Edition: BP 2025 (Ph. Eur. 11.6 update)

Sorbitan Stearate

General Notices

(Ph. Eur. monograph 1043)

Action and use

Non-ionic surfactant.

When sorbitan monostearate is demanded, Sorbitan Stearate shall be supplied.

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DEFINITION

Mixture usually obtained by partial esterification of sorbitol and its mono- and di-anhydrides with *Stearic acid 50 (1474)* or *Stearic acid 70 (1474)*.

CHARACTERS

Appearance

Pale yellow, waxy solid.

Solubility

Practically insoluble but dispersible in water, slightly soluble in ethanol (96 per cent).

IDENTIFICATION

A. Melting point (*2.2.15*): 50 °C to 60 °C.
Introduce the melted substance into the capillary tubes and allow to stand at a temperature below 10 °C for 24 h.

B. Hydroxyl value (see Tests).
C. Composition of fatty acids (see Tests).

TESTS

Acid value (*2.5.1*)

Maximum 10.0, determined on 5.0 g.

Hydroxyl value (*2.5.3, Method A*)

235 to 260.

Peroxide value (*2.5.5*)

Maximum 5.0.

Saponification value (*2.5.6*)

147 to 157.

Carry out the saponification for 1 h.

Composition of fatty acids

Gas chromatography (*2.4.22, Method C*).

Composition of the fatty acid fraction of the substance:

	Type of fatty acid used	Composition of fatty acids
Sorbitan stearate (type I)	Stearic acid 50	*Stearic acid*: 40.0 per cent to 60.0 per cent, *Sum of the contents of palmitic and stearic acids*: minimum 90.0 per cent.
Sorbitan stearate (type II)	Stearic acid 70	*Stearic acid*: 60.0 per cent to 80.0 per cent, *Sum of the contents of palmitic and stearic acids*: minimum 90.0 per cent.

Water (*2.5.12*)

Maximum 1.5 per cent, determined on 1.00 g.

Total ash (*2.4.16*)

Maximum 0.5 per cent.

STORAGE

Protected from light.

LABELLING

The label states the type of sorbitan stearate.

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 sorbitan stearate used as emulsifier and co-solubiliser in creams.

Composition of fatty acids

(see Tests).

Hydroxyl value

(see Tests).

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