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1. AUSTRIA**PARAFFIN WAX
PETROLATUMS**

USAGE : **Pharmacy**

REGULATIONS : Austrian Pharmacopoeia; 9th Issue, from 1960, including a revision from 1966.

GENERAL REQUIREMENTS OF REGULATIONS

- a) Paraffinum solidum (hard paraffin)
- b) Vaselinum album (white petrolatum)
- c) Vaselinum flavum (yellow petrolatum)

QUALITY REQUIREMENTS**a) Paraffinum solidum (hard paraffin)**

Definition : A purified solid mixture of predominantly saturated higher hydrocarbons.

Description : White, more or less translucent, solid, of microcrystalline structure. Greasy to touch. Hard paraffin is tasteless. A freshly broken surface is nearly odourless.

Solubility : Hard paraffin is soluble in ether, chloroform, benzene, petroleum ether, or fatty oils. It is hardly soluble in absolute alcohol. It is insoluble in alcohol.

Testing for identity (characteristic value) :

Congealing point : 50 to 58°C (method specified).

Acidity/alkalinity : Must pass a sulphuric acid test (method specified).

Carbonisable substances : Sulphuric acid test. A 5 mg of hard paraffin is heated with 5 ml 90 % wt sulphuric acid at 100°C for 10 minutes, shaking after 2, 4 and 6 minutes. Colour of acid layer to be no greater than a specified salt solution or quoted equivalent lovibond colour.

Residue on ignition : Max. 0.1 % (method specified).

Storage : Specified.

Sterilisation : Procedure specified.

b) Vaselinum album (white petrolatum)

Definition : A purified and bleached, salve-like mixture consisting predominantly of saturated higher hydrocarbons.

Description : White to faintly greenish, translucent mass of a homogeneous, viscous consistence. Upon heating vaselinum album melts to a clear, faintly yellow-greenish liquid, which is nearly without taste or odour. In daylight the melted material exhibits a faint bluish fluorescence.

Solubility : Vaselinum album is easily soluble in ether, chloroform, benzene, petroleum ether and warm fatty oils. It is practically insoluble in alcohol.

Testing for identity (characteristic value) :

Dropping point : 38 to 56°C (method specified).

Purity : Vaselinum album, when heated to 60/61°C must melt to a clear liquid which may not be darker than a specified colour standard.

Artificial petrolatum : When viewed under a microscope at 200 x magnification only small needle-like crystals may be seen. There may be no granular or coarse crystals.

Acidity/alkalinity : Must pass a specified test limiting acidic or alkaline impurities (using phenolphthalein as indicator).

Carbonisable substances : Sulphuric acid test. A 5 gm of the petrolatum is heated with 5 ml 90 % wt H₂SO₄ at 70°C for 10 minutes, shaking after 2, 4 and 6 minutes. Colour of acid layer to be no greater than a specified salt solution or quoted equivalent lovibond colour.

Residue on ignition : Max. 0.005 % (method specified).

Storage : Specified.

Sterilisation : Procedure specified.

c) Vaselinum flavum (yellow petrolatum)

Definition : A purified, salve-like mixture consisting predominantly of saturated higher hydrocarbons.

Description : Yellow, in thin layer translucent mass of a homogeneous, viscous consistence. Upon heating vaselinum flavum melts to a nearly tasteless and odourless liquid which exhibits a faint bluish fluorescence in daylight.

Solubility : Vaselinum flavum is easily soluble in ether, chloroform, benzene, petroleum ether and warm fatty oils. It is practically insoluble in alcohol.

Testing for identity (characteristic value) :

Dropping point : 38 to 56°C (method specified).

Purity : Vaselinum flavum, when heated to 60/61°C must melt to a clear liquid which may not be darker than a specified colour standard.

Carbonisable substances : Sulphuric acid test. As for the white petroleum jelly, except that the strength of the sulphuric acid is 80 % wt.

All other tests done and applied like those for vaselinum album.

1. AUSTRIA

MONTAN WAXES
POLYOLEFIN WAXES
AMIDE WAXES

USAGE : In contact with food

REGULATIONS

Published in Mitteilungen der Österreichischen Sanitätsverwaltung 77. Jahrgang, 15 March 1976.

1) Montan waxes

Approved as lubricants for plastics up to 2 %.

2) Polyolefin waxes

Approved as lubricants for plastics up to 2 % and as additives for hard paraffin and microwax.

3) Amide waxes

Approved as lubricants for plastics up to 2 %.

1. AUSTRIA**NATURAL ESTER WAXES**

USAGE : **Pharmacy**

REGULATIONS

The European Pharmacopoeia, 2nd Edition, includes monographs for white beeswax and yellow beeswax; for details refer to Section 19 - European Economic Community - as at August 1987 these are the only sections on waxes in the European Pharmacopoeia although it is understood that a monograph on carnauba wax is to be issued.

The Pharmacopoeia requirements for beeswax in all countries adopting the European Pharmacopoeia are therefore now identical and as given in Section 19; these requirements supersede those of the individual national pharmacopoeias.

It is understood that the following countries have agreed to adopt the requirements of the European Pharmacopoeia, either as original parties to the Convention on the Elaboration of a European Pharmacopoeia or through subsequent decisions (the European Pharmacopoeia has official status in the laws of the European Economic Community) :

Austria
Belgium
Denmark
EIRE
Finland
France

Germany
Greece
Italy
Luxembourg
Netherlands
Norway

Portugal
Spain
Sweden
Switzerland
United Kingdom