GPO องค์การเภสัชกรรม COPY No. 2

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title : Benzyl Alcohol BP (For injection dosage form) (Item No. 41030520)	**Spec. No.** : SP-AK30-B002
Reference(s) : BP 2019 p.I-282 to I-284	**Rev. No.** : 06
Other Requirements : -	**Page** : 1/2

BP 2019

Tested Items	Specifications	
Description	Clear, colourless, oily liquid.	
Solubility	Soluble in water, miscible with ethanol (96%) and with fatty and essential oils.	
Relative density	1.043 to 1.049.	
Identification - Infrared absorption spectrophotometry	Conforms to FT-IR standard spectrum.	
Appearance of solution	The solution is clear and colourless.	
Acidity	Not more than 1 ml of 0.1 M sodium hydroxide is required to change the colour of the indicator to pink.	
Refractive index	1.538 to 1.541.	
Peroxide value	Not more than 5.	
Related substances	Impurity A	Not more than 0.05%.
	Impurity B	Not more than 0.10%.
	Sum of other peaks with a relative retention less than that of benzyl alcohol	Not more than 0.02%.
	Sum of peaks with a relative retention greater than that of benzyl alcohol	Not more than 0.2%.
Residue on evaporation	Not more than 0.05%.	
Assay	98.0% to 100.5% of C_7H_8O.	

Prepared by :	Reviewed by :		Approved by :	Eff. Date
Sumanee / 23/04/19	Tanwa / 25/04/19	/ 25/04/19	Vichien / 26/04/19	01/06/19
Head of Raw Material Standard Section 1	Director of Raw Material Standard Division	Director of Regulatory Compliance and Documentation Division	Director of Quality Assurance Department (Acting)	

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Product Information

Approved source (s)	Refer to current version of Approved Vendor List of Benzyl Alcohol BP (For injection dosage form) (Item No. 41030520)
Sampling plan	1. N Plan ($\sqrt{N} + 1$) : for other tests. 2. 100% Identification.
Testing procedure	Tests to be performed as per current version of WI-AK30-B002.
Storage condition	To be stored in an airtight container, under nitrogen, protected from light and at a temperature between 2 °C and 8 °C.
Retest period	1 year after first testing date.

History of changes

Rev. No.	Description	Effective date
05	Update spec. เป็น BP 2014 โดยเนื้อหาของ BP 2009 และ BP 2014 เหมือนกัน	29/05/15
06	Update spec. เป็น BP 2019 ตามประกาศกระทรวงสาธารณสุข เรื่องระบุตำรา พ.ศ. 2561 โดยให้ใช้ตำรายาฉบับ USP 39/ BP 2016 ขึ้นไป นอกจากนี้เนื่องจากเอกสารมีอายุครบ 3 ปี จึงต้องทบทวน โดยเนื้อหาของ BP 2014 และ BP 2019 เหมือนกัน	01/06/19

Prepared by :	Reviewed by :		Approved by :	Eff. Date
Suwannee / 23/04/19 Head of Raw Material Standard Section 1	Tanmai Lukcomt / 25/04/19 Director of Raw Material Standard Division	[signature] / 25/04/19 Director of Regulatory Compliance and Documentation Division	Vichian Kungwongroj / 26/04/19 Director of Quality Assurance Department (Acting)	01/06/19