

# THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

## RAW MATERIAL SPECIFICATION

Title: Sodium benzoate BP

Spec. No. : SP-AK30-S7

(Item No. 41023640)

Reference(s): BP 2020 page II-896 to II-897

Rev. No. : 04

Other Requirements: GPO Specification

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#### **BP 2020**

Test Parameters	Requirement		
Description	White or almost white, crystalline or granular powder or flakes, slightly hygroscopic.		
Solubility	Freely soluble in water, sparingly soluble in ethanol (90 %v/v).		
Identification	A. It gives reactions (b) and (c) of benzoates.		
	B. It gives reaction (a) of sodium.		
Appearance of solution	Solution S is clear and not more intensely coloured than reference solution Y <sub>6</sub> .		
	[Solution S: 10.0% solution.]		
Acidity or alkalinity	Not more than 0.2 mL of 0.1 M sodium hydroxide or 0.1 M hydrochloric acid.		
Halogenated compounds	Not more than 200 ppm for ionised chlorine and maximum 300 ppm for total chlorine.		
Loss on dying	Not more than 2.0%.		
Assay	99.0% to 100.5% of C <sub>7</sub> H <sub>5</sub> NaO <sub>2</sub> (dried substance).		

### **GPO Specification**

Test Parameters	Requirement	
Heavy metals	Not more than 10 ppm.	
Tapping Volume	5.0 g occupies between 7.0 mL and 11.0 mL when tapped down 20 times at 3-mm drop height	
	at a nominal rate of 250 drops/minute.	

เอกสารไม่ควบคุม ใช้ในการจัดซื้อ

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#### **Product Information**

Approved source(s)	Refer to current version of Approved Supplier List of Sodium Benzoate BP (Item No. 41023640).		
Sampling plan	For Identification : 100%.  For Other Tests : n plan.		
Testing procedure	Tests to be performed as per current version of WI-AK30-S7.		
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
02	Update ข้อกำหนดตาม BP 2009 และ GPO Specification	19/10/09
03	Update ข้อกำหนดตาม BP 2013 และ GPO Specification	25/02/16
04	Update ข้อกำหนดตาม BP 2020 และ GPO Specification	25/01/20

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