

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title : Liquid Paraffin (Heavy) BP (Item No. 41032180)	Spec. No : SP-AK30-P012
Reference(s) : BP 2021 page II-539 - II-540 [Liquid Paraffin]	Rev. No : 02
Other Requirements : -	Page : 1/2

BP 2021

Test Parameters	Requirement
Description	Colourless, transparent, oily liquid, free from fluorescence in daylight.
Solubility	Practically insoluble in water, slightly soluble in ethanol (96 per cent), miscible with hydrocarbons.
Identification	A. Infrared absorption spectrophotometry. C. Viscosity (see Tests) : 110 mPa·s to 230 mPa·s.
Acidity or alkalinity	Not more than 0.1 mL of 0.1 M sodium hydroxide is required to change the colour of the indicator to pink.
Relative density	0.827 to 0.890.
Viscosity	110 mPa·s to 230 mPa·s.
Polycyclic aromatic hydrocarbons	At no wavelength between 260 nm and 420 nm does the absorbance of the test solution exceed one-third that of the reference solution at 275 nm.
Readily carbonisable substances	The lower layer is not more intensely coloured than a mixture of 0.5 mL of blue primary solution, 1.5 mL of red primary solution, 3.0 mL of yellow primary solution and 2 mL of a 10 g/L solution of hydrochloric acid .
Solid paraffins	After 4 hours, the liquid is sufficiently clear for a black line, 0.5 mm wide, to be easily seen against a white background held vertically behind the tube.

Prepared by: Benjamin Ubonglee, 02/07/21	Reviewed by: Sivannee (Acting), 04/07/21	Approved by: (Acting) Tarnier Lumbant, 06/07/21	Eff. Date 16/07/21
Head of Raw Material Standard Section 2	Director of Raw Material Standard Division	Director of Regulatory Strategy Division	Director of Quality Assurance Department

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Product Information

Approved source (s)	Refer to current version of Approved Supplier List of Liquid Paraffin BP (Item No. 41032180).
Sampling plan	For Identification: 100%. For Other Tests: $\sqrt{N} + 1$ plan.
Testing procedure	Tests to be performed as per current version of WI-AK30-P012.
Storage condition	To be stored at a condition stated on the label from the manufacturer. Protected from light.
Retest period	1 years after first testing date.

History of changes

Rev. No.	Description	Effective Date
01	อ้างอิงตาม BP 2015	19/07/15
02	ทบทวนเอกสารให้ทันสมัย อ้างอิงตาม BP 2021 โดยเปลี่ยนหัวข้อ Identification เป็น First identification: A, C เท่านั้น	16/07/21

Prepared by: Benjawan Ubongklee, 02/07/21	Reviewed by: Sunwannee (Acting), 07/07/21	Approved by: (Acting) Tanwisa Lumbant, 09/07/21	Eff. Date 16/07/21
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