THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title: Camphor [Racemic Camphor BP] (Item No. 41020500)	**Spec. No.** : SP-AK30-C11
Reference(s): BP 2019 page I-411 to I-412	**Rev. No.** : 08
Other Requirements: GPO Specification	**Page** : 1/2

BP 2019

Test Parameters	Requirement
Description	White or almost white, crystalline powder or friable, crystalline masses, highly volatile even at room temperature.
Solubility	Slightly soluble in water, very soluble in ethanol (96%) and in light petroleum, freely soluble in fatty oils, very slightly soluble in glycerol.
Identification	First identification: A, C. Second identification: A, B, D. A. Optical rotation: - 0.15° to + 0.15°.
	B. Melting point: 172 °C to 180 °C.
	C. Infrared absorption spectrophotometry.
	D. The crystals, dried in vacuo, melt at 118 °C to 121 °C.
Appearance of solution	Test solution (10% w/v in ethanol (96%)) is clear and colourless (Method II).
Acidity or alkalinity	Not more than 0.2 mL of 0.1 M sodium hydroxide is required to change the colour of the indicator.
Optical rotation	- 0.15° to + 0.15°.
Related substances -Any impurity	Not more than 2% (for each impurity).
-Total impurities	Not more than 4%.
Halogens	Not more than 100 ppm.
Water	Dissolve 1 g in 10 mL of light petroleum. The solution is clear.
Residue on evaporation	Not more than 0.05%.

Prepared by:	Reviewed by:		Approved by:	Eff. Date
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Head of Raw Material Standard Section 2	Director of Raw Material Standard Division	Director of Drug Registration and Pharmacovigilance Division	Director of Quality Assurance Department (Acting)	

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Product Information

Approved source(s)	Refer to current version of Approved Supplier List of Camphor [Racemic Camphor BP] (Item No. 41020500).
Sampling plan	For Identification : 100%. For Other Tests : n plan.
Testing procedure	Tests to be performed as per current version of WI-AK30-C11.
Storage condition	Store at a condition stated on the label from the manufacturer.
Retest period	1 year after first testing date.

History of changes

Rev. No.	Description	Effective Date
06	Update ข้อกำหนดตาม BP 2013	19/04/14
07	Update ข้อกำหนดตาม BP 2018	31/01/18
08	Update ข้อกำหนดตาม BP 2019	15/02/20

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