BRITISH PHARMACEUTICAL CODEX

1973

BRITISH PHARMACEUTICAL CODEX

1973

Prepared in the Department of Pharmaceutical Sciences
of the Pharmaceutical Society of Great Britain
and published by direction of the Society's Council

LONDON
THE PHARMACEUTICAL PRESS
17 BLOOMSBURY SQUARE WC1A 2NN

ISBN 0 85369 084 7

Made and printed in Great Britain by
William Clowes & Sons, Limited, London, Beccles and Colchester

having a unicellular spherical head. It contains similar alkaloids to those in *H. niger*.
Some Indian henbane is derived from *H. reticulatus* L. and contains about 0·12 to 0·24 per cent of alkaloids.

Storage. It should be stored in a cool dry place, protected from light.

Actions and uses. Hyoscyamus has actions similar to those described under Belladonna Herb (page 42), but the hyoscine which it contains makes it less likely to give rise to cerebral excitement. Preparations of hyoscyamus are used to counteract the griping action of purgatives and to relieve spasm in the urinary tract.

POISONING. As for Atropine (page 36).

Preparations
HYOSCYAMUS DRY EXTRACT, B.P.C. (page 683)
HYOSCYAMUS LIQUID EXTRACT, B.P.C. (page 683)
GELSEMIUM AND HYOSCYAMUS MIXTURE, COMPOUND, B.P.C. (page 743)
POTASSIUM CITRATE AND HYOSCYAMUS MIXTURE, B.P.C. (page 751)
HYOSCYAMUS TINCTURE, B.P. It contains 0·005 per cent of alkaloids. Dose: 2 to 5 millilitres.

OTHER NAME: Henbane Leaf

HYPROMELLOSE

SYNONYM: Hydroxypropylmethylcellulose

Hypromellose is a mixed ether of cellulose in which the ether groupings are mainly methoxyl groups with a small proportion of hydroxypropoxyl groups.

Hypromellose may be prepared by reacting alkali cellulose with a mixture of methyl chloride and propylene oxide. The name "hypromellose" is followed by a number indicating the approximate viscosity of a 2·0 per cent solution.

Solubility. Soluble in cold water, forming a viscous colloidal solution; insoluble in alcohol, in ether, and in chloroform.

Standard
DESCRIPTION; IDENTIFICATION TESTS; ACIDITY OR ALKALINITY; LOSS ON DRYING; SULPHATED ASH. It complies with the tests described under Methylcellulose 20, page 307.

VISCOSITY. Determine by the method given for Methylcellulose 20, page 307. The limits for various viscosity grades and the viscometer to be used are indicated in the following table:

Viscosity grade	Viscosity at 20° (centistokes)	Capillary diameter of viscometer (mm)
20	15 to 25	0·84 ± 0·02
50	40 to 60	1·15 ± 0·03
125	110 to 140	1·51 ± 0·03
450	350 to 550	2·06 ± 0·04
1500	1200 to 1800	2·74 ± 0·04
4500	3750 to 5250	3·70 ± 0·04
15,000	12,000 to 18,000	4·97 ± 0·04

ARSENIC. It complies with the test given in Appendix 6, page 878 (2 parts per million).

LEAD. It complies with the test given in Appendix 7, page 882 (5 parts per million).

CONTENT OF HYDROXYPROPOXYL. 4·0 to 7·5 per cent, calculated as $C_3H_7O_2$, with reference to the substance dried under the prescribed conditions, determined by the method given in Appendix 22, page 903.

CONTENT OF METHOXYL. 27·0 to 30·0 per cent, calculated as CH_3O, with reference to the substance dried under the prescribed conditions, determined by the method given in Appendix 22, page 903.

Storage. It should be stored in airtight containers, in a cool place.

Uses. Hypromellose has properties similar to those of methylcellulose, but produces aqueous solutions having higher gel-points and greater clarity; for example, a 2 per cent solution of methylcellulose 4500 gels at about 50° and a 2 per cent solution of hypromellose 4500 gels at about 65°. Because of the greater clarity of aqueous solutions and the lower proportion of undispersed fibres, it is used in preference to methylcellulose to increase the viscosity of ophthalmic solutions; an antimicrobial agent such as benzalkonium chloride should be incorporated.
Hypromellose has also been used in the preparation of anhydrous adhesive ointments for the protection of the skin surrounding ileostomies, fistulas, and exuding ulcers. In the preparation of Plaster of Paris Bandage, hypromellose is used for the same purpose as methylcellulose.

Preparation
HYPROMELLOSE EYE-DROPS, B.P.C. (page 692)

ICHTHAMMOL

SYNONYM: Ammonium Ichthosulphonate

Ichthammol consists mainly of the ammonium salts of the sulphonic acids prepared by sulphonating the oily substances resulting from the destructive distillation of a bituminous schist or shale. It contains, in addition, 5 to 7 per cent of ammonium sulphate.

Solubility. Soluble in water; partly soluble in alcohol and in ether; completely soluble in a mixture of equal parts of alcohol and ether.

Standard
DESCRIPTION. An almost black, viscid liquid; odour strong and characteristic.

INDUSTRIAL METHYLATED SPIRIT (ACETONE-FREE)

Industrial Methylated Spirit (Acetone-free) is a mixture, made by a legally authorised methylator, of 19 volumes of alcohol (95 per cent) with 1 volume of approved wood naphtha or other denaturant approved by the Board of Customs and Excise, and is of the quality known as "66 O.P. Industrial Methylated Spirits" but free from acetone.

