

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title : Eucalyptus Oil (Item No. 41032640)	Spec. No. : SP-AK30-O7
Reference(s) : BP 2018 page IV-203 – IV-204	Rev. No. : 02
Other Requirements : -	Page : 1/2

BP 2018

Description	: Colourless or pale yellow liquid; characteristic odour.
Identification	: A. Thin-layer chromatography. B. Gas chromatography. [First identification: B; Second identification: A]
Relative density	: 0.906 to 0.927.
Refractive index	: 1.458 to 1.470.
Optical rotation	: 0° to +10°.
Solubility in alcohol	: It is soluble in 5 volumes of ethanol (70% V/V).
Aldehydes	: Not more than 2.0 mL of 0.5 M potassium hydroxide in alcohol (60% V/V) is require in the 2 nd titration.
Chromatographic profile	
– α-pinene	: 0.05% to 10.0%;
– β-pinene	: 0.05% to 1.5%;
– sabinene	: maximum 0.3%;
– α-phellandrene	: 0.05% to 1.5%;
– limonene	: 0.05% to 15.0%;
– 1,8-cineole	: minimum 70.0%;
– camphor	: maximum 0.1%.

Prepared by :	Reviewed by :	Approved by :	Eff. Date
J. Ropadech, 18/12/18 Head of Raw Material Standard Section 2	J. Ropadech (Acting), 18/12/18 Director of Raw Material Standard Division	VARIPIN, 18/12/18 Director of Regulatory Compliance and Documentation Division	15/01/19
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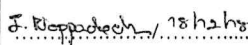

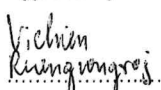
Title : Eucalyptus Oil (Item No. 41032640)	Spec. No. : SP-AK30-O7
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Product Information

Approved source(s)	Refer to current version of Approved Supplier List of Eucalyptus Oil (Item No. 41032640).
Sampling plan	For Identification : 100%. For Other Tests : n plan.
Testing procedure	Tests to be performed as per current version of WI-AK30-O7.
Storage condition	Store at a condition stated on the label from the manufacturer or store at a temperature not exceeding 25 °C.
Retest period	1 year after first testing date.

History of changes

Rev. No.	Description	Effective Date
01	จัดทำข้อกำหนด โดยอ้างอิงตาม BP 1993	22/12/97
02	Update โดยอ้างอิงตาม BP 2018	15/01/19

Prepared by :	Reviewed by :	Approved by :	Eff. Date
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