

Lanolin, Hydrous

1 Nonproprietary Names

BP: Hydrous wool fat
JP: Hydrous lanolin
PhEur: Adeps lanae cum aqua

2 Synonyms

Lipolan.

3 Chemical Name and CAS Registry Number

Hydrous lanolin [8020-84-6]

4 Empirical Formula Molecular Weight

The JP 2001 describes hydrous lanolin as a mixture of lanolin and 25–30% w/w purified water. The PhEur 2002 describes hydrous lanolin as a mixture of lanolin and 25% w/w purified water; *see also* Section 18. The PhEur 2002 additionally permits the inclusion of up to 150 ppm of butylated hydroxytoluene as an antioxidant.

See also Lanolin.

5 Structural Formula

See Section 4.

6 Functional Category

Emulsifying agent; ointment base.

7 Applications in Pharmaceutical Formulation or Technology

Hydrous lanolin is widely used in topical pharmaceutical formulations and cosmetics in applications similar to those for lanolin.

Hydrous lanolin is commonly used in the preparation of water-in-oil creams and ointments. More water may be incorporated into hydrous lanolin than into lanolin.

See also Section 18.

8 Description

Hydrous lanolin is a pale yellow-colored, unctuous substance with a faint characteristic odor. When melted by heating on a water bath, hydrous lanolin separates into a clear oily layer and a clear water layer.

9 Pharmacopeial Specifications

See Table I.

Table I: Pharmacopeial specifications for hydrous lanolin.

Test	JP 2001	PhEur 2002
Identification	+	+
Characters	+	+
Melting point	39°C	38–44°C
Acidity and alkalinity	+	—
Water absorption capacity	—	+
Water-soluble acids and alkalis	+	+
Water-soluble oxidizable substances	+	+
Chloride	≤0.036%	≤115 ppm
Ammonia	+	—
Paraffins	+	≤1.0%
Petrolatum	+	—
Acid value	≤1.0	≤0.8
Peroxide value	—	≤15
Iodine value	18–36	—
Saponification value	—	67–79
Butylated hydroxytoluene	—	≤150 ppm
Nonvolatile matter (wool fat content)	70–75%	72.5–77.5%
Sulfated ash	—	≤0.1%

10 Typical Properties

Solubility: practically insoluble in chloroform, ether, and water. Only the fat component of hydrous lanolin is soluble in organic solvents.

11 Stability and Storage Conditions

Hydrous lanolin should be stored in a well-filled, well-closed container protected from light, in a cool, dry place. Normal storage life is 2 years.

See also Lanolin.

12 Incompatibilities

See Lanolin.

13 Method of Manufacture

Lanolin is melted, and sufficient purified water is gradually added with constant stirring.

14 Safety

Hydrous lanolin is used in cosmetics and a number of topical pharmaceutical formulations and is generally regarded as a nontoxic and nonirritant material, although it has been associated with hypersensitivity reactions. *See* Lanolin for further information.

15 Handling Precautions

Observe normal precautions appropriate to the circumstances and quantity of material handled.

16 Regulatory Status

Included in the FDA Inactive Ingredients Guide (ophthalmic, topical, transdermal, and vaginal preparations). Included in nonparenteral medicines licensed in the UK.

17 Related Substances

Cholesterol; lanolin; lanolin alcohols.

18 Comments

Lanolin (the anhydrous material) may be confused in some instances with hydrous lanolin since the USP formerly contained monographs for 'lanolin' and 'anhydrous lanolin' in which the name 'lanolin' referred to the material containing 25–30% w/w of purified water.

19 Specific References

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20 General References

Barnett G. Lanolin and derivatives. *Cosmet Toilet* 1986; 101(3): 23–44.

Osborne DW. Phase behavior characterization of ointments containing lanolin or a lanolin substitute. *Drug Dev Ind Pharm* 1993; 19: 1283–1302.

Smolinske SC. *Handbook of Food, Drug, and Cosmetic Excipients*. Boca Raton, FL: CRC Press, 1992: 225–229.

21 Author

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22 Date of Revision

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