Other strengths of industrial methylated spirit (acetone-free) are available, such as "Absolute Industrial Methylated Spirits (Acetone-free)", which is 74 O.P., and "64 O.P., Industrial Methylated Spirits (Acetone-free)".

Standard

DESCRIPTION. A colourless, transparent, mobile, volatile liquid; odour of alcohol modified by the odour of the denaturant.

IDENTIFICATION TEST. Dilute 0·5 ml to 5 ml with water, add 2 ml of *potassium permanganate and phosphoric acid solution*, allow to stand for 10 minutes, and add 2 ml of *oxalic acid and sulphuric acid solution*; to the colourless solution add 5 ml of *decolorised magenta solution* and allow to stand at 15° to 30° for 30 minutes; a deep violet colour is produced.

ACIDITY OR ALKALINITY. 25 ml requires not more than 0·2 ml of 0·1N sodium hydroxide to give a pink colour with *phenolphthalein solution*, or not more than 1·0 ml of 0·1N hydrochloric acid to give a red colour with *methyl red solution*.

SPECIFIC GRAVITY (20°/20°). Not higher than 0·814.

ACETONE. Dilute 5 ml to 10 ml with water, add 1 ml of *2-nitrobenzaldehyde solution* followed by 1 ml of a 15 per cent w/v solution of *sodium hydroxide* in water, and allow to stand for 15 minutes; any colour which develops is not deeper than that produced by 10 ml of a 0·025 per cent v/v solution of *acetone* in *alcohol (50 per cent)* when similarly treated (500 parts per million).

OILY AND RESINOUS SUBSTANCES. Mix 5 ml with 95 ml of water; the solution remains clear.

NON-VOLATILE MATTER. Not more than 0·01 per cent w/v, determined by evaporating to dryness and drying the residue to constant weight at 105°.

Uses. Industrial methylated spirit (acetone-free) is used in the preparation of alcoholic solutions of iodine intended for external use.

UNDESIRABLE EFFECTS; POISONING. As for Industrial Methylated Spirit (above).

METHYLCELLULOSE

Methylcellulose is a methyl ether of cellulose. It may be prepared by methylating alkali cellulose with methyl chloride. The name "methylcellulose" is followed by a number indicating the approximate viscosity of a 2·0 per cent solution. The gel-point of a 2 per cent solution in water of Methylcellulose 4500 is about 50°.

Solubility. Soluble in cold water, forming a viscous colloidal solution; insoluble in hot water, in alcohol, in ether, and in chloroform.

Standard

METHYLCELLULOSE 20

DESCRIPTION. A white or creamy-white powder; odourless.

IDENTIFICATION TESTS. 1. Add 1 g to 100 ml of water; the powder swells and disperses, forming a viscous colloidal solution. Boil; a white precipitate is formed which redissolves on cooling.

2. Pour 2 ml of the cold solution prepared in test 1 onto a glass plate and allow the water to evaporate; a thin self-sustaining film is produced.

3. To 10 ml of the cold solution prepared in test 1 add 0·5 ml of a 0·05 per cent w/v solution of *brilliant yellow* in water, 0·05 ml of 0·1N sodium hydroxide, and 10 ml of a saturated solution of *sodium sulphate* in water; a voluminous, flocculent, red precipitate is formed. Filter; the filtrate is colourless.

4. Soak in *iodine water* for a few minutes and remove the excess of reagent; the powder is stained yellow. Add one or two drops of *sulphuric acid (66 per cent v/v)*; it is stained dark brown (distinction from microcrystalline cellulose).

ACIDITY OR ALKALINITY. pH of a 1·0 per cent w/v solution in *carbon dioxide-free water*, 6·0 to 8·0.

VISCOSITY. At 20°, 17·0 to 23·0 centistokes, determined by the following method:
Transfer 2·0 g, calculated with reference to the substance dried under the prescribed conditions, to a wide-mouthed bottle, add 100 ml of water previously heated to 85° to 90°, close the bottle with a stopper fitted with a stirrer, and stir for 10 minutes; place the bottle in an ice-bath, continue stirring until the solution is of uniform consistence, remove the bottle from the ice-bath, and allow the solution to attain room temperature.
Determine the viscosity of this solution by the method of the British Pharmacopoeia, Appendix IVH, for the determination of the viscosity of Methylcellulose, using a suspended-level viscometer with capillary diameter of 0·84 ± 0·02 mm.

ARSENIC. It complies with the test given in Appendix 6, page 879 (1 part per million).

LEAD. It complies with the test given in Appendix 7, page 883 (5 parts per million).

LOSS ON DRYING. Not more than 10·0 per cent, determined by drying to constant weight at 105°.

SULPHATED ASH. Not more than 1·0 per cent.

CONTENT OF METHOXYL. 27·0 to 29·0 per cent, calculated as CH_3O, with reference to the substance dried under the prescribed conditions, determined by the following method:
Carry out the method of the British Pharmacopoeia, Appendix X(I), for the determination of methoxyl, using about 0·05 g, accurately weighed, and a 25 per cent w/v solution of *sodium acetate* in the scrubber; each ml of 0·1N sodium thiosulphate is equivalent to 0·0005172 g of CH_3O.

METHYLCELLULOSE 450

It complies with the requirements of the British Pharmacopoeia.
It has a viscosity at 20° of 400 to 500 centistokes.

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.