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

Sorbitan Laurate

General Notices

(Ph. Eur. monograph 1040)

Action and use

Non-ionic surfactant.

When sorbitan monolaurate is demanded, Sorbitan Laurate shall be supplied.

Ph Eur

DEFINITION

Mixture usually obtained by partial esterification of sorbitol and its mono- and di-anhydrides with lauric (dodecanoic) acid.

CHARACTERS

Appearance

Brownish-yellow, viscous liquid.

Solubility

Practically insoluble but dispersible in water, miscible with ethanol (96 per cent).

Relative density

About 0.98.

IDENTIFICATION

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

TESTS

Acid value (*2.5.1*)

Maximum 7.0, determined on 5.0 g.

Hydroxyl value (*2.5.3, Method A*)

330 to 358.

Iodine value (*2.5.4*)

Maximum 10.

Peroxide value (*2.5.5*)

Maximum 5.0.

Saponification value (*2.5.6*)

158 to 170.

Carry out the saponification for 1 h.

Composition of fatty acids

Gas chromatography (*2.4.22, Method C*).

Prepare reference solution (a) as indicated in tables 2.4.22.-1 and 2.4.22.-2.

Composition of the fatty acid fraction of the substance:

— *caproic acid*: maximum 1.0 per cent;

— *caprylic acid*: maximum 10.0 per cent;

— *capric acid*: maximum 10.0 per cent;

— *lauric acid*: 40.0 per cent to 60.0 per cent;

— *myristic acid*: 14.0 per cent to 25.0 per cent;

— *palmitic acid*: 7.0 per cent to 15.0 per cent;

— *stearic acid*: maximum 7.0 per cent;

— *oleic acid*: maximum 11.0 per cent;

— *linoleic acid*: maximum 3.0 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.

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 laurate used as emulsifier and co-solubiliser in creams.

Composition of fatty acids

(see Tests).

Hydroxyl value

(see Tests).

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