

# THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

## RAW MATERIAL SPECIFICATION

<b>Title :</b> Sodium Benzoate BP (Item No. 41033340) (ใช้สำหรับยาฉีด)	<b>Spec. No. :</b> SP-AK30- S001
<b>Reference(s) :</b> BP 2020 p. II-896 to II-897	<b>Rev. No. :</b> 08
<b>Other Requirements :</b> GPO specification	<b>Page :</b> 1/2

### BP 2020

TEST	Specifications
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	
- Benzoates Test	Conforms.
- Sodium Test	Conforms.
Appearance of solution	Solution S is clear and not more intensely coloured than reference solution Y <sub>6</sub> .
Acidity or alkalinity	<i>Not more than 0.2 ml of 0.1 M HCl or 0.1 M NaOH</i> is required to change the colour of the indicator.
Halogenated compounds	
- Ionised chlorine	Not more than 200 ppm.
- Total chlorine	Not more than 300 ppm.
Loss on drying	Not more than 2.0%.
Assay	99.0% to 100.5% (on dried substance).

### GPO specification

TEST	Specifications
Heavy metals	Not more than 10 ppm.

Prepared by : <i>S. W. W. W. W. W.</i> / 14/10/20 Head of Raw Material Standard Section 1	Reviewed by : <i>T. W. W. W. W.</i> / 14/10/20 Director of Raw Material Standard Division	Approved by : <i>Y. W. W. W. W.</i> / 15/10/20 Director of Drug Registration and Pharmacovigilance Division	Eff. Date 15/12/20
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### Product Information

Approved source (s)	Refer to current version of Approved Vendor List of Sodium Benzoate BP (Item No.41033340).
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-S001.
Storage condition	To be stored in well-closed containers.
Retest period	1 year after first testing date.

### History of changes

Rev. No.	Description	Effective date
06	Update spec เป็น BP 2013	15/02/14
07	Update spec เป็น BP 2016 เนื่องจากเอกสารอายุครบ 3 ปี ต้องทบทวน โดยเนื้อหาของ BP 2013 และ BP 2016 เหมือนกัน	20/01/17
08	เอกสารมีอายุครบ 3 ปี จึงต้องทบทวน โดย update spec. เป็น BP 2020 โดยเนื้อหาของ BP 2016 และ BP 2020 เหมือนกัน	15/12/20

Prepared by : <i>S. Wanee</i> / 14/10/20 Head of Raw Material Standard Section 1	Reviewed by : <i>T. L.</i> / 14/10/20 Director of Raw Material Standard Division	Approved by : <i>[Signature]</i> / 15/10/20 Director of Drug Registration and Pharmacovigilance Division	Eff. Date 15/12/20
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