



COPY No. 6

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title : Sodium Benzoate BP (Item No. 41023640)	Spec. No : SP-AK30-S7
Reference(s) : BP 2013 p.2008	Rev. No : 03
Other Requirements : GPO Specification	Page : 1/2

BP 2013	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	: Test solution (10% w/v) is clear and not more intensely coloured than reference solution Y ₆ (Method II).
	Acidity or alkalinity	: Not more than 0.2 mL of 0.1 M sodium hydroxide or 0.1 M hydrochloric acid is required.
	Halogenated compounds	: Maximum 200 ppm for ionised chlorine and maximum 300 ppm for total chlorine.
	Heavy metals	: Maximum 10 ppm.
	Loss on Drying	: Maximum 2.0%.
	Assay	: 99.0% to 100.5% of C ₇ H ₅ NaO ₂ (dried substance).
GPO Specification	Tapping Volume	: 5.0 g occupies between 7.0 and 11.0 mL when tapped down 20 times at 3-mm drop height at a nominal rate of 250 drops/minute.

เอกสารไม่ควบคุม
ใช้ในการจัดซื้อ

Prepared by : J. Noppadech, 01/02/16 Head of Raw Material Standard Section 2	Reviewed by : N. S. P. A., 01/02/16 Director of Raw Material Standard Division	Approved by : A. Y. P. T., 02/02/16 Director of Regulatory Compliance and Documentation Division	Eff. Date 25/02/16
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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	$\sqrt{N} + 1$ 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. Preserve in well-closed containers.
Retest period	1 year after first testing date.

History of changes

Rev. No.	Description	Reviewed by	Effective Date
02	อ้างอิงตาม BP2009	พอก. มาตรฐานวัตถุดิบ	19/10/09
03	อ้างอิงตาม BP2013	พอก. มาตรฐานวัตถุดิบ	25/02/16

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ใช้ในการจัดซื้อ

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