COPY No. 3

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title: Neomycin Sulfate USP (Item No. 41022360)	**Spec. No.** : SP-AK30-N1
Reference(s): USP 41 page 2882 - 2883	**Rev. No.** : 05
Other Requirements: GPO Specification	**Page** : 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:	Reviewed by:		Approved by:	Eff. Date
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เอกสารไม่ควบคุม
ใช้ในการจัดซื้อ

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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

Prepared by:	Reviewed by:		Approved by:	Eff. Date
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