THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title : Benzoic Acid BP (Item No. 41030500) (ใช้สำหรับยาฉีด)	**Spec. No.** : SP-AK30- B001
Reference(s) : BP 2019 p. I-278 to I-279	**Rev. No.** : 05
Other Requirements : ---------------	**Page** : 1/2

BP 2019

Test Items	Specification
Description	White or almost white, crystalline powder or colourless crystals.
Solubility	Slightly soluble in water, soluble in boiling water, freely soluble in ethanol (96%) and in fatty oils.
Identification A. Melting point B. Benzoates Test	 121 °C to 124 °C. A dull-yellow precipitate, soluble in ether, is formed.
Appearance of solution	Solution S is clear and colourless.
Carbonisable substances	After 5 minutes, the solution is not more intensely coloured than reference solution Y_5.
Oxidisable substances	After 5 minutes, the solution is still coloured pink.
Halogenated compounds and halides	Not more than 300 ppm.
Sulfated ash	Not more than 0.1%.
Assay	99.0% to 100.5% of Benzoic acid ($C_7H_6O_2$).

Prepared by :	Reviewed by :		Approved by :	Eff. Date
Suwannee / 18/04/19 Head of Raw Material Standard Section 1	Turmer Unlerant / 22/04/19 Director of Raw Material Standard Division	.... / 23/04/19 Director of Regulatory Compliance and Documentation Division	Kichan Ruengwongrot / 29/04/19 Director of Quality Assurance Department (Acting)	15/06/19

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Product Information

Approved source (s)	Refer to current version of Approved Vendor List of Benzoic Acid BP (Item No. 41030500) (ใช้สำหรับยาฉีด).
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-B001.
Storage condition	To be stored in well-closed, light-resistant container at temperature below 25 °C.
Retest period	1 year after first testing date.

History of changes

Rev. No.	Description	Effective date
03	- Update spec. เป็น BP 2010	26/11/10
04	- Update spec. เป็น BP 2014 โดยเนื้อหาของ BP 2010 และ BP 2014 เหมือนกัน	29/05/15
05	- 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	15/06/19

Prepared by :	Reviewed by :		Approved by :	Eff. Date
Suwannee ....../18/04/19	Tawnee Lumnlboom / 22/04/19	........../ 23/04/19	Vichien Ruengrongroj / 23/04/19	15/06/19
Head of Raw Material Standard Section I	Director of Raw Material Standard Division	Director of Regulatory Compliance and Documentation Division	Director of Quality Assurance Department (Acting)	