



COPY No. 2

# THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

## RAW MATERIAL SPECIFICATION

<b>Title :</b> Liquid Paraffin (Heavy) BP (Item No. 41032180)	<b>Spec. No</b> : SP-AK30-P012
<b>Reference(s) :</b> BP 2015 p. II-501—II-502 [Liquid Paraffin]	<b>Rev. No</b> : 01
<b>Other Requirements :</b> -	<b>Page</b> : 1/3

<b>BP 2015</b>	<b>Description</b>	: Colourless, transparent, oily liquid, free from fluorescence in daylight.
	<b>Solubility</b>	: Practically insoluble in water, slightly soluble in ethanol (96 per cent), miscible with hydrocarbons.
	<b>Identification</b>	: A. Infrared absorption spectrophotometry B. 0.1 M sodium hydroxide, with continuous shaking, for about 30 seconds. On cooling to room temperature, 2 phases separate. To the aqueous phase add 0.1 mL of phenolphthalein solution R. The solution becomes red. C. Viscosity (see Tests) : 110 mPa·s to 230 mPa·s.
	<b>Acidity or alkalinity</b>	: To 10 mL add 20 mL of boiling distilled water and shake vigorously for 1 minute. Separate the aqueous layer and filter. To 10 mL of the filtrate, add 0.1 mL of phenolphthalein solution R. The solution is colourless. Not more than 0.1 mL of 0.1 M sodium hydroxide is required to change the colour of the indicator to pink.
	<b>Relative density</b>	: 0.827 to 0.890.
	<b>Viscosity</b>	: 110 mPa·s to 230 mPa·s.
	<b>Polycyclic aromatic hydrocarbons</b>	: 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.

เอกสารไม่ควบคุม  
ใช้ในการจัดซื้อ

<b>Prepared by :</b> J. Noppadechy 13/07/15 Head of Raw Material Standard Section 2	<b>Reviewed by :</b> Nalapa, 12/07/15 Director of Raw Material Standard Division	<b>Approved by :</b> Prapanaduc, 14/07/15 Director of Quality Assurance Department	<b>Eff. Date</b> 19/07/15
--	---	---	------------------------------



COPY No. 2

## THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

## RAW MATERIAL SPECIFICATION

Title : Liquid Paraffin (Heavy) BP  
(Item No. 41032180)

Spec. No : SP-AK30-P012

Reference(s) : BP 2015 p. II-501—II-502  
[Liquid Paraffin]

Rev. No : 01

Other Requirements : -

Page : 2/3

Readily carbonisable substances : The lower layer is not more intensely coloured (2.2.2, Method I) 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 R.

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.

เอกสารไม่ควบคุม  
ใช้ในการจัดซื้อ

Prepared by :	Reviewed by :	Approved by :	Eff. Date
S. Neppadach, 13/07/15	Waldapa, 13/07/15	Prapanadach, (Act), 14/07/15	19/07/15
Head of Raw Material Standard Section 2	Director of Raw Material Standard Division	Director of Regulatory Compliance and Documentation Division	Director of Quality Assurance Department



COPY No. 2

## THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

## RAW MATERIAL SPECIFICATION

Title : Liquid Paraffin (Heavy) BP (Item No. 41032180)	Spec. No : SP-AK30-P012
Reference(s) : BP 2015 p. II-501—II-502 [Liquid Paraffin]	Rev. No : 01
Other Requirements : -	Page : 3/3

## Product Information

Approved source (s)	Refer to current version of Approved Supplier List of Liquid Paraffin BP (Item No. 41032180).
Sampling plan	$\sqrt{N} + 1$ 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	2 years after first testing date.

## History of changes

Rev. No.	Description	Reviewed by	Effective Date
01	อ้างอิงตาม BP 2015	ผอ. มาตรฐานวัตถุดิบ	19/07/15

เอกสารไม่ควบคุม  
ใช้ในการจัดซื้อ

Prepared by : J. Noppadech, 13/07/15	Reviewed by : W. Aya, 13/07/15	Approved by : Prasanna (Acting), 14/07/15	Eff. Date 19/07/15
Head of Raw Material Standard Section 2	Director of Raw Material Standard Division	Director of Regulatory Compliance and Documentation Division	Director of Quality Assurance Department