

180800007P

CERTIFICATE OF ANALYSIS

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PHARMACIA & UPJOHN COMPANY LLC
(A SUBSIDIARY OF PFIZER INC)
7000 PORTAGE RD
KALAMAZOO, MI 49001-0199 USA

Generated Date:
07-2018

Item: H001249500
Title: NEOMYCIN SULFATE MICRONIZED USP EP
Retest Date: 17-APR-2020
Expiration Date: 04-2023
Date Of Manufacture: 18-APR-2018
Specification: PCS 249500 US
LOT NUMBER: X54641

<u>TEST NAME</u>	<u>SPECIFICATION</u>	<u>UNITS</u>	<u>RESULTS</u>
NEOMYCIN BASE DRIED BASIS	>= 600	ug/mg	707
DESCRIPTION	MEETS TEST	NONE	MEETS TEST
LOSS ON DRYING	<= 8.0	%	4.0
PH	5.0 - 7.5	NONE	5.8
IDENTIFICATION A - USP	POSITIVE	NONE	POSITIVE
IDENTIFICATION B	POSITIVE	NONE	POSITIVE
IDENTIFICATION C - USP	MEETS TEST	NONE	MEETS TEST
ENDOTOXINS AVERAGE	<= 1.30	EU/mg	< 0.01
CLARITY	MEETS TEST	NONE	MEETS TEST
PATHOGENS	MEETS TEST	NONE	MEETS TEST
MICROCOUNT BACTERIA	<= 500	CFU/g	<10
MICROCOUNT FUNGI	<= 50	CFU/g	<1

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<u>TEST NAME</u>	<u>SPECIFICATION</u>	<u>UNITS</u>	<u>RESULTS</u>
PARTICLE SIZE LT 5 MICRONS	≥ 35	%	49
PARTICLE SIZE LT 10 MICRONS	≥ 75	%	92
PARTICLE SIZE LT 20 MICRONS	≥ 99	%	99
ASSAY USE VALUE	630 - 730	ug/mg	679
NEOMYCIN C - USP	3.0 - 15.0	%	7.8
NEAMINE - USP	≤ 2.0	%	< 1.0
ANY OTHER IMPURITY - USP	≤ 5.0	%	2.6
TOTAL OTHER IMPURITIES - USP	≤ 15.0	%	4.2

COMMENT:

This lot/batch was manufactured and tested according to the standard operating procedures, material specification, and batch records under cGMP's and applicable regulatory guidelines of Pharmacia & Upjohn Company LLC, 7000 Portage Road, Kalamazoo, Michigan, 49001. Telephone: 269-833-4000.

PARENT LOT*: W89495

*Parent Lot is the unique number assigned at time of manufacture. A new unique lot number is assigned each time the material is final packaged.

Electronic Signature: Steven Pitsch Lot Release Local Timestamp: 28-JUN-2018 10:49:12

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LOT NUMBER: X54641

Full

Name: Melissa Lafler

Signature: Melissa Lafler

Date: 17 JUL 2018

Questions concerning this certificate or requests for additional certificates should be directed to your local Pfizer CentreOne Sales office:

- America's region: 7000 Portage Road, Kalamazoo, Michigan, USA 49001, Tel: 269-833-5844 Fax: 269-833-3604
- Europe/Middle East/Africa Region: Hoge Wei 10, B-1930 Zaventem, Belgium, Tel: +32-2-714.63.09
- Asia/Pacific Region: 31 Tuas South Avenue 6, Singapore 637578, Tel: + 6564190240, Fax: +65 6419.0022