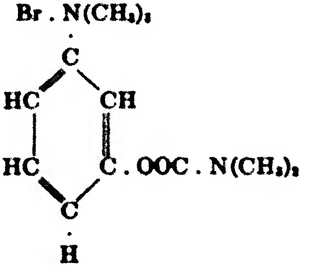
Doses

Metric	Imperial
8 to 20 mgms.	⅛ to ⅓ grain

NEOSTIGMINAE BROMIDUM

(Neostig. Bromid.)

Neostigmine Bromide



$C_{12}H_{19}BrN_2O_2$ Mol. Wt. 303·1

Neostigmine Bromide shall be the dimethyl carbamic ester of 3-hydroxyphenyl-trimethyl-ammonium bromide and may be prepared by the interaction of *m*-dimethylaminophenol and dimethyl-carbamyl chloride and subsequent combination with methyl bromide. When assayed by the method described herein, it shall contain not less than 98 per cent of $C_{12}H_{19}BrN_2O_2$, calculated with reference to the substance dried at 100° for 6 hours, and shall conform to the following specification with respect to characters, tests for identity and tests for purity.

Characters.

Description.—Neostigmine Bromide occurs as a white, crystalline, odourless powder; it has a bitter taste.

Solubility.—Neostigmine Bromide is soluble in about 1 part of *water* at 25°; it is also soluble in *alcohol*.

Melting point.—The melting point of Neostigmine Bromide is about 167°, with some decomposition.

Tests for Identity.

Dissolve 1 mgm. of Neostigmine Bromide in 0·5 mil of *water* and 1 mil of *test solution of sodium hydroxide*; evaporate to dryness on a water bath, and heat the residue, transferred to a small test tube, in an oil bath at 250°, for 30 seconds; cool, dissolve the residue in 0·5 mil of *water*, cool again in ice water and add 1 mil of *solution of diazobenzenesulphonic acid*; a cherry red colour is produced.

An aqueous solution of Neostigmine Bromide yields the *reactions* characteristic of bromides.

Tests for Purity.

Reaction.—A 10 per cent w/v solution in water is neutral to *litmus paper*.

Sulphates.—Dissolve 0·25 Gm. of Neostigmine Bromide in 10 mils of *water*, and add 1 mil of *dilute hydrochloric acid* and 1 mil of *solution of barium chloride*; no turbidity is produced immediately.

Loss on drying and ash.—Neostigmine Bromide loses, on drying at 100° for 6 hours, not more than 2 per cent of its weight; and leaves, on incineration, not more than 0·15 per cent of ash.

Assay.

Dissolve about 0·35 Gm. of Neostigmine Bromide, previously dried and accurately weighed, in 200 mils of water, in a 500 mil Kjeldahl flask, add 26 mils of *test solution of sodium hydroxide*. Connect the flask by means of a distillation trap to a well-cooled condenser, and distil 200 mils, collecting the distillate under the surface of 25 mils of *N/10 sulphuric acid*. Titrate the excess of acid with *N/10 sodium hydroxide*, using *solution of methyl red* as indicator. Carry out a blank test with the reagents employed. Each mil of *N/10 sulphuric acid* is equivalent to 0·03031 Gm. of $C_{12}H_{19}N_2O_2Br$.

Storage.

Neostigmine Bromide should be kept in a well-closed container.

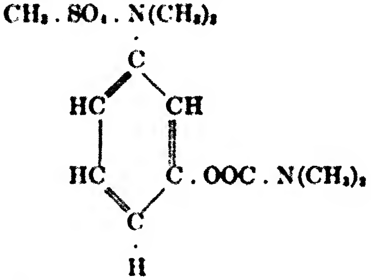
Doses

Metric	Imperial
8 to 30 mgms.	⅛ to ½ grain

NEOSTIGMINAE METHYLSULPHAS

(Neostig. Methylsulph.)

Neostigmine Methylsulphate



$C_{13}H_{22}N_2O_6S$ Mol. Wt. 334·3

Neostigmine Methylsulphate shall be the dimethyl carbamic ester of 3-hydroxy-phenyl-trimethyl-ammonium methyl sulphate and may be prepared by the interaction of *m*-dimethylaminophenol and dimethylcarbamyl chloride and subsequent combination with methyl sulphate. When assayed by the method described herein, it shall contain not less than 98 per cent of $C_{13}H_{22}N_2O_6S$, calculated with reference to the substance dried at 100° for 6 hours; and shall conform to the following specification with reference to characters, tests for identity and tests for purity.

Characters.

Description.—Neostigmine Methylsulphate is a white, odourless, crystalline powder, possessing a bitter taste.

Solubility.—Neostigmine Methylsulphate is soluble in about 10 parts of water at 25°, and is less soluble in *alcohol.*

Melting point.—The *melting point* of Neostigmine Methylsulphate lies between 142° and 145°.

Tests for Identity.

Dissolve 1 mgm. of Neostigmine Methylsulphate in 0·5 mil of *water* and 1 mil of *test solution of sodium hydroxide;* evaporate to dryness on a water bath, and heat the residue, transferred to a small test tube, in an oil bath at 250°, for 30 seconds; cool, dissolve the residue in 0·5 mil of *water,* cool again in ice water and add 1 mil of *solution of diazobenzenesulphonic acid;* a cherry red colour is produced.

Mix 20 mgms. of Neostigmine Methylsulphate with 0·5 Gm. of *anhydrous sodium carbonate,* and fuse. Extract the residue with 10 mils of *water* and filter. Add 5 drops of *solution of bromine,* boil, acidify with *hydrochloric acid,* and boil off the excess of bromine; the resulting solution yields the *reactions* characteristic of sulphates.

Tests for Purity.

Reaction.—A 10 per cent w/v solution in water is neutral to *litmus paper.*

Chloride.—Dissolve 0·2 Gm. of Neostigmine Methylsulphate in 10 mils of *water,* and add 1 mil each of *dilute nitric acid* and of *solution of silver nitrate;* no opalescence is produced immediately.

Sulphate ion.—Dissolve 0·2 Gm. of Neostigmine Methylsulphate in 10 mils of *water,* and add 1 mil each of *dilute hydrochloric acid* and *solution of barium chloride;* no turbidity is produced immediately.

Loss on drying and ash.—Neostigmine Methylsulphate loses, when dried at 100° for 6 hours, not more than 1 per cent of its weight; and leaves, on incineration, not more than 0·1 per cent of ash.

Assay.

Dissolve about 0·35 Gm. of Neostigmine Methylsulphate, previously dried and accurately weighed, in 200 mils of water, in a 500 mil Kjeldahl flask, add 25 mils of *test solution of sodium hydroxide.* Connect the flask by means of a distillation trap to a well-cooled condenser, and distil 200 mils, collecting the distillate under the surface of 25 mils of *N/10 sulphuric acid.* Titrate the excess of acid with *N/10 sodium hydroxide,* using *solution of methyl red* as indicator. Carry out a blank test with the reagents employed. Each mil of *N/10 sulphuric acid* is equivalent to 0·03343 Gm. of $C_{13}H_{22}N_2O_6S$.

Storage.

Neostigmine Methylsulphate should be kept in a well-closed container.

Doses

By subcutaneous injection

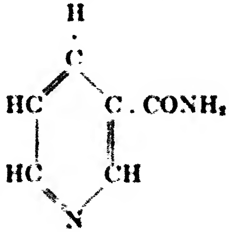
Metric	Imperial
0·25 to 1·5 mgms.	1/240 to 1/30 grain

NICOTINAMIDUM

(Nicotinamid.)

Nicotinamide

Synonyms.—NICOTINIC ACID AMIDE; NIACINAMIDE.



$C_6H_6N_2O$ Mol. Wt. 122·1

Nicotinamide shall be pyridine-β-carboxylic acid amide, and may be prepared by the action of thionyl chloride on nicotinic acid, and treatment of the resulting acid chloride with ammonia. When assayed by the method described herein, Nicotinamide shall contain not less than 98·5 per cent of $C_6H_6N_2O$, calculated with reference to the substance dried over sulphuric acid for 18 hours; and shall conform to the following specification with respect to characters, tests for identity and tests for purity.

Characters.

Description.—Nicotinamide occurs as a white crystalline powder; it is odourless or nearly so, and has a bitter taste.

Solubility.—Nicotinamide is soluble in about 1 part of *water*, in about 1·5 parts of *alcohol*, and in about 10 parts of *glycerin* at 25°.

Melting point.—The *melting point* of Nicotinamide lies between 128° and 131°.

Tests for Identity.

When boiled with *test-solution of sodium hydroxide*, Nicotinamide gives off ammonia.

To the solution remaining in the distilling flask following the completion of the assay, add *dilute sulphuric acid* until the mixture is faintly acid to litmus paper, and then add 2 mils of *solution of copper sulphate;* a dark blue precipitate is produced slowly.

Char about 10 mgms. of Nicotinamide on platinum foil; the characteristic odour of pyridine is evolved.

Tests for Purity.

Carbonisable substances.—Dissolve 0·2 Gm. of Nicotinamide in 5 mils of *sulphuric acid;* the colour is not deeper than pale amber.

Reaction.—A 10 per cent aqueous solution of Nicotinamide is neutral to *litmus paper.*

Lead.—The *lead limit* in Nicotinamide is 30 parts per million.

Loss on drying and ash.—Nicotinamide loses, when dried over *sulphuric acid* for 18 hours, not more than 0·5 per cent of its weight; and leaves, on incineration, not more than 0·1 per cent of ash.

Assay.

Dissolve about 0·3 Gm. of Nicotinamide, previously dried over *sulphuric acid* for 18 hours, and accurately weighed, in 200 mils of *water* in a Kjeldahl flask, and add 50 mils of a 30 per cent w/v aqueous *solution of sodium hydroxide.* Connect the flask to an ammonia distillation apparatus, the receiver of which contains 40 mils of *N/10 sulphuric acid.* Boil gently for 20 minutes and then distil 200 mils. Titrate the excess of acid with *N/10 sodium hydroxide*, using *solution of methyl red* as indicator. Repeat the experiment without the Nicotinamide. The difference between the two titrations represents the acid required to neutralize the ammonia. Each mil of N/10 sulphuric acid is equivalent to 0·01221 Gm. of Nicotinamide.

Storage.

Nicotinamide should be kept in well-closed containers.

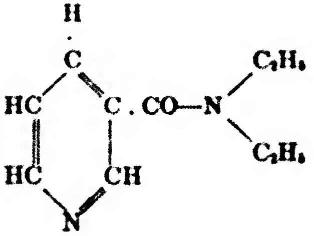
Doses
—daily—

Metric	Imperial
25 to 100 mgms.	⅓ to 1½ grains

NIKETHAMIDUM

(Nikethamid.)

Nikethamide



$C_{10}H_{14}N_2O$ Mol. Wt. 178·1

Nikethamide shall be the diethylamide of pyridine-β-carboxylic acid, and may be prepared by the action of thionyl chloride on nicotinic acid, and treatment of the resulting acid chloride with diethylamine. It shall contain not less than 98 per cent of $C_{10}H_{14}N_2O$; and shall conform to the following specification with respect to characters, tests for identity and tests for purity.

Characters.

Description.—Nikethamide occurs as a colourless or yellowish oily liquid, or crystalline solid; it is almost odourless, and possesses a faintly bitter taste, followed by a faint sensation of warmth.

Solubility.—Nikethamide is miscible in all proportions with *water*; and is readily soluble in *alcohol (90 per cent)*, in *ether*, in *chloroform* and in *acetone*.

Freezing point.—The *freezing point* of Nikethamide lies between 22° and 24°.

Tests for Identity.

A 25 per cent w/v solution of Nikethamide in *water* gives a voluminous precipitate with *alkaline solution of potassio-mercuric iodide* and with *solution of mercuric chloride*; with *solution of tannic acid* it gives a grayish-brown flocculent precipitate. The solution gives no precipitate with *solution of iodine*, with *solution of trinitrophenol* or with *solution of potassio-mercuric iodide*.

Saturate a 25 per cent w/v solution of Nikethamide in *water* with *sodium carbonate*; an oily layer is formed below the aqueous layer.

Tests for Purity.

Refractive index.—The *refractive index* of Nikethamide at 20° varies from 1·525 to 1·526.

Mix 5 mils of a 25 per cent w/v solution of Nikethamide in *water* with 3 drops of 0·1 per cent w/v *solution of potassium permanganate* in *water*; the pink colour is not discharged within two minutes.

Assay.

Heat about 0·4 Gm. of Nikethamide, accurately weighed, in a long-necked flask with 10 mils of 50 per cent *v/v nitrogen-free sulphuric acid* for two hours; cool, dilute with *water*, transfer to an ammonia distillation apparatus, add 50 mils of *test-solution of sodium hydroxide* and distil the liberated diethylamine into 30 mils of *N/10 hydrochloric acid*. Titrate the excess of acid with *N/10 sodium hydroxide*, using *solution of methyl red* as indicator. Repeat the experiment without the pyridine-β-carboxylic acid diethylamide. The difference between the two titrations represents the acid required to neutralize the diethylamine formed. Each mil of *N/10 hydrochloric acid* is equivalent to 0·01781 Gm. of $C_{10}H_{14}N_2O$.

Sterilization of a Solution.

A solution of Nikethamide for injection is sterilised by *heating in an autoclave*, or by *filtration*.

Doses

Metric	Imperial
0·2 to 1·5 Gm.	3 to 8 grains
By intravenous injection as a stimulant.	
0·5 to 1·25 Gm.	8 to 20 grains

NITROGENII MONOXIDUM

(Nitrogen. Monox.)

Nitrous Oxide

N_2O Mol. Wt. 44.02

Nitrous Oxide may be prepared by heating ammonium nitrate. For convenience in use it is compressed in metal cylinders. When drawn from a cylinder in the upright position, it shall contain not less than 98 per cent v/v of nitrous oxide; and shall conform to the following specification with respect to characters, test for identity and tests for purity.

