



COPY No. 2

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title : Stearic acid 50, powder BP (Item No. 41011440) Spec. No. : SP-AK30-S35/1
Reference(s) : BP 2017 p. II-954 to II-955 Rev. No. : 04
Other Requirements : GPO Specification Page : 1/2

BP 2017

Test Items	Specification
Description	White or yellowish-white powder.
Solubility	Practically insoluble in water, soluble in ethanol (96%) and in light petroleum (50-70 °C).
Identification	
A. Freezing point	53-59 °C.
B. Acid value	194 to 212, determined on 0.5 g.
C. GC	The principal peaks in the chromatogram obtained with the test solution are similar in retention time to those in the chromatogram obtained with the reference solution, as obtained in Assay.
Appearance	The resulting liquid is not more intensely coloured than reference solution Y ₇ or BY ₇ .
Acidity	No red colour develops.
Iodine value	Maximum 4.0.
Freezing point	53-59 °C.
Nickel	Maximum 1 ppm.
Assay	Stearic acid : 40.0% to 60.0%.
	Sum of the contents of stearic and palmitic acids : minimum 90.0%.

GPO Specification

Test Items	Specification
Fineness	Pass through sieve No. 30 mesh : Not less than 98% (for information).

เอกสารไม่ควบคุม
ใช้ในการจัดซื้อ

Prepared by : SUNANEE / 15/02/18 Head of Raw Material Standard Section 1	Reviewed by : B. Tantiwanont / 20/02/18 Director of Raw Material Standard Division	Approved by : VAREEN / 20/02/18 Director of Regulatory Compliance and Documentation Division	Eff. Date 01/03/18
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Product Information

Approved source (s)	Refer to current version of Approved Vendor List of Stearic acid 50, powder BP (Item No. 41011440).
Sampling plan	P plan : for Identification. $\sqrt{N} + 1$: for other tests.
Testing procedure	Tests to be performed as per current version of WI-AK30-S35/1.
Storage condition	Preserve in well-closed container.
Retest period	1 year after first testing date.

History of changes

Rev. No.	Description	Effective date
03	Update spec. เป็น BP 2014	28/11/14
04	เอกสารมีอายุครบ 3 ปีจึงต้องทบทวน โดย Update spec. เป็น BP 2017 โดยเนื้อหาของ BP 2017 และ BP 2014 เหมือนกัน	01/03/18

เอกสารไม่ควบคุม
ใช้ในการจัดซื้อ

Prepared by : Sunanee, 15/02/18 Head of Raw Material Standard Section 1	Reviewed by : S. Tantiathanont, 20/02/18 Director of Raw Material Standard Division	Approved by : V. Ratanaporn, 21/02/18 Director of Quality Assurance Department (Aching)	Eff. Date 01/03/18
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