

CERTIFICATE OF ANALYSIS

COA NUMBER: COA/0182/21	DATE PREPARED: 29/09/2021
PRODUCT NAME: ERYTHROMYCIN BASE	
BATCH/LOT NUMBER: EBS/21-030	MANUFACTURING DATE: SEP 2021
RETEST DATE: AUG 2024	BATCH SIZE: 253.06 KG

TESTS	SPECIFICATIONS	RESULTS
Appearance	White or slightly yellow powder or colorless or slightly yellow crystals, slightly hygroscopic	White powder
Solubility	Slightly soluble in : Water Freely soluble in : Ethanol (96%) Soluble in : Methanol	Slightly soluble Freely soluble Soluble
Identification A - IR	Sample spectra confirms to that of Standard spectra	Complies
Identification B - TLC	Principal spot due to test solution is similar in position, color and size to the principal spot obtained with reference solution (a), and its position and color are different from those of the spots obtained with reference solution (b)	Complies
Related Substances by HPLC	Specified Impurities Impurity A : NMT 2.0% Impurity B : NMT 2.0% Impurity C : NMT 3.0% Impurity D : NMT 1.0% Impurity E : NMT 1.0% Impurity F : NMT 1.0% Impurity H : NMT 1.0% Impurity L : NMT 0.4% Unspecified Impurities Any other impurity : NMT 0.4% Total Impurities : NMT 7.0% Reporting Threshold : 0.2%	0.54% 0.69% 1.06% BRT BRT ND BRT BRT 0.20% 2.49%

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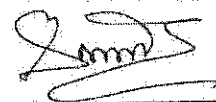
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CERTIFICATE OF ANALYSIS

COA NUMBER: COA/0182/21	DATE PREPARED: 29/09/2021
PRODUCT NAME: ERYTHROMYCIN BASE	
BATCH/LOT NUMBER: EBS/21-030	MANUFACTURING DATE: SEP 2021
RETEST DATE: AUG 2024	BATCH SIZE: 253.06 KG

TESTS	SPECIFICATIONS	RESULTS
	Disregard peaks due to Erythromycin B and Erythromycin C	
Thiocyanate content	NMT 0.3%	0.02%
Water content	NMT 6.5%	1.65%
Sulfated Ash	NMT 0.2%	0.03%
Assay by HPLC	Sum of Erythromycin A, B and C: NLT 93.0% and NMT 102.0%	97.2%
	Erythromycin B : NMT 5.0%	0.1%
	Erythromycin C : NMT 5.0%	0.1%
	(On anhydrous substance basis)	
Residual Solvents by GC	Dichloromethane : NMT 600 ppm	BQL
AR No : FP/2109/0120 Previous COA No.: NA	PREPARED BY: 	29/09/2021
	CHECKED BY: 	29/09/2021
	APPROVED BY: 	29/09/2021
	APPROVED BY: 	29/09/2021

Recommended Storage condition: Store in well closed (air-tight) container and temperature should not exceed 30°C.

Recommended Packaging condition: Packed in a double polyethylene bags and tightly closed with cable tie. The polyethylene bags are further packed in suitable size and tightly closed in HDPE/ Corrugated box and labeled.

Legend:

BRT: Below Reporting Threshold

ND: Not Detected

BQL: Below Quantification Limit

STP No.: FPS/EBS/001, Ver. No. 05

Remarks: The product complies with EP specifications.

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