Characters.

Description.—Nitrous Oxide occurs as a colourless gas, heavier than air, possessing a characteristic odour and a faintly sweetish taste.

Solubility.—One volume of Nitrous Oxide dissolves in about 2 volumes of *water* at temperatures between 15° and 25°.

Test for Identity.

A glowing splinter of wood bursts into flame on being plunged into the gas.

When mixed with an equal volume of nitric oxide, no red fumes are produced (distinction from oxygen).

Tests for Purity.

Carbon Monoxide.—Nitrous Oxide contains not more than 50 parts per million v/v of carbon monoxide. For this determination the gas used is the first portion drawn from the cylinder and is taken with the cylinder in the upright position. Pass a volume equivalent to 5 to 10 litres, measured at normal temperature and pressure, through a purifying train, comprising (1) *fuming sulphuric acid*, (2) *sulphuric acid*, (3) 33 per cent w/v aqueous solution of *potassium hydroxide*, (4) *soda lime*, (5) *potassium hydroxide*, (6) *phosphorus pentoxide*; then pass it through a tube containing *iodine pentoxide* (previously dried at 200°) maintained at a temperature of 120°, absorbing the liberated iodine in *solution of potassium iodide*. Sweep out the apparatus by passing through it 5 litres of air free from carbon monoxide. Titrate the iodine with *N/500 sodium thiosulphate*, and from the amount used subtract the amount required in a similar experiment, in which 5 litres of air free from carbon monoxide is used. Each mil of *N/500 sodium thiosulphate* is equivalent to 0·112 mil of carbon monoxide at normal temperature and pressure.

Water vapour and carbon dioxide.—Pass a measured quantity of Nitrous Oxide successively through absorption tubes, containing (*a*) *phosphorus pentoxide*, and (*b*) *soda lime*. The increase of weight of tube (*a*) does not exceed 2 mgm. per litre of gas, and the increase in weight of tube (*b*) does not exceed 4 mgm. per litre of gas, both the initial and final weighings of the absorption tubes being made when the air in them has been displaced with nitrous oxide.

Uncondensable gases.—Expose a measured volume of Nitrous Oxide to the temperature of liquid air; the proportion of uncondensed gases is not greater than 1·5 per cent v/v.

Arseniuretted hydrogen and phosphoretted hydrogen.—Pass a volume of Nitrous Oxide equivalent to 2 litres, measured at normal temperature and pressure, through a *mercuric chloride paper* attached to a glass tube, as in the *arsenic limit test*; no visible stain is produced.

For the following tests the reagent is placed in a 100-mil cylinder which has a height of about 20 centimetres and is closed with a stopper, containing an inlet tube which has a bore not exceeding 0·5 mil and passes to the bottom of the cylinder, and an exit tube. A volume equivalent to 2 litres, measured at normal temperature and pressure, is passed through the reagent in thirty minutes for each of the following tests:—

Halides and sulphuretted hydrogen.—Pass the gas through 100 mils of *water*, containing 1 mil of *solution of silver nitrate*; neither opalescence nor darkening is produced.

Acidity and alkalinity.—To 300 mils of water add 1 mil of *solution of methyl red*, and boil for five minutes. Transfer 100 mils of this solution to three similar cylinders and label them 1, 2 and 3. While still warm add 0·1 mil of *N/100 sulphuric acid or N/100 hydrochloric acid* to tube 1, and 0·2 mil of the same acid to tube 2, and 0·3 mil to tube 3; cork tubes 1 and 3, and pass the gas through tube 2; the colour in tube 2 is not more yellow than that in tube 1, and not more pink than that in tube 3.

Reducing substances.—Pass the gas through 100 mils of *water*, containing 0·2 mil of *N/10 potassium permanganate*; the colour is not completely discharged.

Oxidising substances.—Pass the gas through a freshly prepared solution of 0·5 Gm. of *soluble starch* and 0·5 Gm. of *potassium iodide* in 100 mils of *water*; no colour is developed.

The vapour pressure of Nitrous Oxide in tanks may serve as a guide to its purity. The following table gives the pressure in pounds measured on a standard gauge, of a sample of Nitrous Oxide, at the temperatures which will be encountered in its manufacture or its use.

Vapour Pressure of 99·3 per cent Nitrous Oxide

Fahrenheit	Centigrade	Pressure in Pounds
32	0	465
50	10	580
59	15	655
68	20	735
77	25	820
86	30	910

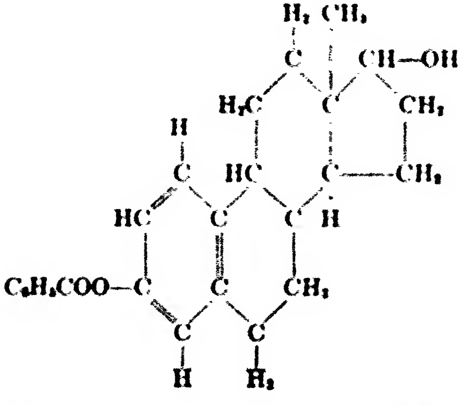
For each per cent of non-liquefied gases (Nitrogen) in Nitrous Oxide between 100 per cent and 94 per cent pure, the pressure rises approximately 20 pounds in the range of temperature given above.

OESTRIADIOLIS BENZOAS

(Oestradiol. Benz.)

Oestradiol Benzoate

Synonym.—ESTRADIOL BENZOATE.



$C_{25}H_{28}O_3$ Mol. Wt. 376·2

Oestradiol Benzoate shall be 3-benzoate-17-α-hydroxy-$\Delta^{1:3:5}$ oestratriene and may be prepared by esterification of the phenolic hydroxy group of 3:17-α dihydroxy-$\Delta^{1:3:5}$ oestratriene with benzoic acid.

Each mgm. shall have a potency of 10,000 international (benzoate) units. Oestradiol Benzoate shall conform to the following specifications with respect to characters, tests for identity, tests for purity and assay.

Characters.

Description.—Oestradiol Benzoate occurs as a white or slightly yellow to brownish, odourless, crystalline powder, stable in air.

Solubility.—Oestradiol Benzoate is practically insoluble in *water*, but dissolves in *alcohol*, in *acetone*, and in *diethylene dioxide*. It is slightly soluble in *ether*, and sparingly soluble in Sesame and other vegetable oils.

Constants.—The *melting point* of Oestradiol Benzoate lies between 191° and 196°. *Optical rotation.*—The specific rotation of Oestradiol Benzoate at 25°, determined on a 2 per cent w/v solution in *diethylene dioxide* in a 100 mm. tube, the substance having been previously dried over sulphuric acid for 4 hours, is not less than 58° and not more than 63°.

Tests for Identity.

A solution of 1 mgm. of Oestradiol Benzoate in 1 mil of *sulphuric acid* is greenish-yellow and exhibits a blue fluorescence; on dilution with 1 mil of *water*, the colour changes to pale orange.

Dissolve 0·1 Gm. of Oestradiol Benzoate in 10 mils of *methyl alcohol*, add 0·5 mils of a 20 per cent w/v solution of *potassium carbonate* in *water* and boil under a reflux condenser on a water-bath for 2 hours. Add 30 mils of *water*, cool, and maintain the temperature between 5° and 10° for one hour. Filter the precipitate, wash thoroughly with cold *water* and dry at 80°. The residue has a *melting point*, 174° to 179°.

Dissolve 5 mgms. of the oestradiol, obtained above, in 5 mils of 10 per cent w/v solution of *potassium hydroxide* in *water* and add the solution to a mixture prepared by mixing 50 mgms. of *sulphanilic acid* with 2 mils of *dilute hydrochloric acid* and warming, then cooling in ice water, and adding slowly, with agitation, 0·3 mils of a 10 per cent w/v aqueous solution of *sodium nitrite*; a deep red colour is produced.

Evaporate the filtrate from the precipitated oestradiol above to about 5 mils and filter again if necessary. Add to the filtrate 2 mils of *dilute hydrochloric acid*. Extract with 5 mils of *ether*, evaporate the *ether* and dry the residue at 70°. The resulting benzoic acid has a *melting point*, 120° to 122°.

Tests for Purity.

Solution.—A 2 per cent w/v solution of Oestradiol Benzoate in warm *alcohol* is clear and without insoluble residue; and after cooling, is only slightly acid to *litmus paper*.

Ash.—Oestradiol Benzoate, on incineration, leaves not more than 0·5 per cent of ash.

Assay.

Carry out the official method of assay employed in the Laboratory of Hygiene.

Storage.

Oestradiol Benzoate should be kept in a well-closed container, protected from light.

Doses

Metric	Imperial
1 to 5 mgms.	1/60 to 1/12 grain

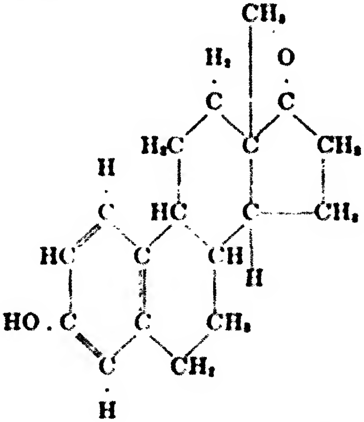
by intramuscular injection.

OESTRONUM

(Oestron.)

Oestrone

Synonyms.—ESTRONE; THEELIN.



$C_{18}H_{22}O_2$ Mol. Wt. 270·2

Oestrone shall be 3-hydroxy-17-keto-$\Delta^{1:3:5}$ oestratriene and may be prepared from the urine of pregnant mares. Each mgm. shall have a potency of 10,000 international units. Oestrone shall conform to the following specification with respect to characters, tests for identity, test for purity and assay.

Characters.

Description.—Oestrone occurs as small, white crystals, or as a white crystalline powder. It is odourless and is stable in air.

Solubility.—Oestrone is slightly soluble in *water*, but dissolves in *alcohol*, in *acetone*, in *diethylene dioxide*, and in solutions of fixed alkali hydroxides.

Constants.—The *melting point* of Oestrone lies between 258° and 262°. The *specific rotation*, determined by using a 1 per cent w/v solution of Oestrone in *diethylene dioxide* in a 200 mm. tube, may vary from +155° to +165°.

Tests for Identity.

Dissolve 50 mgms. of Oestrone in 6 mils of *pyridine* and 2 mils of *acetic anhydride*, and heat at 95° for 24 hours. Add 10 mils of *alcohol (60 per cent)*, and evaporate under reduced pressure to the consistency of a thick oil. Add 1 mil of *alcohol (60 per cent)* and allow to crystallize. Separate the crystals, and recrystallize twice from hot *alcohol*. The crystals have a *melting point*, 126° to 127°.

Dissolve 50 mgms. each of Oestrone and of *hydroxylamine hydrochloride* in 10 mils of *alcohol (95 per cent)* and 1 mil of *glacial acetic acid*, and boil under a reflux condenser for 5 hours. Add 10 mils of *water* and recrystallize the oestrone oxime twice from hot *alcohol (95 per cent)*. The crystals have a *melting point*, 229° to 231°.

Test for Purity.

Ash.—Oestrone leaves, on incineration, not more than 0·5 per cent of ash.

Assay.

Carry out the official method of assay employed in the Laboratory of Hygiene.

Storage.

Oestrone should be kept in a well-closed container, protected from light .

Doses

Metric	Imperial
by intramuscular injection	
0·5 to 1 mgm.	1/120 to 1/60 grain
(5,000 to 10,000 international units)	

OLEUM CASSIAE

(Ol. Cass.)

Oil of Cassia

Oil of Cassia shall be the oil distilled from the leaves and twigs of *Cinnamomum Cassia*, Blume. When assayed by the method indicated herein, it shall

contain not less than 80 per cent by weight of cinnamic aldehyde; and shall conform to the following specification with respect to characters, tests for identity and purity.

Characters.

Description.—Cassia Oil is a yellow liquid when freshly distilled, gradually becoming brown with age; the odour and taste resemble cinnamon, but are somewhat less pleasant.

Solubility.—Cassia Oil is soluble in 2 volumes of *alcohol (70 per cent)*, and in an equal volume of *glacial acetic acid*.

Tests for Identity and Purity.

Reaction.—An alcoholic solution of Oil of Cassia is slightly acid to moistened *litmus paper*.

Constants.—The specific gravity of Cassia Oil at 25° varies from 1·045 to 1·063; the optical rotation, from -1° to +1°; the refractive index at 20° from 1·6020 to 1·6135.

Dissolve 1 drop of Cassia Oil in 5 mils of *alcohol (90 per cent)*, and add one drop of *test-solution of ferric chloride*; a blue or deep brown colour is produced.

Synthetic products.—Rinse the interior surface of a well-cleaned 1,000-mil beaker with successive portions of *water*, and filter the washings; until the last filtered washing fails to give any reaction for *chlorides*; ignite a few drops of the oil on a porcelain dish, and immediately invert the moistened beaker over it; rinse the sides of the beaker with 20 mils of *water*, filter the washings, add 1 drop of *nitric acid* and 1 drop of *solution of silver nitrate*; no turbidity is produced.

Colophony.—Mix 2 mils with 4 mils of light *petroleum (boiling point 50° to 60°)*, and shake with 10 mils of *dilute solution of copper acetate*; the light petroleum layer is not coloured green.

Assay.

Carry out the *method for the determination of aldehydes in volatile oils*, as described for Oil of Cinnamon.

Storage.

Oil of Cassia should be kept in a well-closed container, protected from light, and stored in a cool place.

Doses

Metric	Imperial
0·06 to 0·2 mils.	1 to 3 minims.

NOTE.—Oil of Cassia may replace Oil of Cinnamon in Canada unless Oil of Ceylon or true Cinnamon is ordered.

