



COPY No. 2

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title: Sodium Metabisulfite BP (Item No. 41033280)

Spec. No. : SP-AK30-S005

Reference(s) : BP 2016 p. II 865 – II 866

Rev. No. : 03

Other Requirements : GPO Specification

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BP 2016

Test Items	Specification
Description	White or almost white, crystalline powder or colourless crystals.
Solubility	Freely soluble in water, slightly soluble in ethanol (96%).
Identification	
A. pH	3.5 to 5.0 for solution S.
B. Sulfates Test	A white precipitate is formed.
C. Sodium Test	A dense white precipitate is formed.
Appearance of solution	Solution S is clear and colourless.
pH	3.5 to 5.0 for solution S.
Thiosulfates	The solution remains clear for at least 15 minutes.
Arsenic	Not more than 5 ppm, Method A.
Iron	Not more than 20 ppm.
Heavy metals	Not more than 20 ppm, Test A.
Assay	95.0% to 100.5% of $\text{Na}_2\text{S}_2\text{O}_5$.

GPO Specification

Test Items	Specification
Packaging	Well-closed recappable plastic or glass bottle, original from the manufacturer.

เอกสารไม่ควบคุม
ใช้ในการจัดซื้อ

Prepared by : Sunanee, 20/03/17 Head of Raw Material Standard Section 1	Reviewed by : Yuwapan, 20/03/17 Director of Raw Material Standard Division	Vichien Ruengwong, 24/03/17 Director of Regulatory Compliance and Documentation Division	Approved by : B. Cu, 24/03/17 Director of Quality Assurance Department	Eff. Date 15/05/17
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Product Information

Approved source (s)	Refer to current version of Approved Vendor List of Sodium Metabisulfite BP (Item No. 41033280)
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-S005.
Storage condition	Protected from light.
Retest period	1 year after first testing date.

History of changes

Rev. No.	Description	Effective date
02	อ้างอิง spec เป็น BP 2013	15/02/14
03	Up spec เป็น BP 2016 โดยเนื้อหาของ BP 2013 และ BP 2016 เหมือนกัน เนื่องจากเอกสารมีอายุครบ 3 ปี จึงต้องทบทวน	15/05/17

เอกสารไม่ควบคุม
ใช้ในการจัดซื้อ

Prepared by : S. Wannee... 10/03/17 Head of Raw Material Standard Section 1	Reviewed by : Y. Manom... 10/03/17 Director of Raw Material Standard Division	Approved by : Vichin Rungwongroj, 24/03/17 Director of Regulatory Compliance and Documentation Division	Eff. Date B. Cu 24/03/17 Director of Quality Assurance Department 15/05/17
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