

# THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

## RAW MATERIAL SPECIFICATION

**Title :** Neostigmine Methylsulfate BP (Item No. 41032530)  
(Neostigmine Metilsulfate)

**Spec. No. :** SP-AK30-N17

**Reference(s) :** BP 2016 p. II-359 to II-360

**Rev. No. :** 04

**Other Requirements :** -

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### BP 2016

Test Items	Specification	
Description	White or almost white crystalline powder.	
Solubility	Very soluble in water, freely soluble in ethanol (96%).	
Identification		
- Melting point	144 °C to 149 °C.	
- Infrared absorption spectrophotometry	Conforms to <i>FT-IR standard spectrum</i> .	
Appearance of solution	Solution S is clear and colorless.	
Acidity and alkalinity	Conforms.	
Related substances	Impurity B	: Not more than 0.01%.
	Unspecified impurity	: Not more than 0.10%.
	Total impurities	: Not more than 0.2%.
Sulfates	Not more than 200 ppm, determined on solution S.	
Loss on drying	Not more than 0.5%.	
Sulfated ash	Not more than 0.1%.	
Assay	98.5 – 101.0% of $C_{13}H_{22}N_2O_6S$ , calculated with reference to the dried substance.	

เอกสารไม่ควบคุม  
ใช้ในการจัดซื้อ

Prepared by : SUNAMNEE / 04/05/16 Head of Raw Material Standard Section 1	Reviewed by : WALAPA / 04/05/16 Director of Raw Material Standard Division	Vichien Rungvongroj / 16/05/16 Director of Regulatory Compliance and Documentation Division	Approved by : A. Y. H. / 17/05/16 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 Neostigmine Methylsulfate BP (Neostigmine Metilsulfate) (Item No. 41032530).
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-N17.
Storage condition	To be stored in an airtight container, protected from light.
Retest period	1 year after first testing date.

**History of changes**

Rev. No.	Description	Effective date
03	อ้างอิง spec เป็น BP 2011	28/02/12
04	Up spec เป็น BP 2016 เนื่องจากเอกสารมีอายุมากกว่า 3 ปี จึงต้องทบทวน อ้างอิง CR No. AN80-59091	24/05/16

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