OLEUM COCOIS

(Ol. Cocois)

Coconut Oil

Coconut Oil shall be the fat expressed from the kernels of the fruit of the coconut tree, *Cocos nucifera*, Linn. and *C. butyracea*, Linn. and shall conform to the following specification with respect to characters and tests for purity.

Characters.

Description.—Coconut Oil occurs as a solid, pearl-white fat, breaking at temperatures below 15° with a characteristic fracture; the odour is reminiscent of coconut; and the taste, bland and agreeable. It readily becomes rancid.

Solubility.—Coconut Oil is soluble in 2 parts of *alcohol* at 60°, less soluble at ordinary temperatures; it is readily soluble in *ether*, in *chloroform* and in *carbon disulphide*.

Tests for Purity.

Constants.—The *melting point* varies from 23° to 26°; the *refractive index* at 40°, from 1·4485 to 1·4495; the *acid value* is not more than 6; the *saponification value* varies from 225 to 260; and the *iodine value* from 7·9 to 9·5.

Storage.

Coconut oil should be kept in a well-closed container in a cool place, as it readily becomes rancid.

OLEUM HIPPOGLOSSI

(Ol. Hippoglos.)

Halibut Liver Oil

Halibut Liver Oil shall be the fixed oil extracted from the fresh, or suitably preserved liver of the halibut, *Hippoglossus hippoglossus*, Linn., and other species of *Hippoglossus*. It shall contain in each Gm. not less than 60,000 international units of vitamin-A activity; and shall conform to the following specifications with respect to characters, test for identity, tests for purity and assay.

Characters.

Description.—Halibut Liver Oil is a yellow to brownish-yellow oily liquid, possessing a slightly fishy, but not rancid, odour; and a fishy taste.

Solubility.—Halibut Liver Oil is slightly soluble in *alcohol (90 per cent)*; and is miscible with *ether*, with *chloroform*, with *carbon disulphide* and with *ethyl acetate*.

Test for Identity.

Dissolve 1 drop of Halibut Liver Oil in 1 mil of *chloroform* and shake the mixture with 1 drop of *sulphuric acid*; a blue colour is produced, which changes to violet, then to dark green and finally to black.

Tests for Purity.

Constants.—The *specific gravity* of Halibut Liver Oil at 25° varies from 0·920 to 0·930; the *saponification value*, from 160 to 180; the *iodine value*, from 125 to 155; and the *unsaponifiable matter*, from 7 to 13·5 per cent.

Acid value.—The *acid value* of Halibut Liver Oil is not greater than 2·8 when determined as follows: Dissolve 2 Gm. of Halibut Liver Oil in a mixture of 10 mils each of *alcohol (95 per cent)* and *ether*, previously neutralized to *phenolphthalein*, and titrate with *N/10 sodium hydroxide*, using *solution of phenolphthalein* as indicator; the titration is complete when a pink colour persists after shaking for 15 seconds.

Assay.

Carry out the official method of assay employed in the Laboratory of Hygiene.

Storage.

Halibut Liver Oil should be kept in a well-filled, well-closed container, from which air has beeen excluded, and in a dark, cool place.

Doses

Metric Imperial

Prophylactic

0·08 mil ½ minim.

(approximately equivalent to 5,000 international units of Vitamin A.)

Therapeutic

0·3 to 1 mil 5 to 15 minims.

(approximately equivalent to from 18,000 to 55,000 international units of Vitamin A.)

OLEUM MAYDIS

(Ol. Mayd.)

Corn Oil

Synonym.—Maize Oil.

Corn Oil shall be the fixed oil, expressed from the germ of the seed of Zea Mays, Linn. and shall comply with the following specification with respect to characters and tests for purity.

Characters.

Description.—Corn Oil is a clear, light yellow liquid; it is odourless or nearly odourless and possesses a bland taste.

Solubility.—Corn Oil is slightly soluble in alcohol; it is miscible with *ether*, with *chloroform*, with *benzene* and with *light petroleum (boiling point 50° to 60°)*.

Tests for Purity.

Constants.—*Specific gravity* at 25° is 0·917 to 0·923; *refractive index* at 20°, 1·4680-1·4706; *acid value*, not more than 1·2; *saponification value*, 188 to 193; *iodine value*, 111 to 130.

Cottonseed Oil.—Corn Oil complies with the *test for the absence of cottonseed oil*.

Doses

Metric	Imperial
15 to 30 mils	½ to 1 fluid ounce.

PARAFFINUM LIQUIDUM LEVE

(Paraff. Liq. Lev.)

Light Liquid Paraffin

Synonym.—Light Liquid Petrolatum

Light Liquid Paraffin shall be a mixture of liquid hydrocarbons, obtained from petroleum; and shall conform to the following specification with respect to characters and tests for purity.

Characters.

Description.—Light Liquid Paraffin is a transparent, colourless, oily liquid, free from fluorescence by daylight; it is odourless and tasteless when cold, but may possess not more than a faint odour of petroleum when heated.

Solubility.—Light Liquid Paraffin is insoluble in *water*, and in *alcohol (90 per cent)*; it dissolves in *ether* and in *chloroform*, and is miscible with fixed and volatile oils.

Tests for Purity.

Constants.—The *Specific gravity* of Light Liquid Paraffin at 25° varies from 0·828 to 0·880; the *kinematic viscosity* is not greater than 37 centistokes at 37·8°.

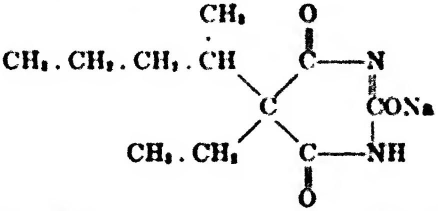
Other tests.—Light Liquid Paraffin complies with the requirements of the other tests described under "Paraffinum Liquidum, B.P."

PENTOBARBITONUM SOLUBILE

(Pentobarbiton. Sol.)

Soluble Pentobarbitone

Synonym.—Pentobarbital Sodium



$C_{11}H_{17}N_2O_3Na$ Mol. Wt. 248·1

Soluble Pentobarbitone shall be the mono-sodium derivative of ethyl (1-methyl-butyl) barbituric acid and may be prepared by the condensation of ethyl (1-methylbutyl) malonate with urea and subsequent interaction of the product with sodium hydroxide. When assayed by the method described herein, it shall contain not less than 99·2 per cent of $C_{11}H_{17}N_2O_3Na$; and not less than 9·2 per cent, and not more than 9·4 per cent of Na, both calculated with reference to the substance dried at 90° for 6 hours; and it shall conform to the following specification with respect to characters, tests for identity and tests for purity.

Characters.

Description.—Soluble Pentobarbitone occurs as a white powder or white crystalline granules; it is odourless, and has a slightly bitter taste.

Solubility.—Soluble Pentobarbitone dissolves in less than 1 part of *water*; it is soluble in *alcohol* but practically insoluble in *ether*.

Tests for Identity.

A 10 per cent w/v solution of Soluble Pentobarbitone in *water* is alkaline to *litmus paper* and to *solution of phenolphthalein*.

To a 10 per cent w/v solution of Soluble Pentobarbitone in *water* add an excess of *dilute hydrochloric acid*; collect the crystalline precipitate on a filter, wash with *water* and dry at 100°; the crystals have a *melting point*, 127° to 130°.

Evaporate the filtrate to dryness; the residue yields the *reactions* characteristic of sodium.

Tests for Purity.

Readily carbonizable substances.—Dissolve 0·5 Gm. of Soluble Pentobarbitone in 5 mils of *sulphuric acid*; not more than a faint yellow colour is produced.

Free pentobarbitone.—Shake 1 Gm. of Soluble Pentobarbitone with 50 mils of *ether*, filter, evaporate the filtrate, and dry the residue at 90°; the residue weighs not more than 1·2 mgms.

Loss on drying.—Soluble Pentobarbitone loses, when dried at 90° for 6 hours, not more than 5 per cent of its weight.

Assay.

For sodium.—Dissolve 0·5 Gm. of Soluble Pentobarbitone, accurately weighed, in 20 mils of *water*, add 1 drop of *solution of methyl red* and titrate with *N/10 sulphuric acid* until the pink colour is restored. Each mil of *N/10 sulphuric acid* is equivalent to 0·0023 Gm. of Na. The result should be calculated on a moisture-free basis.

For $C_{11}H_{17}N_2O_3Na$.—To the liquid from the Assay for Sodium add a further 10 mils of *N/10 sulphuric acid*, and 25 mils of *ether*; shake vigorously. Separate the *ether* extract and wash it with 15 mils of water. Repeat the extraction of the acid liquid with two further quantities of 15 mils of *ether*, and wash each extract with the water used for the first extraction. Remove the ether from the mixed ether extracts, add 5 mils of *dehydrated alcohol*, evaporate to dryness, and dry the crystalline residue at 90°. One Gm. of residue is equivalent to 1·102 Gm. of $C_{11}H_{17}N_2O_3Na$. The result should be calculated on a moisture-free basis.

Sterilization of a Solution.

Soluble Pentobarbitone is prepared in solution for injection by dissolving it in the requisite amount of Sterilized Water.

Storage.

Soluble Pentobarbitone should be kept in a well-closed, glass container.

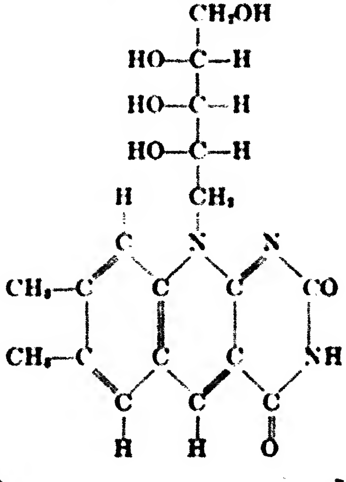
Doses

Metric	Imperial
For oral administration	
30 to 100 mgms.	½ to 1½ grains
For pre-operative use	
0·2 Gm.	3 grains

RIBOFLAVINA

(Riboflav.)

Riboflavin



$C_{17}H_{20}N_4O_6$ Mol. Wt. 376·2

Riboflavin shall be 7:8-dimethyl-10-(1′-*d*-ribityl) isoalloxazine, and may be prepared synthetically. It shall contain not less than 14·5 per cent and not more than 15·2 per cent of N, calculated with reference to the substance dried in a vacuum desiccator over sulphuric acid for 18 hours; and shall conform to the following specification with respect to characters, test for identity and tests for purity.

Characters.

Description.—Riboflavin occurs as an orange-yellow crystalline powder, possessing a slight, aromatic odour, and a slightly bitter taste. When dry, it is not affected appreciably by diffused light, but in solution, and especially in the presence of alkalies, it deteriorates rapidly, the deterioration being accelerated by light.

Solubility.—Riboflavin is soluble in about 10,000 parts of *water* at 25°; it is more soluble in *physiological solution of sodium chloride;* it is less soluble in *alcohol;* insoluble in *ether* and in *chloroform;* but very soluble in dilute solutions of alkaline hydroxides.

Melting point.—The *melting point* of Riboflavin is about 280°, with decomposition. In carrying out the test, preheat the bath to 250° and continue the heating at the rate of 5° per minute.

Optical rotation.—The *optical rotation* of Riboflavin is not less than -112° and not more than -122°, when determined as follows: Weigh accurately 50 mgms. of Riboflavin, previously dried in the dark in a vacuum desiccator over sulphuric acid for 18 hours, dissolve in a mixture of 1·5 mils of *N/10 alcoholic potassium hydroxide* and sufficient recently boiled and cooled *water* to produce 10 mils, and complete the determination in a 100 millimetre tube within 30 minutes.

Test for Identity.

Dissolve 1 mgm. of Riboflavin in 100 mils of *water;* the solution is pale greenish-yellow when viewed by transmitted light, and exhibits an intense yellowish-green fluorescence which disappears upon the addition of mineral acids or alkalies.

Tests for Purity.

Lumiflavin.—25 mgms. of Riboflavin, shaken for 5 minutes with 10 mils of *chloroform*, yields a filtrate which has no more colour than an equal volume of a solution of 3 mils of *N/10 potassium dichromate* in 1000 mils of *water.*

Limit of free acid.—A saturated aqueous solution of Riboflavin is neutral to *litmus paper.*

Loss on drying and ash.—Riboflavin loses, when dried in a vacuum desiccator over *sulphuric acid* for 18 hours, not more than 1·5 per cent of its weight; and leaves, on incineration, not more than 0·2 per cent of ash.

Assay.

Determine the nitrogen in Riboflavin by any suitable method, using material which has been previously dried in a vacuum desiccator over *sulphuric acid* for 18 hours.

Storage.

Riboflavin should be kept in well-closed, light-resistant containers.

Doses

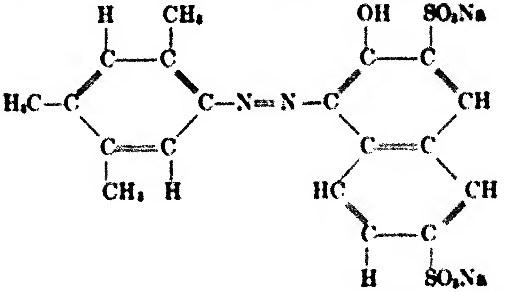
Metric	Imperial
1 to 5 mgms.	1/60 to 1/12 grain

RUBRUM CUMIDINUM

(Rubr. Cumid.)

Cumidine Red

Synonyms.—PONCEAU-3R; COLOUR INDEX (Society of Dyers and Colourists) No. 80 FD&C. Red No. 1.



$C_{19}H_{16}N_2O_7S_2Na_2$ Mol. Wt. 494·3

Cumidine Red shall be the disodium salt of φ-cumyl-azo-2-naphthol-3:6-disulphonic acid and may be prepared by the diazotization of crude φ-cumidine and coupling with 2-naphthol-3:6-disulphonic acid.

