

# THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

## RAW MATERIAL SPECIFICATION

<b>Title:</b> Neomycin Sulfate USP (Item No. 41022360)	<b>Spec. No. :</b> SP-AK30-N1
<b>Reference(s):</b> USP 41 page 2882 - 2883	<b>Rev. No. :</b> 05
<b>Other Requirements:</b> GPO Specification	<b>Page :</b> 1/2

### USP 41

Test Parameters	Requirement
Description	White to slightly yellow powder, or cryodesiccated solid; odorless or practically odorless.
Solubility	Freely soluble in water; very slightly soluble in alcohol; insoluble in acetone, in chloroform, and in ether.
Identification	A. It meets the requirements for neomycin under Thin-Layer Chromatographic Identification Test <201BNP>.
	B. A vivid pink-red color develops upon standing.
	C. A solution (1 in 20) responds to the tests for Sulfate <191>.
pH	Between 5.0 and 7.5, in a solution containing 33 mg of neomycin per mL.
Loss on drying	Not more than 8.0% of its weight.
Assay	It has a potency equivalent to not less than 600 µg of neomycin per mg, calculated on the dried basis.

### GPO Specification

Test Parameters	Requirement
Particle size	Not less than 95.0% by number is smaller than 37 micron in size.
GPO's receiving date	Upon receipt of the raw material at the GPO warehouse, the raw material must have a minimum shelf life of at least three years and six months.

Prepared by: <u>J. Roppodach / 21/01/20</u> Head of Raw Material Standard Section 2 Benjawan <u>Ubunklee / 21/01/20</u> Head of Microbiological Analysis Section 1	Reviewed by: <u>Turner / 21/01/20</u> Director of Raw Material Standard Division <u>Pong / 21/01/20</u> Director of Microbiological Analysis Division	Approved by: <u>Vichien / 21/01/20</u> Director of Quality Assurance Department (Acting)	Eff. Date 25/01/20
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### Product Information

Approved source(s)	Refer to current version of Approved Supplier List of Neomycin Sulfate USP (Item No. 41022360).
Sampling plan	For Identification : 100%. For Other Tests : n plan.
Testing procedure	Tests to be performed as per current version of WI-AK30-N1.
Storage condition	Store at a condition stated on the label from the manufacturer. Preserve in tight, light-resistant containers.
Retest period	1 year after first testing date.

### History of changes

Rev. No.	Description	Effective Date
03	Update โดยอ้างอิงตาม USP 36 และ GPO Specification	29/09/13
04	ทบทวนเอกสาร อ้างอิงตาม USP 36 และ GPO Specification	30/03/18
05	Update โดยอ้างอิงตาม USP 41 และ GPO Specification	25/01/20

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