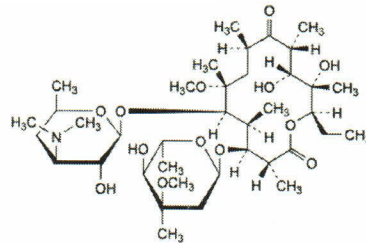




Batch no 260306-9
Mfg date Mar 06 2026
Retest Mar 05 2029

Molecular Structure



Molecular Formula $C_{38}H_{69}NO_{13}$
Molecular Weight 747.95
CAS Registry Number 81103-11-9

May 07 2026

Tests	Specifications	Results
Appearance	White to off-white crystalline powder	Conforms
Identification	IR, HPLC	Positive
Specific optical rotation	-94 ~ -102°	-97.9°
pH	8.0 ~ 10.0	8.8
Crystallinity	Meets the requirements	Conforms
Water	≤ 2.0%	0.32%
Residue on ignition	≤ 0.2%	0.01%
Related substances (HPLC)	Impurity I ≤ 1.0% Impurity A ≤ 1.0% Impurity J ≤ 1.0% Impurity L ≤ 1.0% Impurity B ≤ 1.0% Impurity M ≤ 1.0% Impurity C ≤ 1.0% Impurity D ≤ 1.0% Impurity N ≤ 1.0% Impurity E ≤ 1.0% (Clarithromycin related compound A USP) Impurity F ≤ 1.0% Impurity P ≤ 1.0% Impurity O ≤ 1.0% Impurity K ≤ 1.0% Impurity G ≤ 1.0% Impurity H ≤ 1.0% Any other impurities ≤ 0.1% Impurities exceed 0.4% ≤ 4 Total impurities ≤ 3.5%	ND 0.31% ND < 0.1% 0.1% ND 0.1% 0.21% ND 0.36% 0.2% < 0.1% ND ND < 0.1% < 0.1% < 0.1% 0 1.2%
Residual solvents	Ethanol ≤ 5000 ppm	ND
Assay (oab) HPLC	96.0 ~ 102.0%	98.8%

Packaging and storage	Preserve in tight containers
Conclusion	Material complies with USP43