

# THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

#### RAW MATERIAL SPECIFICATION

Title: Neomycin Sulfate USP

(Item No. 41022360)

Spec. No : SP-AK30-N1

**Reference(s)**: USP 36 p.4463-4464

Rev. No : 03

Other Requirements: GPO Specification

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**USP 36** 

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. Dissolve about 10 mg in 1 mL of water, add 5 mL of 15 N sulfuric acid, and heat at 100°C for 100 minutes. Allow to cool, add 10 mL of xylene, and shake for 10 minutes. Allow to separate, and decant the xylene layer. To the xylene layer add 10 mL of p-bromoaniline TS, and shake: a vivid pink-red

color develops upon standing.

C. A solution (1 in 20) responds to the tests for Sulfate <191>.

pΗ

: 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

Particle size

: Not less than 95.0% by number is smaller than 37 micron

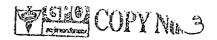
in size.

GPO's receiving date: The date that receive of raw material at the GPO warehouse

must be within 3 years and 6 months after the raw material

manufacturing date.

Prepared by:	Reviewed by :		Approved by:	Eff. Date
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#### **Product Information**

Approved source (s)	Refer to current version of Approved Vendor List of Neomycin Sulfate USP (Item No. 41022360).	
Sampling plan	$\sqrt{N}+1$ plan	
Testing procedure	Tests to be performed as per current version of WI-AK30-N1 and WI-AK61-T32.	
Storage condition	Preserve in tight, light-resistant containers.	
Retest period	1 year after first testing date.	



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