

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title: Sodium benzoate BP (Item No. 41023640)	Spec. No. : SP-AK30-S7
Reference(s): BP 2020 page II-896 to II-897	Rev. No. : 04
Other Requirements: GPO Specification	Page : 1/2

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 ₆ . [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 drying	Not more than 2.0%.
Assay	99.0% to 100.5% of C ₇ H ₅ NaO ₂ (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.

Prepared by : <i>J. Koppach</i> 17/01/20 Head of Raw Material Standard Section 2	Reviewed by : <i>Turner</i> <i>Unborn</i> 20/01/20 Director of Raw Material Standard Division	Approved by : <i>Wichin</i> <i>Rungrongroj</i> 20/01/20 Director of Quality Assurance Department	Eff. Date 25/01/20
---	---	--	---------------------------

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title: Sodium benzoate BP (Item No. 41023640)	Spec. No. : SP-AK30-S7
Reference(s): BP 2020 page II-896 to II-897	Rev. No. : 04
Other Requirements: GPO Specification	Page : 2/2

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

Prepared by : S. Dappadech 17/01/20 Head of Raw Material Standard Section 2	Reviewed by : [Signature] 20/01/20 Director of Raw Material Standard Division	Approved by : [Signature] 20/01/20 Director of Quality Assurance Department	Eff. Date 25/01/20
--	--	--	-----------------------