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Wool Alcohols

General Notices

Wool Wax Alcohols

(Ph. Eur. monograph 0593)

Preparation

Wool Alcohols Ointment

Ph Eur

DEFINITION

Mixture of sterols and higher aliphatic alcohols from wool fat. A suitable antioxidant may be added.

Content

Minimum 30.0 per cent of cholesterol.

CHARACTERS

Appearance

Pale-yellow or brownish-yellow, brittle mass becoming plastic on heating.

Solubility

Practically insoluble in water, soluble in boiling anhydrous ethanol and in methylene chloride, slightly soluble in ethanol (90 per cent *V/V*).

IDENTIFICATION

Dissolve 50 mg in 5 mL of *methylene chloride R* and add 1 mL of *acetic anhydride R* and 0.1 mL of *sulfuric acid R*. Within a few seconds, a green colour develops.

TESTS

Appearance of solution

To 1.0 g add 10 mL of *light petroleum R1* and shake while warming in a water-bath. The substance dissolves completely. After cooling, the solution is clear (*2.2.1*).

Alkalinity

Dissolve 2.0 g in 25 mL of hot *ethanol (90 per cent V/V) R* and add 0.5 mL of *phenolphthalein solution R1*. No red colour develops.

Melting point (*2.2.15*)

Minimum 56 °C.

Melt the substance to be examined by heating in a water-bath at a temperature which exceeds the expected melting point by not more than 10 °C; introduce the substance to be examined into the capillary tubes and allow to stand on ice for at least 2 h.

Water-absorption capacity

Place 0.6 g of the substance to be examined and 9.4 g of *white soft paraffin R* in a mortar and melt on a water-bath. Allow to cool and incorporate 20 mL of *water R*, added in portions. Within 24 h no water is released from the almost white, ointment-like emulsion.

Acid value (*2.5.1*)

Maximum 2.0.

If necessary, heat in a water-bath under a reflux condenser to dissolve the substance to be examined.

Hydroxyl value (*2.5.3, Method A*)

120 to 180.

Peroxide value (*2.5.5, Method A*)

Maximum 15.

Take from the substance to be examined wedge-shaped pieces whose base consists of part of the surface. Melt the pieces before carrying out the determination. Before adding 0.5 mL of *saturated potassium iodide solution R*, cool the solution obtained to room temperature.

Saponification value (*2.5.6*)

Maximum 12.0, determined on 10.00 g. Heat under reflux for 4 h.

Loss on drying (*2.2.32*)

Maximum 0.5 per cent, determined on 2.000 g by drying in an oven at 105 °C for 1 h.

Total ash (*2.4.16*)

Maximum 0.1 per cent.

ASSAY

Gas chromatography (*2.2.28*). *Homogenise the sample before use*.

Internal standard solution Dissolve 0.125 g of *pregnenolone isobutyrate CRS* in *heptane R* and dilute to 50.0 mL with the same solvent.

Test solution Dissolve 75.0 mg of the substance to be examined in 10.0 mL of the internal standard solution and dilute to 25.0 mL with *heptane R*.

Reference solution Dissolve 25.0 mg of *cholesterol CRS* in 10.0 mL of the internal standard solution and dilute to 25.0 mL with *heptane R*.

Injection liner:

— *packing material*: quartz wool;

— *size*: *l* = 78.5 mm, Ø = 4.0 mm.

Column:

— *material*: fused silica;

— *size*: *l* = 30 m, Ø = 0.25 mm;

— *stationary phase*: *methylpolysiloxane R* (film thickness 0.25 µm).

Carrier gas *helium for chromatography R*.

Flow rate 1 mL/min.

Split ratio 1:50.

Temperature:

— *column*: 275 °C;

— *injection port*: 285 °C;

— *detector*: 300 °C.

Detection Flame ionisation.

Injection 1 µL.

Run time 30 min.

Relative retention With reference to pregnenolone isobutyrate (retention time = about 8 min): cholesterol = about 1.2.

System suitability Reference solution:

— *resolution*: minimum 5.0 between the peaks due to pregnenolone isobutyrate and cholesterol.

Calculate the percentage content of cholesterol in the substance to be examined taking into account the assigned content of *cholesterol CRS*.

STORAGE

In a well-filled container, protected from light.

FUNCTIONALITY-RELATED CHARACTERISTICS

This section provides information on characteristics that are recognised as being relevant control parameters for one or more functions of the substance when used as an excipient (see chapter 5.15). Some of the characteristics described in the Functionality-related characteristics section may also be present in the mandatory part of the monograph since they also represent mandatory quality criteria. In such cases, a cross-reference to the tests described in the mandatory part is included in the Functionality-related characteristics section. Control of the characteristics can contribute to the quality of a medicinal product by improving the consistency of the manufacturing process and the performance of the medicinal product during use. Where control methods are cited, they are recognised as being suitable for the purpose, but other methods can also be used. Wherever results for a particular characteristic are reported, the control method must be indicated.

The following characteristics may be relevant for wool alcohols used in water-emulsifying ointments and lipophilic creams.

Melting point

(see Tests).

Water-absorption capacity

(see Tests).

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