



METAPHARMACEUTICAL

N DE LOTE:

0050724

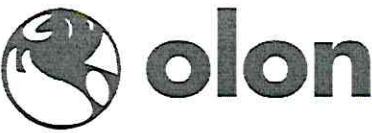
Certificate of Analysis

08/07/2024

Product name AMINOSIDINE SULFATE (PAROMOMYCIN SULFATE)
Product Code 100050
Batch Number 0024612001
Order 1241012
Quantity 11,000 KG
Manufacturing date 26/05/2024
Re-test date 26/05/2027
Certificate Nr. 100000034608
Batch Size 336,000 KG
Ref. Order 2024 -1/250

Test	References	Specification	M.U.	Result
Description	48E.01.01	White or white-yellowish fine powder		COMPLIES
Identification (max at 280 nm)	48E.02.09	Complies		COMPLIES
Identification (IR spectrum)	48E.02.10	Complies		COMPLIES
Identification (yellow-orange colour)	48E.02.13	Complies		COMPLIES
Identification (Sulfates) A	48E.02.15	Complies		COMPLIES
Identification (Sulfates) B	48E.02.15	Complies		COMPLIES
25% water solution (solution S)	48E.09.01	Clear		CLEAR
pH (of solution S)	48E.11.10	5,0 - 7,0	pH	6,4
Optical Rotation 20°C (C=5; water) calculated on the dried basis (105°C)	48E.14.02	50 - 57	°	55
Methanol (GLC)	48E.42.02	<= 4000	ppm	787
Acetone (GLC)	48E.42.02	<= 5000	ppm	4124
Related Substances (TLC) No spot greater than 5%. Only one spot greater than 1.5%	48E.45.01	Complies		COMPLIES
Loss on drying at 105°C for 15 hours	48E.50.12	<= 5,0	%	3,1
Sulphated ash	48E.53.01	<= 1,0	%	0,4
Sulphates	48E.47.02	23,5 - 27,5	%	23,5
Aminosidine A calculated as base (HPLC)	48E.41.01	50 - 75	%	66
Aminosidine B calculated as base (HPLC)	48E.41.01	<= 15	%	3
5N-acetylaminoisidine A%	48E.41.01	<= 2,0	%	1,3
Impurity RRT about 0.7	48E.41.01	<= 1,0	%	0,3
Max single unknow impurity	48E.41.01	<= 0,5	%	0,1
Total Related Substances	48E.41.01	<= 5,0	%	1,8
Potency on the dried basis (105°C)	48E.114.01	>= 660	UI/mg	797
Total Aerobic Microbial Count (TAMC)	48E.106.02	<= 1000	CFU/g	10
Total Yeast & Mould Count (TYMC)	48E.109.02	<= 100	CFU/g	0

Andrea Gascone QC Manager Approved June 24, 2024	Antonella Pivetta Qualified Person Released June 25, 2024		
'Emission'	Antonella Pivetta	Qualified Person	July 01, 2024



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I, Qualified Person of OLON S.p.a. Settimo Torinese plant, hereby certify that this batch has been manufactured, packed and tested under applicable regulations and GMP conditions, using current manufacturing and test instructions. The documentation of manufacturing, packaging and testing is complete and has been reviewed and approved. During the course of manufacturing, packaging and testing there were no significant deviations or in case of deviations, they were properly notified, reviewed and approved in accordance with the relevant customer's quality agreement, prior to the release.

Specification N° 48E-S1
Meets the requirements of FU (Italian Pharmacopoeia)

MANUFACTURING SITE:
OLON SPA - SETTIMO TORINESE PLANT
VIA SCHIAPPARELLI 2
WITH ENTRANCE FROM VIA SOLFERINO 2
10036 SETTIMO TORINESE (TO)
ITALY
PHONE NUMBER: +39.011.8966.1

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