Characters.

Description.—Cumidine Red occurs as a dark red powder.

Solubility.—Cumidine Red is soluble in *water,* giving a cherry-red solution; it is sparingly soluble in *alcohol (95 per cent).*

Standard.

Cumidine Red shall be from stocks specially prepared for food purposes (*see* Section V, Division I, of these Regulations), and shall not contain more than 10 parts per million of arsenic, calculated as As_2O_3, and, with the exception of iron, shall not contain heavy metals.

SAPO DURUS

(Sap. Dur.)

Hard Soap

Hard Soap shall be soap made by the interaction of sodium hydroxide with any suitable vegetable oil or oils except coconut oil or palm kernel oil, or with fatty acids derived therefrom, and shall conform to the following specification with respect to characters and tests for purity.

Characters.

Description.—Hard Soap is a greyish-white or yellowish-white substance; it is nearly odourless. It becomes horny and pulverisable when dried.

Solubility.—Hard Soap is soluble in *water*, and in *alcohol (90 per cent)*; it is more quickly dispersed when these solvents are warmed.

Tests for Purity.

Composition.—Hard Soap complies with the tests for limit of alkali hydroxide, limit of free fatty acid, and limit of total free alkali described under "Sapo Mollis", the tests being carried out on the material which has been reduced to thin shavings, or to powder.

Unsaponified and Unsaponifiable matter.—Carry out the test for limit of unsaponified neutral fat and unsaponifiable matter described under "Sapo Mollis", on the material which has been reduced to thin shavings, or to powder; the weight of the residue is not more than 50 mgms.

Alcohol-insoluble substances.—Carry out the test for limit of alcohol-insoluble substances described under "Sapo Mollis"; the weight of the residue is not more than 60 mgms.

Rosin.—Hard Soap complies with the test for absence of rosin described under "Sapo Mollis".

Dissolve about 20 Gms. of Hard Soap in hot *water*, add a slight excess of *dilute sulphuric acid*, and heat on a water-bath, until the liberated fatty acids form a transparent layer. Separate the fatty acids on a wet filter paper, and wash with hot *water* until the washings are neutral to *solution of methyl orange*. Filter the oily layer through a dry filter-paper in a warm oven; the fatty acids have the following characters: *Solidifying-point*, not less than 28° (unless the soap is made entirely from olive oil), *acid value*, determined on 2 to 3 Gms. of the fatty acids, *using N/2 aqueous potassium hydroxide* and multiplying the number of millilitres required by 5, not greater than 206.

Loss on drying.—Hard Soap loses, when dried at 100°, not more than 30 per cent of its weight.

Hard Soap in powder complies with the tests for purity prescribed for Hard Soap with the following modifications:—

Limit of alkali hydroxide.—Not more than 1·3 mil of *N/10 hydrochloric acid* is required.

Limit of free fatty acid.—Not more than 0·25 mil of *N/10 sodium hydroxide* is required.

Limit of total free alkali.—The volume of *N/1 sulphuric acid* neutralised by the soap is not more than 1·3 mil.

Limit of unsaponified neutral fat and unsaponifiable matter.—The weight of the residue is not more than 70 mgms.

Limit of alcohol-insoluble substances.—The weight of the residue is not more than 70 mgms.

Loss on drying.—Hard Soap, in powder, loses, when dried at 110°, not more than 5 per cent of its weight.

SAPO MOLLIS

(Sap. Moll.)

Soft Soap

Soft Soap shall be soap made by the interaction of potassium hydroxide, or sodium hydroxide, with any suitable vegetable oil or oils, except coconut oil or palm kernel oil, or with fatty acids derived therefrom. When assayed by the method described herein, it shall yield not less than 44 per cent of fatty acids and shall conform to the following specifications with respect to characters and tests for purity.

Characters.

Description.—Soft Soap occurs as a yellowish-white to green, or brown unctuous substance.

Solubility.—Soft Soap is soluble in *water,* and in *alcohol (90 per cent).*

Tests for Purity.

Boil 300 mils of *alcohol (95 per cent),* to remove carbon dioxide, add 1·5 mil of 0·5 per cent w/v *solution of phenolphthalein,* allow to cool to 70° and neutralize, if necessary, with *N/10 sodium hydroxide* or *N/10 sulphuric acid.*

Alkali hydroxide.—To 100 mils of the neutral alcohol add 10 Gm. of Soft Soap and warm until dissolved. Add in a thin stream 5 mils of hot *solution of barium chloride* previously neutralized to *solution of phenolphthalein,* mix thoroughly, and titrate with *N/10 hydrochloric acid* until the pink colour disappears; not more than 1 mil is required.

Free fatty acid.—If no free alkali hydroxide is found, to 100 mils of the neutral alcohol add 10 Gm. of Soft Soap and dissolve it as quickly as possible by heating. Cool to 70° and titrate at that temperature with *N/10 sodium hydroxide;* not more than 0·2 mil is required.

Total free alkali.—To the remainder of the neutral alcohol add 10 Gm. of Soft Soap and dissolve it as quickly as possible by heating. Add immediately 3 mils of *N/1 sulphuric acid* and boil on a water-bath for at least ten minutes. If the solution is not pink, cool to 70° and titrate with *N/1 sodium hydroxide* until a pink colour appears. If, after boiling with the acid, the pink colour returns, a further quantity of *N/1 sulphuric acid* must be added and the boiling repeated. The volume of N/1 sulphuric acid neutralized by the soap is not more than 1 mil.

Unsaponified neutral fat and unsaponifiable matter.—Dissolve 5 Gm. of Soft Soap in 80 mils of a mixture of 50 mils of *alcohol (95 per cent)* and 100 mils of *water*, without heating more than is necessary; transfer to a separator, washing the vessel with the remaining 70 mils of the mixture. Extract with 100 mils of *ether* while still slightly warm, run off the alcohol soap layer into a second separator and extract with 50 mils of ether. Repeat the extraction with 50 mils of *ether* and pour the three ethereal extracts into a separator containing 20 mils of *water*. Rotate the separator without violent shaking and, after allowing the liquids to separate, run off the water. Repeat the washing with *water* in the same way, until the separated water is not more than faintly turbid when acidified. Wash the ethereal solution twice by shaking vigorously with 20 mils of *N/2 potassium hydroxide*, each washing with alkali being immediately followed by washing with 20 mils of *water*, shaking vigorously each time. Acidify the last alkali washing after separating it and, if the liquid becomes turbid, repeat the washing with *N/2 potassium hydroxide* and *water* until the alkali washing remains clear on acidification. Finally wash with successive quantities of 20 mils of *water* until the water no longer gives a pink colour with *solution of phenolphthalein*. Transfer the ethereal solution to a weighed flask and remove the ether. When nearly all the ether is evaporated, add 3 mils of acetone. By the aid of a gentle current of air remove the solvent completely from the flask, which is preferably almost entirely immersed, held obliquely and rotated in a boiling water-bath. Repeat this operation until the weight of the residue is constant. The residue weighs not more than 40 mgms.

Alcohol-insoluble substances.—Dissolve 5 Gm. of Soft Soap in 100 mils of hot *alcohol (90 per cent)*, previously neutralised to phenolphthalein, filter through a dried and tared filter, wash the residue thoroughly with hot neutralised *alcohol (95 per cent)*, and dry at 100°; the weight of the residue is not more than 0·15 Gm.

The fatty acids, obtained in the Assay, have the following characters:—*solidifying-point*, not higher than 31°; *acid value*, determined on 2 to 3 Gms. of the fatty acids, using *N/2 aqueous potassium hydroxide* and multiplying the number of millilitres required by 5, not greater than 205; *iodine value (iodine monochloride method)*, not less than 83.

Rosin.—Mix 0·5 mil of the melted fatty acids in a test-tube with 2 mils of *acetic anhydride*, warm, shake until clear, and cool to 15·5°. Transfer one drop of this solution to a white porcelain tile, place one drop of a cold mixture of equal volumes of *sulphuric acid* and *water* near to it, and gently bring the drops together with a glass rod; no transient violet colour is produced.

Assay.

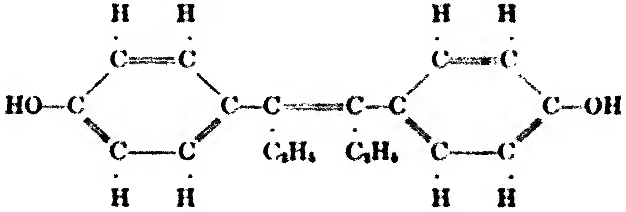
For fatty acids.—Dissolve about 20 Gm. of Soft Soap, accurately weighed, in 100 mils of water, transfer to a separator, acidify with *dilute sulphuric acid*, and extract with three successive quantities of 70 mils of *ether*. Mix the ethereal solutions in a separator, and wash with *water*, until the washings are free from mineral acid. Transfer the ethereal solution to a weighed flask, remove the ether, dry the residue at 80°, and weigh.

STILBOESTROL

(Stilboestr.)

Stilboestrol

Synonym.—DIETHYLSTILBOESTROL



$C_{18}H_{20}O_2$ Mol. Wt. 268·2

Stilboestrol shall be α-α′-diethyl-4-4′-stilbenediol and may be prepared from anisaldehyde by synthesis. It shall conform to the following specification with respect to characters, tests for identity and tests for purity.

Characters.

Description.—Stilboestrol occurs as a white, odourless, crystalline powder.

Solubility.—Stilboestrol is practically insoluble in *water*; it is soluble in *alcohol*, in *chloroform*, in *ether*, in *benzene*, in fatty oils and in dilute solutions of alkali hydroxides; and slightly soluble in *acetone*.

Melting point.—The *melting point* of Stilboestrol lies between 169° and 171°. In carrying out the determination, the bath should be preheated to 156° and the temperature raised at the rate of 0·5° per minute.

Tests for Identity.

Stilboestrol produces vaginal oestrus in ovariectomized adult female albino rats following the subcutaneous injection of 0·002 mg. in oil.

Dissolve 10 mgms. of Stilboestrol in 1 mil of *sulphuric acid;* an orange colour is produced which disappears on addition of 10 mils of *water.*

To 20 mgms. of Stilboestrol dissolved in 2 mils of *alcohol (60 per cent)* add 1 drop of a mixture of one part of *solution of ferric chloride* diluted with 5 volumes of *water;* a green colour is produced which changes to yellow.

To 5 mils of a 0·01 per cent solution of Stilboestrol in *alcohol-free chloroform,* add a few drops of a 50 per cent w/v solution of *antimony pentachloride* in *alcohol-free chloroform:* a red colour is produced.

More concentrated solutions yield a red precipitate.

Boil 0·1 Gm. of Stilboestrol with 2 mils of *pyridine* and 1 mil of *acetic anhydride* under a reflux condenser for 5 minutes. Dilute the mixture with 20 mils of *water,* filter and wash the precipitate with *water,* and recrystallize it from *alcohol (60 per cent);* dry the crystals at 100° for an hour; the *melting point* lies between 122° and 124°.

Tests for Purity.

Reaction.—A solution of 0·1 Gm. of Stilboestrol in 5 mils of *alcohol (70 per cent)* is neutral to *litmus paper.*

Loss on drying and ash.—Stilboestrol loses, when dried at 100° for 4 hours, not more than 0·5 per cent of its weight; and leaves, when moistened with *sulphuric acid* and incinerated, not more than 0·05 per cent of ash.

Storage.

Stilboestrol should be kept in well-closed containers, protected from light.

Doses

Metric	Imperial
0·5 to 1 mgm.	1/120 to 1/60 grain

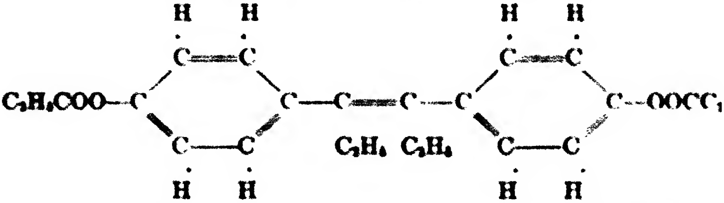
for oral administration or by intramuscular injection.

STILBOESTROLIS DIPROPIONAS

(Stilboestr. Diprop.)

Stilboestrol Dipropionate

Synonym.—Diethylstilboestrol Dipropionate.



$C_{24}H_{28}O_4$ Mol. Wt. 380·2

Stilboestrol Dipropionate shall be the di-propionic ester of diethylstilboestrol and may be prepared by the action of propionic anhydride on diethylstilboestrol. When assayed by the method indicated herein, it shall contain not less than 99 per cent of $C_{24}H_{28}O_4$; and shall conform to the following specification with respect to characters, tests for identity and tests for purity.

Characters.

Description.—Stilboestrol Dipropionate occurs in colourless, or pale cream crystalline plates, or as a white powder, free from odour.

Solubility.—Stilboestrol Dipropionate is insoluble in water, but dissolves in *alcohol*, in *chloroform*, in *ether*, in *benzene* and in fatty oils.

Melting point.—The *melting point* of Stilboestrol Dipropionate lies between 103° and 106°.

Tests for Identity.

Stilboestrol Dipropionate produces vaginal oestrus in ovariectomised adult female albino rats following the subcutaneous injection of 0·002 mg. in oil.

Saponify 0·1 Gm. of Stilboestrol Dipropionate with 20 mils of *N/2 alcoholic potassium hydroxide*, evaporate off the alcohol and dilute with water; filter and wash the precipitate and recrystallize from *alcohol (45 per cent)*; the crystals, when dried at 100° for 4 hours, have a *melting point*, 169° to 171°.

Tests for Purity.

Reaction.—A solution of 10 mgms. of Stilboestrol Dipropionate in 1 mil of *alcohol* is neutral to *litmus*.

