

Erythromycin

CODE ARTICLE: 92663	BATCH: 0120976	Active pharmaceutical ingredient
TEST DATE: 25/07/2023	TEST: QC-00255616	
EXPIRY DATE: 30/04/2026	FABRICATION DATE: 01/05/2023	MR: 733,90
CAS: [114-07-8]	FORMULA: C37H67NO13	
SYNONYMS / BOTANICAL NAME: Ermicina; Eritromicina A; Eritromicina base		
STORAGE: Store in tightly closed containers in a cool, dry place.		

TEST	RESULTS	Units	MIN	MAX	METHOD
APPEARANCE	CONFORM	-		POLVO / CRISTAL	PH.EUR.*
COLOUR	CONFORM	-		BLANCO / AMARILLENTO	PH.EUR.*
<u>SOLUBILITY</u>					
SOLUBLE		METHANOL			PH.EUR.*
SOLUBLE		FREELY SOLUBLE IN ETHANOL			PH.EUR.*
SOLUBLE		SLIGHTLY SOLUBLE IN WATER			PH.EUR.*
<u>IDENTIFICATION</u>					
IR IDENTIFICATION	CONFORM				PH.EUR.*
THIOCYANATE	0,03 %			0,3	PH.EUR.*
<u>RELATED SUBSTANCES (HPLC)</u>					
TOTAL IMPURITIES	3 %		0,0	7	PH.EUR.*
OTHER IMPURITIES	<RT=0,2 %			0,4	PH.EUR.*
IMPURITY A	0,4 %		0,0	2	PH.EUR.*
IMPURITY B	1,4 %		0,0	2	PH.EUR.*
IMPURITY C	0,8 %		0,0	3	PH.EUR.*
IMPURITY D	0,4 %		0,0	1	PH.EUR.*
IMPURITY E	<RT=0,2 %			1,0	PH.EUR.*
IMPURITY F	<RT=0,2 %			1	PH.EUR.*
IMPURITY H	<RT=0,2 %			1,0	PH.EUR.*
IMPURITY L	<RT=0,2 %			1,0	PH.EUR.*
WATER	1,6 %		0,0	6,5	PH.EUR.*
SULPHATED ASH	0,02 %		0,0	0,2	PH.EUR.*
ASSAY (HPLC, SUM.A+B+C)	101,9 %		93	102	PH.EUR.*
ERYTHROMYCIN B	N.D. %			5,0	PH.EUR.*
ERYTHROMYCIN C	4,5 %		0,0	5	PH.EUR.*
<u>RESIDUAL SOLVENTS</u>					
METHYLENE CHLORIDE	23,36 ppm			600	Manufacture's Standard
PARTICLE SIZE 99%	<14,50 MICRONS			<20	Manufacture's Standard
SAMPLING	COLLECT				Manufacture's Standard
CORRECT BATCH	YES				Manufacture's Standard
SPECIFICATION	PH.EUR 11				Manufacture's Standard
Elemental Impurities ICHQ3D	CONFORM				
Risk Assessment Evaluation for Nitrosamines	CONFORM				
<i>This product has been handled in a non-sterile room. for batches suitable for sterile use, consult availability.</i>					

The data expressed in this certificate of analysis is facilitated by our supplier and/or obtained in our control laboratory, in no case being exempted of the controls demanded by each sector. Tests marked with (*) are verified in Guinama.

Manufacturer: 46517 A. PHARMA LTD. (India) Manufacturer Batch: CEPEB 019 E 23 P Manufacturer original CoA available under request

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Este producto ha sido manipulado en sala NO estéril, para lotes aptos uso estéril consultar disponibilidad.

Silvia Sancho-Tello Ripoll
Technical Director.

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