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 (same as BP 2020)	**Rev. No.** : 05
Other Requirements : -	**Page** : 1/2

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 - Infrared absorption spectrophotometry	 144 °C to 149 °C. Conforms to IR standard spectrum.	
Appearance of solution	Solution S is clear and colorless.	
Acidity or 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.	

Prepared by :	Reviewed by :		Approved by :	Eff. Date
Suwannee, 12/10/20	Taweesri Limlomwongse, 12/10/20	, 12/10/20	, 14/10/20	30/11/20
Head of Raw Material Standard Section 1	Director of Raw Material Standard Division	Director of Drug Registration and Pharmacovigilance	Director of Quality Assurance Department (Acting)	

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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	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-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	Update spec. เป็น BP 2016 เนื่องจากเอกสารมีอายุมากกว่า 3 ปี จึงต้องทบทวน อ้างอิง CR No. AN80-59091	24/05/16
05	เอกสารมีอายุครบ 3 ปี จึงต้องทบทวน อ้างอิงตาม BP 2016 เพื่อให้สอดคล้องกับ Neostigmine injection ซึ่งขึ้นทะเบียนตาม Monograph BP 2016 (วัตถุดิบ Neostigmine Metilsulfate BP 2016 เทียบเท่ากับ BP 2020)	30/11/20

Prepared by :	Reviewed by :		Approved by :	Eff. Date
Suwannee, 12/10/20 Head of Raw Material Standard Section 1	Luenmboonl, 12/10/20 Director of Raw Material Standard Division	, 12/10/20 Director of Drug Registration and Pharmacovigilance	Chawaporn, 14/10/20 Director of Quality Assurance Department (Acting)	30/11/20