Loss on drying and ash.—Stilboestrol Dipropionate loses, when dried at 100° for 4 hours, not more than 0·5 per cent of its weight; and leaves, when moistened with *sulphuric acid* and incinerated, not more than 0·05 per cent of ash.

Assay.

Carry out the *method for the determination of esters in volatile oils*. Each mil of *N/2 potassium hydroxide* is equivalent to 0·09505 Gm. of $C_{24}H_{28}O_4$.

Storage.

Stilboestrol Dipropionate should be kept in a well-closed container, protected from light.

Doses

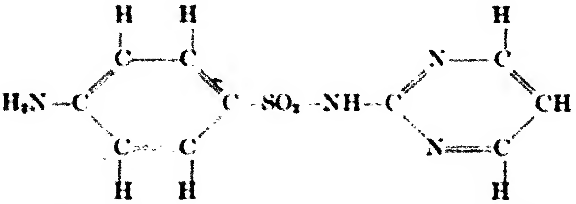
Metric	Imperial
1 to 5 mgms.	1/60 to 1/12 grain

by intramuscular injection.

SULPHADIAZINA

(Sulphadiazin.)

Sulphadiazine



$C_{10}H_{10}N_4O_2S$ Mol. Wt. 250·2

Sulphadiazine shall be 2-sulphanilamido-pyrimidine, and may be prepared by the condensation of *p*-acetylamino-benzene-sulphonyl chloride with 2-amino-pyrimidine, and subsequent hydrolysis. When assayed by the method described herein, it shall contain not less than 99 per cent of $C_{10}H_{10}N_4O_2S$, calculated with reference to the substance dried at 105°, and shall conform to the following specification with respect to characters, tests for identity and tests for purity.

Characters.

Description.—Sulphadiazine occurs as a white powder; it is odourless, or almost odourless, and tasteless; whilst stable in air, it slowly darkens on exposure to light.

Solubility.—Sulphadiazine dissolves in about 13,000 parts of *water* at 25°, and is sparingly soluble in *alcohol* and in *acetone*. It dissolves in about 620 parts of blood serum at 37°, and is freely soluble in dilute mineral acids and in aqueous solutions of alkali hydroxides.

Melting point.—The *melting point* of Sulphadiazine lies between 252° and 256°. In making the determination, the bath should be preheated to 240°.

Tests for Identity.

Heat 50 mgms. of Sulphadiazine in a test tube until it melts; a reddish-brown colour is produced (distinction from sulphanilamide which gives off ammonia and leaves a violet-blue residue). The fumes do not discolour filter paper moistened with *solution of lead acetate* (distinction from sulphathiazole).

Digest 20 mgms. of Sulphadiazine with 5 mils of *water*, and add, drop by drop, *test solution of sodium hydroxide* until dissolved; then add 2 drops of *solution of copper sulphate;* an olive-green precipitate is produced which becomes purple-grey on standing.

Tests for Purity.

Acidity.—Digest 1·5 Gm. of Sulphadiazine with 75 mils of *water* at 70° for 5 minutes; cool rapidly and filter. Titrate 25 mils of the filtrate with *N/10 sodium hydroxide*, using *solution of phenolphthalein* as indicator; not more than 0·2 mil of *N/10 sodium hydroxide* is required.

Clarity and colour of solution.—One Gm. of Sulphadiazine dissolved in 20 mils of *water* and 5 mils of *test solution of sodium hydroxide* yields a clear solution which is not deeper in colour than pale yellow.

Chlorides and sulphates.—One Gm. of Sulphadiazine complies with the *limit test for chlorides* and with the *limit test for sulphates.*

Arsenic and lead.—The *arsenic limit* in Sulphadiazine is 1 part per million; the *lead limit*, 20 parts per million.

Loss on drying and ash.—Sulphadiazine loses, when dried at 105°, not more than 0·5 per cent of its weight; and leaves, on incineration, not more than 0·1 per cent of ash.

Assay.

Dissolve 0·5 Gm. of Sulphadiazine, previously dried at 105° for 4 hours and accurately weighed, in a mixture of 20 mils of *hydrochloric acid* and 50 mils of *water*. Cool to 15°, add about 25 Gm. of crushed ice and titrate slowly with *N/10 sodium nitrite*, using *mucilage of starch and potassium iodide* as external indicator; the titration is complete when the end-point is reproducible after the mixture has stood for one minute. Each mil of *N/10 sodium nitrite* is equivalent to 0·02502 Gm. of $C_{10}H_{10}N_4O_2S$.

Storage.

Sulphadiazine should be kept in a well-closed container, protected from light.

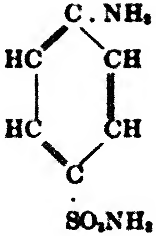
Doses

Metric	Imperial
0·5 to 2 Gm.	7½ to 30 grains.

SULPHANILAMIDUM

(Sulphanilamid.)

Sulphanilamide



$C_6H_8N_2O_2S$ Mol. Wt. 172·1

Sulphanilamide shall be *p*-aminobenzenesulphonamide and may be prepared by hydrolysis of the amide of acetylsulphanilic acid with hydrochloric acid, followed by decomposition of the resulting hydrochloride with alkali. When assayed by the method described herein, it shall contain not less than 99·0 per cent, and not more than the equivalent of 100·5 per cent, of $C_6H_8N_2O_2S$, calculated with reference to the substance dried in vacuo at 100°; and shall conform to the following specification with respect to characters, tests for identity and tests for purity.

Characters.

Description.—Sulphanilamide occurs as colourless crystals or as a white crystalline powder; it is odourless and possesses a slightly bitter taste with a sweet aftertaste.

Solubility.—Sulphanilamide is soluble in 125 parts of *water*, in 37 parts of *alcohol (95 per cent)*, and in 5 parts of *acetone* at 25°. It is also soluble in *glycerin* and in *dilute hydrochloric acid* and in aqueous solutions of *potassium and sodium hydroxides*. It is very soluble in boiling *water*, but is insoluble in *ether*, in *chloroform*, and in *benzene*.

Melting point.—The *melting point* of Sulphanilamide lies between 164·5° and 166·5°.

Tests for Identity.

Heat about 10 mgms. of Sulphanilamide in a dry tube; an intense violet-blue colour is produced and on further heating the odours of aniline and of ammonia are recognizable.

Dissolve about 50 mgms. of Sulphanilamide in 2 mils of warm *dilute hydrochloric acid*; cool in ice and add 2 mils of a 1 per cent w/v *solution of sodium nitrite* in water; add 2 mils of *water* and 1 mil of *solution of β-naphthol*; an orange precipitate is produced.

Tests for Purity.

Reaction.—A saturated aqueous solution of Sulphanilamide is neutral to *solution of litmus*.

Clarity of solution.—One Gm. of Sulphanilamide dissolves completely in 10 mils of *dilute hydrochloric acid*.

One Gm. of Sulphanilamide dissolves completely in 5 mils of a 10 per cent w/v *solution of sodium hydroxide* in *water*.

Ammonium salts.—Boil 0·25 Gm. of Sulphanilamide with 5 mils of *test-solution of sodium hydroxide*; no ammonia is evolved.

Chlorides and Sulphates.—One Gm. of Sulphanilamide complies with the *limit test for chlorides* and with the *limit test for sulphates*.

Arsenic and lead.—The *arsenic limit* in Sulphanilamide is 1 part per million; the *lead limit* is 20 parts per million.

Loss on drying and ash.—Sulphanilamide loses, when dried at 100° for 4 hours, not more than 0·5 per cent of its weight, and leaves, on incineration, not more than 0·1 per cent of ash.

Assay.

Dissolve about 0·4 Gm. of Sulphanilamide, previously dried at 100° for 4 hours and accurately weighed, in 50 mils of *dilute hydrochloric acid*, cool to 15°, and add about 25 Gm. of crushed ice. Slowly titrate with *N/10 sodium nitrite*, stirring vigorously, and using *mucilage of starch and potassium iodide* as external indicator; the titration is complete when the end-point is reproducible after the mixture has stood for one minute. Each mil of *N/10 sodium nitrite* is equivalent to 0·01721 Gm. of $C_6H_8N_2O_2S$.

Storage.

Sulphanilamide should be kept in a well-closed container, protected from light.

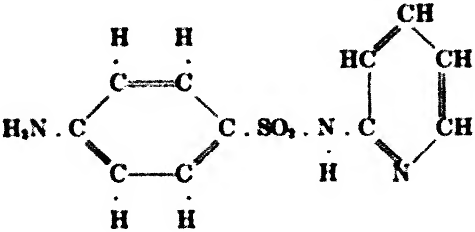
Doses

Metric	Imperial
0·5 to 2 Gm.	7½ to 30 grains

SULPHAPYRIDINA

(Sulphapyridin.)

Sulphapyridine



$C_{11}H_{11}N_3O_2S$ Mol. Wt. 249·2

Sulphapyridine shall be 2-*p*-aminobenzene-sulphonamide-pyridine and may be prepared by the interaction of 2-amino-pyridine and *p*-acetyl-aminobenzene-sulphonyl chloride, followed by hydrolysis with solution of sodium hydroxide. It shall contain not less than 99 per cent of $C_{11}H_{11}N_3O_2S$, calculated with reference to the substance dried at 100° for 4 hours, when assayed by the method described herein; and shall conform to the following specification with respect to characters, tests for identity and tests for purity.

Characters.

Description.—Sulphapyridine occurs as white, or slightly yellowish-white crystals, granules or powder; it is odourless, or nearly so, and tasteless; it is stable in air, but slowly darkens on exposure to light.

Solubility.—Sulphapyridine is soluble in about 3,500 parts of *water* and about 440 parts of *alcohol (95 per cent)* at 25°, in about 100 parts of *boiling water*, and in about 65 parts of *acetone* at 25°, and is very soluble in dilute mineral acids and in solutions of alkaline hydroxides.

Melting point.—The *melting point* of Sulphapyridine lies between 191° and 193°.

Tests for Identity.

Heat about 50 mgms. of Sulphapyridine in a dry tube until it melts; a brown colour is produced; on further heating, yellow fumes are given off and sulphur dioxide is evolved. (Sulphanilamide produces a blue colour and fumes of ammonia.)

Dissolve about 20 mgms. of Sulphapyridine in 5 mils of *water* with the aid of 2 drops of *test-solution of sodium hydroxide*, and add 3 drops of *solution of copper sulphate*; a green precipitate is produced, which becomes grayish on standing (distinction from sulphathiazole).

Dissolve 50 mgms. of Sulphapyridine in 2 mils of warm *dilute hydrochloric acid*; cool in ice and add 2 mils of a 1 per cent *solution of sodium nitrite in water*, and 1 mil of *solution of β-naphthol*; an orange-red precipitate is produced which darkens on standing.

Tests for Purity.

Reaction.—A saturated aqueous solution is neutral to *solution of litmus.*

Clarity of solution.—One Gm. of Sulphapyridine dissolves completely in 10 mils of *dilute hydrochloric acid*. One Gm. of Sulphapyridine dissolves completely in 5 mils of a 10 per cent *w/v solution of sodium hydroxide* in *water*.

Ammonium salts.—Boil 0·25 Gm. of Sulphapyridine with 5 mils of *test-solution of sodium hydroxide*; no ammonia is evolved.

Chlorides and Sulphates.—One Gm. of Sulphapyridine complies with the *limit test for chlorides* and with the *limit test for sulphates.*

Arsenic and lead.—The *arsenic limit* is 1 part per million, the *lead limit*, 20 parts per million.

Loss on drying and ash.—Sulphapyridine loses, when dried at 100° for four hours, not more than 5 per cent, and leaves, on incineration, not more than 0·1 per cent of ash.

Assay.

Dissolve about 0·5 Gm. of Sulphapyridine, previously dried at 100° and accurately weighed, in 50 mils of warm *dilute hydrochloric acid*, and cool to 15°, add about 25 Gm. of crushed ice and titrate slowly with *N/10 sodium nitrite*, using *mucilage of starch and potassium iodide* as external indicator; the titration is complete when the end-point is reproducible after the mixture has stood for one minute. Each mil of *N/10 sodium nitrite* is equivalent to 0·02492 Gm. of $C_{11}H_{11}N_3O_2S$.

Storage.

Sulphapyridine should be kept in a well-closed container, protected from light.

Doses

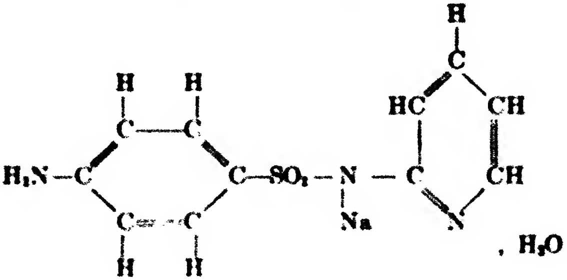
Metric	Imperial
0·5 to 2 Gm.	7½ to 30 grains

SULPHAPYRIDINA SOLUBILIS

(Sulphapyridin. Sol.)

Soluble Sulphapyridine

Synonym.—SULPHAPYRIDINE SODIUM



$C_{11}H_{10}N_3O_2SNa, H_2O$ Mol. Wt. 289·2

Soluble Sulphapyridine shall be the sodium salt of 2-*p*-aminobenzene-sulphonamido-pyridine and may be prepared by the interaction of 2-*p*-aminobenzene-sulphonamido-pyridine and sodium hydroxide. It shall contain not less than 99 per cent of $C_{11}H_{10}N_3O_2SNa$, calculated with reference to the substance dried at 105° for 4 hours; and shall conform to the following specification with respect to characters, tests for identity and tests for purity.

Characters.

Description.—Soluble Sulphapyridine occurs as a white crystalline, odourless and tasteless powder. Prolonged exposure to humid air tends to make it incompletely soluble in water. Soluble Sulphapyridine is affected by light.

