

Erythromycin EP10.7

Batch no

231101-2

Mf date

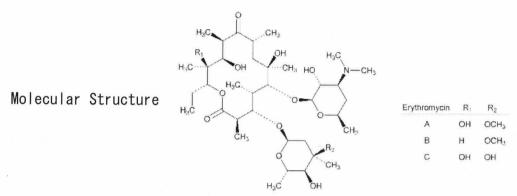
Nov 03 2023

Retest

Nov 02 2027

Batch size

895.6 kg



Molecular Formula $C_{17}H_{67}NO_{13}$ Molecular Weight 733.93 CAS Registry Number 114-07-8

Feb 21 2024

<u>Tests</u>	<u>Specifications</u>	Results
Appearance Identification	White or off-white crystalline powder IR	Conforms Positive
Specific rotation Related substances	-71.0 ~ -78.0° Impurity A ≤ 2.0% Impurity B ≤ 2.0%	-74. 0° 0. 6% 0. 33%
	Impurity C $\leq 3.0\%$ Impurity D $\leq 1.0\%$	0. 86% 0. 22%
	Impurity E \leq 1.0% Impurity F \leq 1.0%	0. 02% 0. 001%
*	Impurity H $\leq 1.0\%$ Impurity L $\leq 0.4\%$	0. 01% 0. 008%
Thiocyanate	Any other impurity ≤ 0.4% Total impurities ≤ 7.0% ≤ 0.3%	0. 14% 2. 4% 0. 03%
Water Sulfated ash	≤ 6.5% ≤ 0.2%	0. 5% 0. 03%
Residual solvents Assay (oab)	Methylene chloride ≤ 600 ppm Erythromycin B ≤ 5.0%	ND 0. 33%
	Erythromycin C ≤ 5.0% Erythromycin (A+B+C) 93.0 ~ 102.0%	0. 86% 97. 3%

Packing & storage	Preserve in tight	containers and store	in a dry place.
Conclusion	Material complies	with EP10.7	

