

# THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

## RAW MATERIAL SPECIFICATION

<b>Title :</b> White Vaseline [White Soft Paraffin BP] (Item No. 41034000)	<b>Spec. No</b> : SP-AK30-V001
<b>Reference(s) :</b> BP 2016 p.II-506 (White Soft Paraffin)	<b>Rev. No</b> : 03
<b>Other Requirements :</b> GPO Specification	<b>Page</b> : 1/2

<b>BP 2016</b>	Description	: White or almost white, translucent, soft unctuous mass, slightly fluorescent in daylight when melted; odourless.
	Solubility	: Practically insoluble in water; slightly soluble in methylene chloride; practically insoluble in ethanol (96%) and in glycerol.
	Appearance	: The substance is white. The melted mass is not more intensely coloured than a mixture of 1 volume of yellow primary solution and 9 volumes of a 10 g/L solution of hydrochloric acid.
	Acidity or alkalinity	: Not more than 0.5 ml of 0.01 M sodium hydroxide is required to change the colour of the indicator to red.
	Consistency	: 60 to 300.
	Polycyclic aromatic hydrocarbons	: At no wavelength in the range 260 nm to 420 nm does the hydrocarbons absorbance of the test solution exceed that of the reference solution at 278 nm.
	Sulfated ash	: Maximum 0.05%.
<b>GPO Specification</b>	Drop point	: 48°C to 56°C.
	Identification	: A. Drop point : between 48°C and 56°C B. Infrared absorption spectrophotometry C. Appearance

Prepared by : <i>J. Dopeedech, 21/03/16</i> Head of Raw Material Standard Section 2	Reviewed by : <i>W. A. A. P. A., 21/03/16</i> Director of Raw Material Standard Division	<i>16644, 23/03/16</i> Director of Regulatory Compliance and Documentation Division	Approved by : <i>A. Y. K. M. P., 23/03/16</i> Director of Quality Assurance Department	Eff. Date 21/04/16
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### Product Information

Approved source (s)	Refer to current version of Approved Vendor List of White Vaseline [White Soft Paraffin BP] (Item No. 41034000).
Sampling plan	$\sqrt{N} + 1$ plan
Testing procedure	Tests to be performed as per current version of WI-AK30-V001.
Storage condition	Store at a condition stated on the label from the manufacturer. Protected from light. The label states the nominal drop point.
Retest period	2 years after first testing date.

### History of changes

Rev. No.	Description	Reviewed by	Effective Date
02	ทบทวนเอกสารให้ทันสมัย (อ้างอิงตาม BP 2011 และ GPO Specification)	ผอภ. มาตรฐานวัตถุดิบ	25/01/12
03	ทบทวนเอกสารให้ทันสมัย (อ้างอิงตาม BP 2016 และ GPO Specification)	ผอภ. มาตรฐานวัตถุดิบ	21/04/16

Prepared by : S. Noppadech, 21/03/16 Head of Raw Material Standard Section 2	Reviewed by : N. A. P., 21/03/16 Director of Raw Material Standard Division	Approved by : P. Y. H., 23/3/16 Director of Regulatory Compliance and Documentation Division	Eff. Date 21/04/16
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