Solubility.—Soluble Sulphapyridine is soluble in 1·5 parts of *water*, yielding an alkaline solution, and in 10 parts of *alcohol (95 per cent)* at 25°.

Tests for Identity.

Dissolve 1 Gm. of Soluble Sulphapyridine in 25 mils of *water* and add 2 mils of *acetic acid*. Collect the precipitate, wash with water, recrystallise from boiling *water* and dry at 100° for 4 hours. The crystals have a *melting point*, 191° to 193°, and yield the tests for identity described under "Sulphapyridina".

The filtrate from the precipitate yields the reactions characteristic of sodium.

Tests for Purity.

Reaction.—A solution of Soluble Sulphapyridine in water is alkaline to *solution of phenolphthalein.*

Chlorides and sulphates.—One Gm. of Soluble Sulphapyridine complies with the *limit test for chlorides* and with the *limit test for sulphates.*

Arsenic and lead.—The *arsenic limit* in Soluble Sulphapyridine is 1 part per million; the *lead limit,* 20 parts per million.

Loss on drying.—Soluble Sulphapyridine loses, when dried at 105° for 4 hours, not less than 5 per cent, and not more than 7 per cent of its weight.

Assay.

Dissolve about 0·5 Gm. of Soluble Sulphapyridine, previously dried at 105° for 4 hours and accurately weighed, in 25 mils of *water,* add 5 mils of *hydrochloric acid* and about 25 Gm. of crushed ice, and titrate with *N/10 sodium nitrite,* using *mucilage of starch and potassium iodide* as external indicator; the titration is complete when the end-point is reproducible after the mixture has stood for one minute. Each mil of *N/10 sodium nitrite* is equivalent to 0·02712 Gm. of $C_{11}H_{10}N_3O_2SNa$.

Storage.

Soluble Sulphapyridine should be kept in a well-closed container, protected from light.

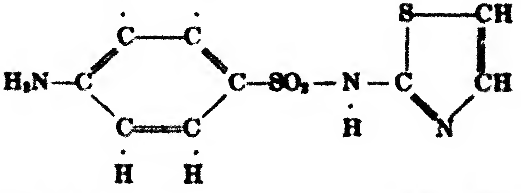
Doses

Metric	Imperial
0·5 to 2 Gm.	7½ to 30 grains.

SULPHATHIAZOLUM

(Sulphathiazol.)

Sulphathiazole



$C_9H_9N_3O_2S_2$ Mol. Wt. 255·2

Sulphathiazole shall be 2-sulphanilamidothiazole and may be prepared by the condensation of *p*-acetylamino-benzene-sulphonyl chloride with 2-aminothia-

sole in pyridine, and subsequent hydrolysis. It shall contain not less than 99 per cent of $C_9H_9N_3O_2S_2$, calculated with reference to the substance dried at 100° for 4 hours; and shall conform to the following specifications with respect to characters, tests for identity, tests for purity and assay.

Characters.

Description.—Sulphathiazole occurs as a white, or yellowish white, crystalline powder, or in granules; it is odourless and tasteless. It is stable in air, but slowly darkens on exposure to light.

Solubility.—Sulphathiazole is soluble in about 1700 parts of *water* and in about 200 parts of *alcohol (95 per cent)* at 25°; it is insoluble in *chloroform* and in *ether;* but readily soluble in dilute mineral acids and in solutions of alkaline hydroxides.

Melting point.—The *melting point* of Sulphathiazole lies between 200° and 204°.

Tests for Identity.

Heat about 50 mgms. of Sulphathiazole in a dry tube until it is melted; a brown to red colour is produced and on further heating the odours of aniline, ammonia and hydrogen sulphide are recognizable. (Distinction from sulphanilamide and sulphapyridine.)

Dissolve 20 mgms. of Sulphathiazole in 2 mils of warm *dilute hydrochloric acid;* cool in ice and add 2 mils of a 1 per cent *solution of sodium nitrite* in *water,* and 1 mil of *solution of β-naphthol;* an orange-red precipitate is produced which darkens on standing.

Tests for Purity.

Clarity of solution.—A solution of 1 Gm. of Sulphathiazole in 20 mils of a 1 per cent w/w *solution of sodium hydroxide* in water is clear and colourless.

Acidity.—Heat 2 Gm. of Sulphathiazole in 100 mils of water at 70° for 5 minutes; cool at once to 20° and filter. Titrate 25 mils of the filtrate with *N/10 sodium hydroxide,* using *solution of phenolphthalein* as indicator. Not more than 0·5 mil is required for neutralisation.

Chlorides and sulphates.—One Gm. of Sulphathiazole complies with the *limit test for chlorides* and with the *limit test for sulphates.*

Arsenic and lead.—The *arsenic limit* of Sulphathiazole is 1 part per million; the *lead limit,* 20 parts per million.

Loss on drying and ash.—Sulphathiazole loses, when dried at 100° for 4 hours, not more than 0·5 per cent of its weight; and leaves, on incineration, not more than 0·1 per cent of ash.

Assay.

Dissolve about 0·5 Gm. of Sulphathiazole, previously dried at 100° and accurately weighed, in 50 mils of warm *dilute* *hydrochloric acid*, and cool to 15°; add about 25 Gm. of crushed ice and titrate slowly with *N/10 sodium nitrite*, using *mucilage of starch and potassium iodide* as external indicator; the titration is complete when the end-point is reproducible after the mixture has stood for one minute. Each mil of *N/10 sodium nitrite* is equivalent to 0·02552 Gm. of $C_9H_9N_3O_2S_2$.

Storage.

Sulphathiazole should be kept in a well-closed container, protected from light.

Doses

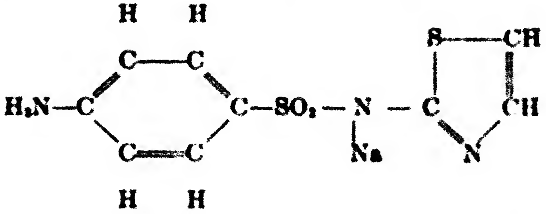
Metric	Imperial
0·5 to 2 Gm.	7½ to 30 grains.

SULPHATHIAZOLUM SOLUBILE

(Sulphathiazol. Sol.)

Soluble Sulphathiazole

Synonym.—SULPHATHIAZOLE SODIUM.



$C_9H_8N_3O_2S_2Na$ Mol. Wt. 277·2

Soluble Sulphathiazole shall be the sodium salt of 2-sulphanilamido-thiazole and may be prepared by the interaction of 2-sulphanilamido-thiazole and sodium hydroxide. It shall contain not less than 99 per cent and not more than the equivalent of 101 per cent of $C_9H_8N_3O_2S_2Na$, calculated with reference to the substance dried under reduced pressure at 100°; and shall conform to the following specifications with respect to characters, tests for identity, tests for purity and assay.

Characters.

Description.—Soluble Sulphathiazole occurs as a white, or faintly yellowish white, odourless, crystalline powder, pos- a saline and bitter taste. It is affected by light.

Solubility.—Soluble Sulphathiazole is very soluble in *water*, yielding an alkaline solution, and soluble in *alcohol;* but it is insoluble in *ether*.

Tests for Identity.

An aqueous solution of Soluble Sulphathiazole is alkaline to *solution of phenolphthalein*.

Dissolve 1 Gm. of Soluble Sulphathiazole in 10 mils of *water* and add slowly 1 mil of *dilute hydrochloric acid*. Collect the precipitate and recrystallize from boiling *water;* the crystals have a *melting point*, 200° to 204°, and yield the tests for identity described under "Sulphathiazolum".

An aqueous solution yields the *reactions* characteristic of sodium.

Tests for Purity.

Dissolve 1 Gm. of Soluble Sulphathiazole in 10 mils of *water;* the solution is clear and colourless.

Chlorides and sulphates.—One Gm. of Soluble Sulphathiazole complies with the *limit test for chlorides* and with the *limit test for sulphates*.

Arsenic and lead.—The *arsenic limit* in Soluble Sulphathiazole is 1 part per million; the *lead limit*, 20 parts per million.

Loss on drying.—Soluble Sulphathiazole loses, when dried under reduced pressure at 100°, not more than 9 per cent of its weight.

Assay.

Dissolve about 0·5 Gm. of Soluble Sulphathiazole, previously dried under reduced pressure and accurately weighed, in 25 mils of *water*, add 5 mils of *hydrochloric acid* and about 25 Gm. of crushed ice, and titrate with *N/10 sodium nitrite*, using *mucilage of starch and potassium iodide* as external indicator; the titration is complete when the end-point is reproducible after the mixture has stood for one minute. Each mil of *N/10 sodium nitrite* is equivalent to 0·02772 Gm. of $C_9H_8N_3O_2S_2Na$.

Storage.

Soluble Sulphathiazole should be kept in a well-closed container, protected from light.

Doses

Metric	Imperial
0·5 to 2 Gm.	7½ to 30 grains.

SYRUPUS FERRI PHOSPHATIS CUM STRYCHNINA

(Syr. Ferri Phosph. C. Strych.)

Syrup of Ferrous Phosphate with Strychnine

Synonym.—EASTON'S SYRUP.

Syrup of Ferrous Phosphate with Strychnine shall be prepared from the following ingredients in the amounts specified and shall contain iron, equivalent to not less than 1·62 per cent, and not more than 1·98 per cent w/v of anhydrous ferrous phosphate, $Fe_3(PO_4)_2$; and not less than 0·022 per cent, and not more than 0·027 per cent w/v of strychnine, when assayed by the methods described herein.

Iron	8·6 Gm.
Phosphoric Acid	38 mils
Dilute Hypophosphorous Acid	10 mils
Strychnine Hydrochloride	0·3 Gm.
Syrup	700 mils
Distilled Water, sufficient to produce	1000 mils

Dilute the Phosphoric Acid with 80 mils of Distilled Water contained in a flask of suitable size; add the Iron and heat on a water-bath, until the iron is dissolved; add the solution to the Strychnine Hydrochloride previously dissolved in 30 mils of Distilled Water; when solution is complete add the Dilute Hypophosphorous Acid and make up to 250 mils with Distilled Water; filter it into the Syrup, and pass sufficient Distilled Water through the filter to produce the required volume.

Assay.

For iron.—Carry out the method for the Assay for iron, described under "Syrupus Ferri Phosphatis Compositus." Each mil of *N/10 titanous chloride* is equivalent to 0·01192 Gm. of $Fe_3(PO_4)_2$.

For strychnine.—Mix in a separator about 100 mils, accurately weighed, with 5 Gm. of *sodium citrate*, dissolved in 100 mils of *water*. Add 30 mils of *solution of sodium hydroxide*, and extract with successive quantities of *chloroform*, until complete extraction of the alkaloid is effected, washing each of 4-*p*-sulphophenylazo-1-*p*-sulphophenyl-5-hydroxypyrazole-3-carboxylic acid and may be prepared by the condensation of 2 molecular proportions of phenylhydrazine-*p*-sulphonic acid with 1 molecular proportion of dioxytartaric acid.

Characters.

Description.—Tartrazine occurs as an orange-yellow powder.

Solubility.—Tartrazine is soluble in *water*, giving a golden-yellow solution; it is incompletely soluble in *alcohol (95 per cent)*.

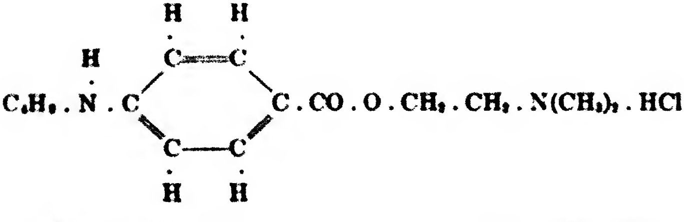
Standard.

Tartrazine shall be from stocks specially prepared for food purposes, (*see* Section V, Division I, of these Regulations), shall not contain more than 10 parts per million of arsenic, calculated as As_2O_3, and, with the exception of iron, shall not contain heavy metals.

TETRACAINAE HYDROCHLORIDUM

(Tetracain. Hydroch.)

Tetracaine Hydrochloride



$C_{15}H_{24}N_2O_2$, HCl. Mol. Wt. 300·7

Tetracaine Hydrochloride shall be the hydrochloride of the base, prepared by the interaction of chloroethyldimethylamine with sodium *p*-butylamino-benzoate. When assayed by the method described herein, it shall contain not less than 86·5 per cent, and not more than 88·5 per cent of $C_{15}H_{24}N_2O_2$, calculated with reference to the substance dried over sulphuric acid for 18 hours; and shall conform to the following chloroform solution with the same 20 mils of *water* contained in a second separator. Evaporate the chloroform, add to the residue 1 mil of *alcohol (95 per cent)*, dry at 100°, and weigh the strychnine.

Storage.

Syrup of Ferrous Phosphate with strychnine should be kept in a completely-filled, well-closed container, and protected from light.

Doses

Metric	Imperial
2 to 4 mils	30 to 60 minims.

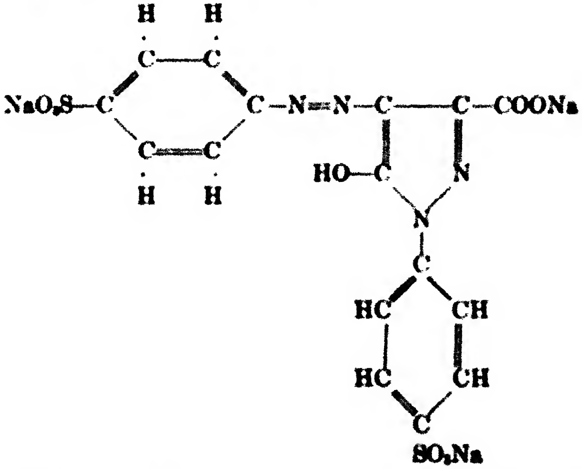
Syrup of Ferrous Phosphate with Strychnine contains in 4 mils the equivalent of 72 mgms. of anhydrous ferrous phosphate, or about 34 mgms. of iron and about 1·2 mgm. of Strychnine Hydrochloride; and in 60 minims the equivalent of about 1 grain of anhydrous ferrous phosphate, or about ½ grain of iron and about 1/60 grain of Strychnine Hydrochloride.

