

**15 Handling Precautions**

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

**16 Regulatory Status**

Approved for use in medicinal products in Europe, Japan and the US.

**17 Related Substances**

Polyethylene glycol; polyvinyl alcohol.

**18 Comments**

Ethylene glycol and vinyl alcohol grafted copolymer is available as a spray-dried powder (*Kollicoat IR*), in combination with polyvinyl alcohol as a basis for moisture protective coatings (*Kollicoat IR Protect*), or as a ready-to-use colored system (*Kollicoat IR Coating Systems, Sepifilm IR*).

**19 Specific References**

- 1 BASF SE. Technical information sheet: *Kollicoat IR*, February 2010.
- 2 BASF SE. Product information: *Kollicoat IR*, 2011. <http://www.pharma-ingredients.basf.com/Kollicoat/Product.aspx> (accessed 16 October 2015).
- 3 Garsuch V, Breitzkreutz J. Novel analytical methods for the characterization of wafers. *Eur J Pharm Biopharm* 2009; 73: 195–201.
- 4 Siepmann G, *et al.* How to adjust desired drug release patterns from ethylcellulose-coated dosage forms. *J Control Release* 2007; 119: 182–189.
- 5 Siepmann F, *et al.* How to improve the storage stability of aqueous polymeric film coatings. *J Control Release* 2008; 126: 26–33.

- 6 Ensslin S, *et al.* Modulating pH-independent release from coated pellets: effect of coating composition on solubilization processes and drug release. *Eur J Pharm Biopharm* 2009; 72: 111–118.
- 7 Strübing S, *et al.* Mechanistic analysis of drug release from tablets with membrane controlled drug delivery. *Eur J Pharm Biopharm* 2007; 66: 113–119.
- 8 Dashevsky A, *et al.* Effect of water-soluble polymers on the physical stability of aqueous polymeric dispersions and the implications on the drug release from coated pellets. *Drug Dev Ind Pharm* 2010; 36(2): 152–160.
- 9 Janssens S, *et al.* The use of a new hydrophilic polymer, *Kollicoat IR*, in the formulations of solid dispersions of itraconazole. *Eur J Pharm Sci* 2007; 30: 288–294.
- 10 Janssens S, *et al.* Spray drying from complex solvent systems broadens the applicability of *Kollicoat IR* as a carrier in the formulation of solid dispersions. *Eur J Pharm Sci* 2009; 37: 241–248.
- 11 Guns S, *et al.* Characterization of the copolymer poly(ethyleneglycol-g-vinylalcohol) as a potential carrier in the formulation of solid dispersions. *Eur J Pharm Biopharm* 2010; 74: 239–247.
- 12 Bühler V. *Kollicoat Grades: Functional polymers for the pharmaceutical industry*. BASF SE, January 2007.

**20 General References**

- BASF. Material safety data sheet: *Kollicoat IR*, version: 2.0, 17 February 2015.
- BASF SE. Excipients. <http://www.pharma-ingredients.basf.com/Excipients/Home.aspx> (accessed 16 October 2015).

**21 Authors**

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**22 Date of Revision**

4 May 2017.

## Ethylene Glycol Stearates

**1 Nonproprietary Names**

BP: Ethylene Glycol Monopalmitostearate

PhEur: Ethylene Glycol Monopalmitostearate

USP–NF: Ethylene Glycol Stearates

**2 Synonyms**

*DUBCARE SMEG*; ethyleneglycoli monopalmitostearas.

**3 Chemical Name and CAS Registry Number**

Ethylene glycol palmitostearate

See Sections 8 and 17.

**4 Empirical Formula and Molecular Weight**

See Section 8.

**5 Structural Formula**

See Section 8.

**6 Functional Category**

Emollient; emulsion stabilizing agent.

**7 Applications in Pharmaceutical Formulation or Technology**

Ethylene glycol stearates are used as stabilizers for water-in-oil emulsions, although they have poor emulsifying properties. They have emollient properties and are also used as opacifying, thickening, and dispersing agents.

In cosmetics, ethylene glycol stearates are used as a ‘fatty body’ for lipsticks, as pearling agents in opalescent and cream shampoos, and as additives for tanning lubricants.

**8 Description**

The USP 40–NF 35 S1 and PhEur 9.2 describe ethylene glycol stearates as a mixture of ethylene glycol monoesters and diesters of stearic and palmitic acids, containing not less than 50% of monoesters produced from the condensation of ethylene glycol and stearic acid, of vegetable or animal origin.

Ethylene glycol stearates occur as a white or almost white waxy solid.

**9 Pharmacopeial Specifications**

See Table I.