COPY No. 2

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title: Benzyl Benzoate BP (Item No. 41030540)	**Spec. No.** : SP-AK30-B8
Reference(s): BP 2019 page I-284	**Rev. No.** : 05
Other Requirements: -	**Page** : 1/2

BP 2019

Test Parameters	Requirement
Description	Colourless or almost colourless, oily liquid; characteristic odour.
Solubility	Practically insoluble in water, miscible with ethanol (96%), with methylene chloride and with fatty and essential oils.
Boiling Point	About 320 °C.
Identification	First identification: A. Second identification: B, C.
	A. Infrared absorption spectrophotometry.
	B. The dried precipitate melts at 121 °C to 124 °C [from liquid remaining].
	C. The dried precipitate melts at 121 °C to 124 °C [from the distillated].
Acidity	Not more than 0.2 mL of 0.1 M sodium hydroxide is required to change the colour of the indicator to pink.
Relative density	1.118 to 1.122, at 20 °C.
Refractive index	1.568 to 1.570, at 20 °C.
Freezing point	Minimum 17.0 °C.
Sulfated ash	Not more than 0.1%.
Assay	99.0% - 100.5% of Benzyl benzoate ($C_{14}H_{12}O_2$).

Prepared by:	Reviewed by:		Approved by:	Eff. Date
J. Noppadech, 28/09/20	Lumnboont, 29/09/20	, 29/09/20	Sirithorn, 29/09/2020	15/10/20
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	

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Product Information

Approved source(s)	Refer to current version of Approved Supplier List of Benzyl Benzoate BP (Item No. 41030540).
Sampling plan	For Identification : 100%. For Other Tests : n plan.
Testing procedure	Tests to be performed as per current version of WI-AK30-B8.
Storage condition	Store at a condition stated on the label from the manufacturer or store in airtight, well-filled containers. Protected from light.
Retest period	1 year after first testing date.

History of changes

Rev. No.	Description	Effective Date
03	Update ข้อกำหนด โดยอ้างอิงตาม BP 2008	13/09/08
04	Update ข้อกำหนด โดยอ้างอิงตาม BP 2013	24/05/16
05	Update ข้อกำหนด โดยอ้างอิงตาม BP 2019	15/10/20

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