TARTRAZINA

(Tartrazin.)

Tartrazine

Synonym.—FD&C, YELLOW No. 5.



$C_{16}H_9N_4O_9S_2Na_3$ Mol. Wt. 534·2

Tartrazine [Colour Index (Society of Dyers and Colourists) No. 640] shall be the trisodium salt specifications with respect to characters, tests for identity and test for purity.

Characters.

Description.—Tetracaine Hydrochloride occurs as a fine, white, crystalline, odourless powder; the taste is somewhat bitter, imparting a sense of numbness to the tongue.

Solubility.—Tetracaine Hydrochloride is soluble in 7 parts of *water;* it is also soluble in *alcohol,* but insoluble in *ether.*

Melting point.—The *melting point* of Tetracaine Hydrochloride lies between 147° and 150°.

Tests for Identity.

To 0·1 Gm. of Tetracaine Hydrochloride dissolved in 10 mils of *water,* add 1 mil of a 25 per cent w/v solution of *potassium thiocyanate* in *water;* collect the precipitate; crystallise from hot water and dry at 80°. The crystals have a *melting point,* 130° to 132°.

Dissolve 0·1 Gm. of Tetracaine Hydrochloride in 10 mils of *water,* add 3 drops of *dilute hydrochloric acid,* and 2 mils of a 1 per cent *solution of sodium nitrite,* and pour the mixture into 1 mil of *solution of β-naphthol;* a white to pale salmon pink precipitate is produced, but no pronounced colour is developed.

An aqueous solution yields the *reactions* characteristic of chlorides.

Test for Purity.

Loss on drying and ash.—Tetracaine Hydrochloride loses when dried over *sulphuric acid* for 18 hours, not more than 1 per cent of its weight; and leaves, on incineration, not more than 0·1 per cent of ash.

Assay.

Dissolve about 0·3 Gm. of Tetracaine Hydrochloride, previously dried over *sulphuric acid* for 18 hours and accurately weighed, in 20 mils of *water,* add 1 mil of *test-solution of sodium hydroxide* and extract completely with *chloroform;* wash the combined *chloroform* extracts with 5 mils of *water,* remove the chloroform in a stream of warm air and dry the residue finally over *sulphuric acid* and weigh.

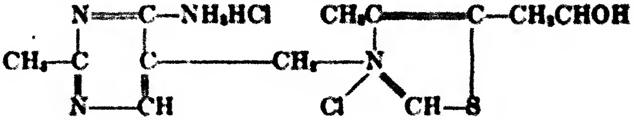
Storage.

Tetracaine Hydrochloride should be kept in a well-closed container, protected from light.

THIAMINÆ HYDROCHLORIDUM

(Thiamin. Hydrochl.)

Thiamine Hydrochloride



$C_{12}H_{17}Cl\ N_4OS,\ HCl.$ Mol. Wt. 337·2

Thiamine Hydrochloride shall be 3-(4′-amino-2′-methyl-pyrimidyl-5′-methyl)-4-methyl-5-β-hydroxyethylthiazolium chloride hydrochloride. It may be obtained from rice polishings, yeast and other natural sources, or by synthesis. It shall contain not less than 9·9 per cent, and not more than 10·7 per cent of Cl present as hydrochloride; not less than 16·2 per cent, and not more than 16·8 per cent of N, calculated with reference to the substance dried over sulphuric acid in a vacuum desiccator for 24 hours; and it shall conform to the following specification with respect to characters, tests for identity and tests for purity.

Characters.

Description.—Thiamine Hydrochloride occurs as small white crystals or as a crystalline powder; the odour and taste are faint and bran-like. When exposed to the air, anhydrous Thiamine Hydrochloride rapidly absorbs about 4 per cent of water.

Solubility.—Thiamine Hydrochloride is soluble in about 1 part of *water*, and in about 100 parts of *alcohol (95 per cent)* at 25°; it is soluble in *glycerin*, but insoluble in *ether* and in *benzene*.

Tests for Identity.

An aqueous solution of Thiamine Hydrochloride gives a white precipitate with *solution of mercuric chloride*, and a red-brown precipitate with *solution of iodine*; it is also precipitated by *solution of potassio-mercuric iodide*, and by *solution of trinitrophenol*.

Dissolve about 5 mgms. of Thiamine Hydrochloride in a mixture of 1 mil each of *solution of lead acetate* and of a 10 per cent w/v solution of *sodium hydroxide*; a yellow colour is produced. On being heated for a few minutes on a water-bath, the colour changes to brown, and, on standing, a black precipitate of lead sulphide separates.

Dissolve 5 mgms. of Thiamine Hydrochloride in 5 mils of *N/2 sodium hydroxide*, add 0·5 mil of *solution of potassium* *ferricyanide* and 5 mils of *isobutyl alcohol*, shake for two minutes and allow the liquids to separate; when illuminated by a vertical beam of light entering from above, and viewed at right angles from the beam, the uppermost meniscus of the top layer shows a vivid blue fluorescence, which disappears when the mixture is made slightly acid, but reappears on addition of a slight excess of the solution of *sodium hydroxide*.

Test for Purity.

Reaction.—A 2 per cent w/v aqueous solution of Thiamine Hydrochloride is acid to litmus paper.

Colour of solution.—Dissolve 1 Gm. of Thiamine Hydrochloride in 10 mils of water and compare the colour, with the aid of matched tubes, with that produced by a solution of 2 mils of *N/10 potassium dichromate* in 1000 mils of *water*; the colour is not deeper than that of the dichromate solution.

Sulphates.—Dissolve 50 mgms. of Thiamine Hydrochloride in 5 mils of *water*, add 0·5 mil of *dilute hydrochloric acid* and 0·5 mil of *solution of barium chloride*; no turbidity is produced within 5 minutes.

Ammonium salts.—To 5 mils of a 1 per cent w/v aqueous solution of Thiamine Hydrochloride add 5 mils of *N/10 sodium hydroxide* and heat gently; no ammonia is evolved.

Loss on drying and ash.—Thiamine Hydrochloride loses, when dried in a vacuum desiccator over sulphuric acid for 24 hours, not more than 5 per cent of its weight; and leaves, on incineration, not more than 0·15 per cent of ash.

Assay.

For Cl as hydrochloride.—Dissolve about 0·1 Gm. of Thiamine Hydrochloride previously dried in a vacuum desiccator over sulphuric acid for 24 hours and accurately weighed, in 20 mils of freshly boiled and cooled *water*, and titrate with *N/10 sodium hydroxide*, adding *solution of phenolphthalein* and taking the first development of colour to indicate the end of the titration. Each mil of N/10 sodium hydroxide is equivalent to 0·003546 Gm. of Cl.

For N.—Determine the nitrogen by any suitable method.

Storage.

Thiamine Hydrochloride should be kept in a stoppered glass bottle, protected from light. Solutions of Thiamine Hydrochloride are stable if faintly acid (pH 6 to 6·5). Neutral and alkaline solutions deteriorate rapidly, especially in contact with air.

Doses

Metric	Imperial
Daily Prophylactic	
1 mgm.	1/64 grain
(330 international units)	
Therapeutic	
2 to 10 mgms.	1/32 to 1/6 grain
(660 to 3,300 international units)	

THYROIDEUM SICCUM

(Thyroid. Sicc.)

Dried Thyroid

Dried Thyroid shall be the cleaned, dried, powdered thyroid glands of domestic animals used for food. When assayed as described herein, it shall contain not less than 0·27 per cent, and not more than 0·33 per cent of I, and shall contain no added iodine in either inorganic or organic form; and it shall conform to the following specifications with respect to characters and tests for purity.

Characters.

Description.—Dried Thyroid occurs as a cream-coloured, amorphous powder; the odour and taste are faint and meat-like.

When suitably mounted and examined under the microscope, Dried Thyroid shows numerous smooth to striated hyaline fragments of colloid, of angular to irregular shape which are colourless to pale yellow in water mounts, brown in *Mallory's stain* and pink in *solution of eosin*, some of these fragments containing granules, minute vacuoles, crystalloidal bodies and cells; numerous irregular fragments of follicular epithelium staining brown with *Mallory's stain*, the individual cells more or less polygonal to rounded-angular or irregularly cuboidal, often with prominent nuclei staining dark blue, their cytoplasm purplish with *Delafield's solution of haematoxylin*; slender glistening segments of capillaries of closely undulate outline; numerous slender segments of neuraxone; numerous aggregates of particles of intercellular substance and slender, mostly straight connective tissue fibres staining blue to greenish blue with a mixture of *Mallory's stain* and *solution of phosphotungstic acid*, the bundles of fibres often appearing reddish in *Mallory's stain*; few glistening fragments of blood vessels with serrated or crenated ends as viewed in water mounts.

Tests for Purity.

Inorganic iodine.—Digest 0·5 Gm. of Dried Thyroid with 1 mil of *strong solution of ammonia* and 9 mils of *alcohol (95 per cent)* for 15 minutes with frequent shaking; filter and evaporate the filtrate on a water-bath; take up the residue with 1 mil of *water* and filter again; add to the filtrate 3 drops of *solution of ferric chloride* and 1 mil of *chloroform*. The chloroform layer is not coloured violet.

Ash.—Dried Thyroid leaves, on incineration, not more than 4 per cent of ash soluble in water, and not more than 3·5 per cent insoluble in water.

Assay.

Mix in a nickel crucible, of approximately 100 mils capacity, about 0·7 Gm. of Dried Thyroid, accurately weighed, with 5 Gm. of *anhydrous sodium carbonate* and 5 mils of saturated solution of *sodium hydroxide;* mix thoroughly with a glass stirring rod, leave the rod in the crucible and add about 1·5 Gm. of shredded filter paper. Dry the crucible and contents at 115° and then ignite in a muffle furnace pre-heated to a temperature of 525° to 560° and maintain this temperature for 20 minutes. Allow to cool, add 20 mils of water, heat to boiling and decant through an 18 centimetre filter paper into a 500 mil flask. Boil the residue with another 20 mil portion of *water,* then wash the crucible and the char on the filter with hot *water,* until the filtrate measures about 200 mils; add 7 mils of *solution of bromine,* and then slowly add 25 mils of a solution containing equal parts of *phosphoric acid* and *water,* and boil thoroughly until starch iodide paper is no longer coloured blue by the vapours. Then add 2 mgms. of *salicylic acid.* Wash the sides of the flask with 5 mils of *water* and cool to between 20° and 30°, then add 1 mil of *phosphoric acid* and 5 mils of *solution of potassium iodide* and titrate with *N/200 sodium thiosulphate* using at the end of titration *mucilage of starch* as indicator. Each mil of *N/200 sodium thiosulphate* is equivalent to 0·1058 mgm. of I.

Storage.

Dried Thyroid should be kept in a well-closed container, and stored in a cool place.

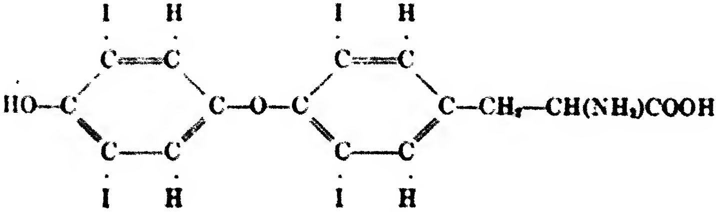
Doses

Metric	Imperial
0·03 to 0·2 Gm.	½ to 3 grains.

THYROXINUM

(Thyroxin.)

Thyroxine



$C_{15}H_{11}NO_4I_4$ Mol. Wt. 776·8

Thyroxine shall be dl-β-(3:5-diiodo-4-(3′:5′-diiodo-4′-hydroxyphenoxy)—phenyl)-α-aminopropionic acid.

It may be prepared by synthesis or by the controlled hydrolysis of thyroid gland with barium hydroxide followed by liberation with hydrochloric acid and subsequent purification. When assayed by the method described herein, it shall contain not less than 64 per cent of I as an integral part of the thyroxin molecule, calculated with reference to the substance dried over sulphuric acid for 18 hours; and it shall conform to the following specification with respect to characters, tests for identity, test for purity and assay.

Characters.

Description.—Thyroxine occurs as a white crystalline powder.

Solubility.—Thyroxine is sparingly soluble in cold *water;* it is more soluble in *solution of sodium carbonate*, and in *test-solution of sodium hydroxide*. It is unstable in alkaline solutions.

Tests for Identity.

Mix 5 mgms. of Thyroxine with 0·1 Gm. of *sodium carbonate* and ignite. Cool and dissolve in 2 mils of *water*. The solution yields the *reactions* characteristic of iodides.

Dissolve about 5 mgms. of Thyroxine in 2 mils of *alcohol (50 per cent)* with the aid of one drop of *hydrochloric acid*, add one drop of a 20 per cent w/v solution of *sodium nitrite* in *water;* a yellow colour is produced which deepens on boiling, and changes to red, when the liquid is cooled and treated with excess of *strong solution of ammonia*.

Test for Purity.

Soluble halides.—Shake 10 mgms. of Thyroxine with 10 mils of *water* for 5 minutes and filter. Acidify the filtrate with one drop of *dilute nitric acid* and add one drop of *solution of silver nitrate;* the turbidity so produced is not greater than that produced by 0·1 mil of *N/50 hydrochloric acid* tested under identical conditions.

Assay.

