



COPY No. 2

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title : Glyceryl monostearate SE40

Spec. No : SP-AK30-M20

(Item No. 41021800)

Reference(s) : BP 2013 p.1052

Rev. No : 02

Other Requirements : -

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BP 2013

Description	: A white to cream coloured, hard, waxy solid.
Solubility	: Dispersible in hot water; soluble in hot absolute ethanol, in hot liquid paraffin and subject to turbidity at concentrations below 20%, in hot vegetable oils.
Acid value	: Not more than 6.
Iodine value	: Not more than 3 (iodine monochloride method).
Alkalinity	: Shake 1 g with 20 mL of hot carbon dioxide-free water and allow to cool with continuous shaking. The pH of the aqueous layer is 8.0 to 10.0.
Heavy metals (Method C)	: Not more than 10 ppm.
Water	: Not more than 2.0%.
Assay	
- For free glycerol	: Not more than 7.0% (on anhydrous substance).
- For monoglycerides	: Not less than 30.0% (on anhydrous substance).
- For soap	: Not more than 6.0% (on anhydrous substance).

GPO Specification

Melting point : Between 55°C and 60°C.

Prepared by : S. Noppadechy 19/03/14 Head of Raw Material Standard Section 2	Reviewed by : S. Noppadechy 19/03/14 Director of Raw Material Standard Division	Approved by : S. Noppadechy 19/03/14 Director of Regulatory Compliance and Documentation Division	Approved by : S. Noppadechy 19/03/14 Director of Quality Assurance Department เอกสารไม่ควบคุม	Eff. Date 19/04/14
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ใช้ในการจัดซื้อ



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Product Information

Approved source (s)	Refer to current version of Approved Vendor List of Glyceryl monostearate SE40 (Item No. 41021800).
Sampling plan	$1 + \sqrt{N}$ plan.
Testing procedure	Tests to be performed as per current version of WI-AK30-M20.
Storage condition	Store at a condition stated on the label from the manufacturer.
Retest period	1 year after first testing date.

เอกสารไม่ควบคุม
ใช้ในการจัดซื้อ

Prepared by : J. Peppadechy 19/03/14 Head of Raw Material Standard Section 2	Reviewed by : C. Sumritwong 20/03/14 Director of Raw Material Standard Division	Approved by : K. P. 20/03/14 Director of Regulatory Compliance and Documentation Division	Eff. Date 19/04/14
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