



Certificate of Analysis

Product name **PAROMOMYCIN SULFATE**

Product Code 100050
Batch Number 22049IS48E
Batch Size 409,000 KG

Manufacturing date 26/09/2022
Re-test date 25/09/2025
Certificate Nr. 890000012576

<u>Test</u>	<u>References</u>	<u>Specification</u>	<u>M.U.</u>	<u>Result</u>
Description	48E.01.01	White or almost white fine powder		COMPLIES
Identification (TLC)	48E.02.12	Complies		COMPLIES
Identification (Sulfates)	48E.02.15	Complies		COMPLIES
25% water solution	48E.09.01	Clear		CLEAR
Optical Rotation 25°C (C=5; water) calculated on the dried basis (60°C)	48E.14.03	50 - 55	°	52
pH (3% in water)	48E.11.11	5,0 - 7,5	pH	6,1
Loss on drying at 60°C for 3 hours under vacuum	48E.50.07	<= 5,0	%	2,6
Sulphated ash	48E.53.01	<= 1,0	%	0,3
Potency on the dried basis (60°C)	48E.114.01	>= 675	µg/mg	729
Paromomycin A calculated as base (HPLC)	48E.41.01	50 - 75	%	71
Paromomycin B calculated as base (HPLC)	48E.41.01	<= 15	%	3
Total related substances (A% HPLC)	48E.41.01	<= 5,0	%	2,7
5N-acetylaminosidine A%	48E.41.01	<= 2,0	%	1,7
Impurity RRT about 0.7	48E.41.01	<= 1,0	%	0,9
Max single unknown impurity	48E.41.01	<= 0,5	%	0,1
Methanol (GLC)	48E.42.02	<= 4000	ppm	1751
Acetone (GLC)	48E.42.02	<= 5000	ppm	491
Sieve 40 Mesh	48E.63.03	>= 85,0	%	99,6
Sieve 60 Mesh	48E.63.06	>= 70,0	%	93,2
Bulk Density	48E.61.01	0,450 - 0,650	g/ml	0,582

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,

Tiziana Turchet QC Manager Approved January 17, 2023	Davide Rosso Qualified Person Approved January 17, 2023
--	---



Certificate of Analysis

Product name **PAROMOMYCIN SULFATE**

Product Code 100050
Batch Number 22049IS48E
Batch Size 409,000 KG

Manufacturing date 26/09/2022
Re-test date 25/09/2025
Certificate Nr. 890000012576

<u>Test</u>	<u>References</u>	<u>Specification</u>	<u>M.U.</u>	<u>Result</u>
-------------	-------------------	----------------------	-------------	---------------

they were properly notified, reviewed and approved in accordance with the relevant customer's quality agreement, prior to the release.

Specification N° 48E-S2
Meets the requirements of USP

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

Tiziana Turchet QC Manager Approved January 17, 2023	Davide Rosso Qualified Person Approved January 17, 2023
--	---