

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title : Sodium Sulfite Anhydrous BP (Item No. 41033580)

Spec. No. : SP-AK30-S67

Reference(s) : BP 2016 p. II-885-886

Rev. No. : 02

Other Requirements : ----

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BP 2016

Test Items	Specification
Description	White or almost white powder.
Solubility	Freely soluble in water, very slightly soluble in ethanol (96%).
Identification	
A. Alkaline Test	Solution S is slightly alkaline.
B. Sulphates Test	A white precipitate is formed.
C. Sodium Test	A dense white precipitate is formed.
Appearance of solution	Solution S is clear and colorless.
Thiosulfates	The difference between the volumes used in the titrations is not more than 0.15 ml (0.1%).
Iron	Not more than 10 ppm.
Selenium	Not more than 10 ppm.
Zinc	Not more than 25 ppm.
Heavy metals	Not more than 10 ppm.
Assay	95.0% to 100.5% of Na_2SO_3 .

เอกสารไม่ควบคุม
ใช้ในการจัดซื้อ

Prepared by : Sunanee / 10/05/16 Head of Raw Material Standard Section I	Reviewed by : Nalaph / 10/05/16 Director of Raw Material Standard Division	Vichin Rungwongroj / 13/05/16 Director of Regulatory Compliance and Documentation Division	Approved by : Prapanadee A. / 16/05/16 Director of Quality Assurance Department	Eff. Date 24/05/16
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Product Information

Approved source.(s)	Refer to current version of Approved Vendor List of Sodium Sulfite Anhydrous BP (Item No. 41033580).
Sampling plan	P plan : for Identification. $\sqrt{N} + 1$: for other tests.
Testing procedure	Tests to be performed as per current version of WI-AK30-S67.
Storage condition	Preserve in tight containers. Store at room temperature.
Retest period	1 year after first testing date.

History of changes

Rev. No.	Description	Effective date
01	ประกาศใช้ครั้งแรก อ้างอิง BP 2011	31/10/11
02	Up spec เป็น BP 2016 เนื่องจากเอกสารอายุมากกว่า 3 ปี ต้องทบทวน โดยเนื้อหาของ BP 2011 และ BP 2016 เหมือนกัน	24/05/16

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ใช้ในการจัดซื้อ

Prepared by : Sutarnee, 10/05/16 Head of Raw Material Standard Section 1	Reviewed by : Nalaga, 10/05/16 Director of Raw Material Standard Division	Approved by : Vichin Rungvongroj, 13/05/16 Director of Regulatory Compliance and Documentation Division	Eff. Date 24/05/16
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