Mix in a small nickel crucible about 20 mgms. of Thyroxine, accurately weighed and previously dried over *sulphuric acid* for 18 hours, with about 0·5 Gm. of *anhydrous potassium carbonate*. Cover the mixture with a further 1 Gm. of *anhydrous potassium carbonate* and heat gradually until it is completely decomposed. Allow to cool, treat the contents with *water* and transfer completely to a 100 mill graduated flask. Heat the solution on a water-bath, add 5 per cent w/v aqueous solution of *potassium permanganate*, drop by drop, until the liquid remains pink. Then add, drop by drop, just sufficient *alcohol (95 per cent)* to discharge the pink colour, allow to cool and dilute to 100 mils with recently boiled and cooled *water*. Mix well and filter through a dry filter into a dry flask rejecting the first 20 mils of the filtrate.

To 50 mils of the subsequent filtrate add 5 mils of *solution of potassium iodide* and 30 mils of *dilute sulphuric acid*, and titrate with *N/200 sodium thiosulphate* using at the end of titration *mucilage of starch* as indicator. Carry out a blank test with the same reagents and in the same manner and make any necessary corrections. Each mil of *N/200 sodium thiosulphate* is equivalent to 0·1058 mgms. of I.

Storage.

Thyroxine should be kept in a well-closed container.

Doses

Metric	Imperial
0·1 to 1 mgm.	1/640 to 1/64 grain.

UNGUENTUM HYDRARGYRI

(Ung. Hydrarg.)

Ointment of Mercury

Ointment of Mercury shall be prepared from the following ingredients in the proportions specified and when assayed by the method described herein shall contain not less than 28 per cent and not more than 32 per cent of Mercury.

Mercury	300 Gm.
Oleated Mercury	15 Gm.
Wool Fat	430 Gm.
White Beeswax	70 Gm.
Soft White Paraffin	185 Gm.

Add the Mercury gradually to the Oleated Mercury in a warm mortar, with constant trituration, until all the Mercury is dispersed. Melt together the Wool Fat, White Beeswax and Soft White Paraffin, allow to cool partially, add about 15 Gm. to the mercurial mixture and continue the trituration until metallic globules cease to be visible when examined under a lens magnifying four diameters; incorporate the remainder of the mixture of Wool Fat, White Beeswax and Soft Paraffin.

Assay.

Boil gently for five minutes about 1 Gm. of Ointment of Mercury, accurately weighed, in 10 mils of *nitric acid* and 25 mils of *water;* cool, and dilute with 25 mils of *water*. Decant the acid solution on to the moistened filter paper, filter, and wash the melted fat several times with small quantities of hot *water*. To the warm mixture of filtrate and washings add sufficient *solution of potassium permanganate* to produce a permanent pink colour. Decolourise by the addition of a trace of *ferrous sulphate*, and titrate with *N/10 ammonium thiocyanate*, using *solution of ferric ammonium sulphate* as indicator. Each mil of *N/10 ammonium thiocyanate* is equivalent to 0·01003 Gm. of Hg.

Preparation.

Unguentum Hydrargyri Compositum
Unguentum Hydrargyri Dilutum
See note under "Unguentum Hydrargyri Dilutum".

UNGUENTUM HYDRARGYRI DILUTUM

(Ung. Hydrarg. Dil.)

Dilute Ointment of Mercury

Dilute Ointment of Mercury shall be prepared from the following ingredients in the amount specified and, when assayed by the method indicated herein, shall contain not less than 9 per cent, and not more than 11 per cent of Hg.

Ointment of Mercury	333·3 Gm.
Simple Ointment	666·7 Gm.

Mix by trituration.

Assay.

Carry out the Assay as directed under "Unguentum Hydrargyri", using about 3 Gm., accurately weighed. Each mil of *N/10 ammonium thiocyanate* is equivalent to 0·01003 Gm. of Hg.

NOTE.—When "Mercury Ointment", "Mercurial Ointment", or "Blue Ointment" is prescribed or demanded, Dilute Ointment of Mercury shall be dispensed or supplied, unless, on enquiry, it is ascertained that Ointment of Mercury is required.

APPENDICES

APPENDIX I

Materials and Solutions Employed in Tests

NOTE.—Any reagent not listed below, but mentioned in the monographs of the Canadian Supplement to the British Pharmacopoeia, will be found in the corresponding appendices of the British Pharmacopoeia and of the First Addendum, 1936.

Amylene Hydrate: of the Canadian Supplement to the British Pharmacopoeia.

Aniline Blue: A mixture of triphenyl-*p*-rosaniline hydrochloride and di-phenyl-*p*-rosaniline hydrochloride, No. 689, Colour Index, Society of Dyers and Colourists of Great Britain, 1924.

Butyl Alcohol: isobutyl alcohol $(CH_3)_2CH\,CH_2OH$, of Reagent purity.

Ceric Sulphate: $Ce(SO_4)_2$, of Reagent purity.

Diazobenzene Sulphonic Acid, Solution of: Dissolve 0·9 Gm. of *sulphanilic acid* and 10 mils of *hydrochloric acid* in sufficient *water* to produce 100 mils. To 3 mils of this solution add 3 mils of a 5 per cent w/v solution of *sodium nitrite* in *water*; cool in ice for five minutes; add a further 12 mils of the solution of *sodium nitrite* and again cool in ice; dilute with *water* to 100 mils and keep cooled in ice.

Diethylene Dioxide: $(CH_2\text{-}O\text{-}CH_2)_2$, of Reagent purity.

Eosin: The di-sodium salt of tetrabromofluorescein, $C_{20}H_6Br_4O_5Na_2$, of Reagent purity.

Eosin, Solution of: A 0·5 per cent solution of *eosin* in *water*.

Ethyl Cyanoacetate: $CN\text{-}CH_2COOC_2H_5$, of Reagent purity.

Haematoxylin, Delafield's Solution of: Dissolve 4 Gm. of *haematoxylin* in 25 mils of *alcohol (95 per cent)*, mix with 400 mils of a saturated solution in *water* of *alum* and set aside for 4 days in a flask closed with a plug of cotton wool, and exposed to light and air. Then add a mixture of equal volumes of *glycerin* and *methyl alcohol*, mix thoroughly, and allow to stand for 6 weeks in a warm place, exposed to light until the colour darkens. Keep the solution in a tightly stoppered bottle.

Iron Wire: Containing not less than 99·9 per cent Fe.

Mallory's Stain: Dissolve 0·5 Gm. of aniline blue, 2 Gm. of orange G. and 2 Gm. of *oxalic acid* in 100 mils of *water*.

Methyl Alcohol: CH_3OH, of Reagent purity.

β-Naphthol: Betanaphthol of the British Pharmacopoeia.

β-Naphthol, Solution of: Dissolve 5 Gm. of β-naphthol, freshly recrystallized, in 40 mils of *test-solution of sodium hydroxide*, and add sufficient *water* to produce 100 mils. Solution of β-naphthol must be freshly prepared.

Nitrobenzyl Chloride: *p*-nitrobenzyl chloride, $C_6H_4CH_2\text{-}Cl\text{-}NO_2$, of Reagent purity.

***O*-Phenanthrolin:** $C_{12}H_8N_2H_2O$, of Reagent purity.

Orange-G: The sodium salt of benzene-azo-β-naphthol-6-sulphonic acid. $C_6H_5N{=}N\text{-}C_{10}H_4(OH)(SO_3Na)_2$, No 27, Colour Index, Society of Dyers and Colourists of Great Britain, 1924.

Paraffin, Light Liquid: Of the Canadian Supplement to the British Pharmacopoeia.

Phenylhydrazine Acetate, Solution of: Dissolve 10 mils of *phenylhydrazine* and 5 mils of *glacial acetic acid* in a sufficient quantity of *water* to produce 100 mils.

Phosphotungstic Acid: $P_2O_5\text{-}24WO_2xH_2O$, of Reagent purity

Phosphotungstic Acid, Solution of: a 1 per cent w/v solution of *phosphotungstic acid* in *water*.

Sodium Bisulphite: $NaHSO_3$, of Reagent purity.

Sodium Hydroxide, Test-solution of: a 20 per cent w/v solution of *sodium hydroxide* in *water*.

Vanillin, Solution of, in sulphuric acid: a 1 per cent w/v solution of *vanillin* in *sulphuric acid*.

Zinc Chloride: $ZnCl_2$, of Reagent purity.

APPENDIX II

A. Solutions Employed in Volumetric Determinations

Solution of Ceric Sulphate N/10.

Solution of Ceric Sulphate, N/10, contains in each litre 33·32 Gm. of $Ce(SO_4)_2$ dissolved in water with the aid of *sulphuric acid.*

Dissolve 42 Gm. of *ceric sulphate* in 500 mils of *water* containing 28 mils of *sulphuric acid*, warming if necessary. Cool the solution, and add a sufficient quantity of *water* to produce 1000 mils. Standardize the solution as follows:

Dissolve, with the aid of heat, about 0·2 Gm. of *iron wire*, previously cleaned, dried, and accurately weighed, in 50 mils of *dilute sulphuric acid* contained in a 200 mil round flask, closed by a valve-stopper*. Cool, add 50 mils of freshly boiled and cooled *water*, and titrate with the solution of ceric sulphate, using *solution of o-phenanthrolin* as indicator. The end point is reached when the colour changes from red to pale blue. Each mil of *N/10 ceric sulphate* is equivalent to 0·005584 Gm. Fe.

*The valve stopper consists of a perforated rubber stopper through which passes a short glass tube attached to a short piece of rubber tubing with a small slit in one side, cut longitudinally and about 15 mm. in length. The other end of the rubber tube is closed by a short length of glass rod.

Solution of Hydrochloric acid, N/1000:—

for N/1000 .... 0·03646 Gm. of HCl.

Solution of Sodium Nitrite, N/10:—

for N/10 ....6·901 Gm. $NaNO_2$.

B. Indicators Employed in Volumetric Determinations and in pH Determinations

Congo Red, Solution of: Dissolve 0·1 Gm. of *Congo red* in 20 mils of *alcohol (90 per cent)* and a sufficient quantity of *water* to produce 100 mils.

***O*-phenanthrolin, Solution of:** Dissolve 0·15 Gm. of *o-phenanthrolin* and 0·148 Gm. of *ferrous sulphate* in 100 mils of *water*. The solution should be freshly prepared.

Starch, Mucilage of, with Potassium Iodide: Titrate 5 Gm. of *starch* with 20 mils of water, add 7·5 mils of *solution of potassium iodide* and 1 Gm. of *zinc chloride*, dissolved in 5 mils of *water*. Add the mixture to 100 mils boiling *water*, and boil for one minute. For use, the mucilage should be spread on filter paper and dried.

APPENDIX VI

Quantitative Test for Lead

NOTE.—The information given below supplements the table contained in the British Pharmacopoeia and the First Addendum thereto.

Acidum Nicotinicum	*7a*	5	*2a*	5	10	20
Nicotinamidum	7	5	2	5	15	30
Sulphadiazina	*2b*	-	*1b*	-	2	20
Sulphanilamidum	*2b*	-	*1b*	-	2	20
Sulphapyridina	*2b*	-	*1b*	-	2	20
Sulphapyridina Solubilis	*2b*	-	1	-	2	20
Sulphathiazolum	*2b*	-	*1b*	-	2	20
Sulphathiazolum Solubile	*2b*	-	*1b*	-	2	20

For signs (*a*) and (*b*), see British Pharmacopoeia, p. 552-558.

APPENDIX VII

Quantitative Test for Arsenic

NOTE.—The following is supplementary to that given in the British Pharmacopoeia and the First Addendum thereto.

Acidum Nicotinicum: Limit 2 parts per million.

Treat 5 Gm. as described under "Acidum Acetylsalicylicum".

Amaranthum: Limit 10 parts per million.

Treat 1 Gm. as described under "Methylthioninae Chloridum".

Caeruleum Nitens: Limit 10 parts per million.

Treat 1 Gm. as described under "Methylthioninae Chloridum".

Rubrum Cumidinum: Limit 10 parts per million.

Treat 1 Gm. as described under "Methylthioninae Chloridum".

Sulphadiazina: Limit 1 part per million.

Treat 10 Gm. as described under "Sulphanilamidum".

Sulphanilamidum: Limit 1 part per million.

Dissolve 10 Gm. in 50 mils of *water* and 15 mils of *stannated hydrochloric acid As T*.

Sulphapyridina: Limit 1 part per million.

Treat 10 Gm. as described under "Sulphanilamidum".

Sulphapyridina Solubilis: Limit 1 part per million.

Treat 10 Gm. as described under "Sulphanilamidum".

Sulphathiazolum: Limit 1 part per million.

Treat 10 Gm. as described under "Sulphanilamidum".

Sulphathiazolum Solubile: Limit 1 part per million.

Treat 10 Gm. as described under "Sulphanilamidum".

Tartrazina: Limit 10 parts per million.

Treat 1 Gm. as described under "Methylthioninae Chloridum".

APPENDIX XIX

Alternative Preparations Sanctioned for Use in Canada

Linimentum Camphorae. When Olive Oil is not readily obtainable, any vegetable oil, free from objectionable odour, pale yellow or pale green in colour, with an iodine value not exceeding 135 and a freezing point not above 0°, may be used in place of Olive Oil for making Liniment of Camphor of the British Pharmacopoeia.

Oleum Olivae. When Olive Oil is not readily obtainable, Arachis Oil, Corn Oil, Cottonseed Oil or Sesame Oil may be used in place of Olive Oil in making official Injections, Plasters and Ointments for which it is directed that Olive Oil be used.

His Excellency in Council, on the same recommendation, is further pleased to order and doth hereby order and direct that the contents of Division III may be known and cited as "The Canadian Supplement to the British Pharmacopoeia".

A. D. P. HEENEY,
Clerk of the Privy Council.

INDEX