

THE GOVERNMENT PHARMACEUTI



Title: Sodium Benzoate BP (Item No. 41033340) (ใช้สำหรับยาฉีด)

Spec. No.

: SP-AK30- S001

Reference(s): BP 2016 p. II-836-II837

Rev. No.

: 07

Other Requirements: -----

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BP 2016

| 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 ₆ . | | |
| Acidity or alkalinity | Not more than 0.2 ml of 0.1 M HCl or 0.1 M NaOH 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. | | |
| Heavy metals | Not more than 10 ppm. | | |
| Loss on drying | Not more than 2.0%. | | |
| Assay | 99.0% to 100.5% (on dried substance). | | |

| | Prepared by: | |
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| | Head of Raw Material | l |
| Ì | Standard Section 1 | Į |

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Department

Eff. Date 20/01/17

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THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title : Sodium Benzoate BP (Item No. 41033340) (ใช้สำหรับยาที่ด)

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Product Information

| Refer to current version of Approved Vendor List of Sodium Benzoate BP (Item No.41033340). |
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| P plan : for Identification. |
| $\sqrt{N} + 1$: for other tests. |
| Tests to be performed as per current version of WI-AK30-S001. |
| To be stored in well-closed containers. |
| 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 ด้องทบทวน โดยเนื้อหาของ BP 2013 และ BP 2016 | 20/01/17 |
| | เหมือนกับ | |
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| Prepared by: | Reviewed by: | | Approved by : | Eff. Date |
|--|--|---|--|-----------|
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