

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

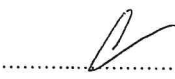
Title: Glyceryl monostearate SE40 (Item No. 41021800)	Spec. No : SP-AK30-M20
Reference(s): BP 2020 page II-1199 - II-1200 [Self-emulsifying Glyceryl Monostearate]	Rev. No : 03
Other Requirements: GPO Specification	Page : 1/2

BP 2020

Test Parameters	Requirement
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	The pH of the aqueous layer is 8.0 to 10.0.
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

Test Parameter	Requirement
Melting point	Between 55 °C and 63 °C.
Heavy metals (Method C)	Not more than 10 ppm.

Prepared by: Benjawan Ubongklee, 01/03/21 Head of Raw Material Standard Section 2	Reviewed by: Tanna Lumbant, 01/03/21 Director of Raw Material Standard Division	Approved by:  02/03/21 Director of Registration and Pharmacovigilance Division	Eff. Date 03/03/21
		Yurayorn, 2/03/21 Acting Director of Quality Assurance Department	

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Product Information

Approved source(s)	Refer to current version of Approved Supplier List of Glyceryl monostearate SE40 (Item No. 41021800).
Sampling plan	For Identification : 100%. For Other Tests : 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.

History of changes

Rev. No.	Description	Effective Date
02	ทบทวนเอกสารให้ทันสมัย อ้างอิงตาม BP 2013 และ GPO Specification	19/04/14
03	ทบทวนเอกสารให้ทันสมัย อ้างอิงตาม BP 2020 ในส่วนของ GPO Specification ได้ปรับ Requirement ของ Melting point จาก 55 - 60 °C เป็น 55 - 63 °C โดยอ้างอิงข้อมูลจากบันทึกข้อความ เลขที่ QA-AN80-64/0103 ลง 10 กุมภาพันธ์ 2564 จากกองพัฒนาระบบคุณภาพ	01/03/21

Prepared by: Benjawan Ubongklee, 01/03/21 Head of Raw Material Standard Section 2	Reviewed by: Tarnma Limkumthong, 01/03/21 Director of Raw Material Standard Division	Approved by: Yanwapan, 2/03/21 Acting Director of Quality Assurance Department	Eff. Date 03/03/21
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