

Erythromycin

CODE ARTICLE: 92663	BATCH: 0129714	Active pharmaceutical ingredient
TEST DATE: 31/07/2024	TEST: QC-00266965	
EXPIRY DATE: 30/11/2027	FABRICATION DATE: 01/05/2024	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	PASS	-		POLVO / CRISTAL	PH.EUR.*
COLOUR	PASS	-		BLANCO / AMARILLENTO	PH.EUR.*
SOLUBILITY					
SOLUBLE		METHANOL			PH.EUR.*
SOLUBLE		FACILMENTE SOLUBLE EN ETANOL 96			PH.EUR.*
SOLUBLE		SLIGHTLY SOLUBLE IN WATER			PH.EUR.*
IDENTIFICATION					
IR IDENTIFICATION	PASS				PH.EUR.*
THIOCYANATE	0,03 %			0,3	PH.EUR.*
RELATED SUBSTANCES (HPLC)					
TOTAL IMPURITIES	2,4 %		0,0	7	PH.EUR.*
OTHER IMPURITIES	<LQ=0,2 %			0,4	PH.EUR.*
IMPURITY A	0,5 %		0,0	2	PH.EUR.*
IMPURITY B	1,3 %		0,0	2	PH.EUR.*
IMPURITY C	0,7 %		0,0	3	PH.EUR.*
IMPURITY D	<LQ=0,2 %			1,0	PH.EUR.
IMPURITY E	<LQ=0,2 %			1,0	PH.EUR.*
IMPURITY F	<LQ=0,2 %			1,0	PH.EUR.*
IMPURITY H	<LQ=0,2 %			1,0	PH.EUR.*
IMPURITY L	<LQ=0,2 %			1,0	PH.EUR.*
WATER	1,7 %		0,0	6,5	PH.EUR.*
SULPHATED ASH	0,04 %		0,0	0,2	PH.EUR.*
ASSAY (HPLC, SUM.A+B+C)	101,1 %		93	102	PH.EUR.*
ERYTHROMYCIN B	2,4 %			5,0	PH.EUR.*
ERYTHROMYCIN C	3,9 %		0,0	5	PH.EUR.*
RESIDUAL SOLVENTS					
METHYLENE CHLORIDE	18,3 ppm			600	Manufacture's Standard
PARTICLE SIZE 99%	99,53 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	PASS				
Risk Assessment Evaluation for Nitrosamines	PASS				
NON-sterile					

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 003 E 24 P Manufacturer original CoA available under request

GUINAMA S.L. Calle Oslo, 3 46185 La Pobla de Vallbona (Valencia) Spain

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TEST	RESULTS	Units	MIN	MAX	METHOD
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The product has been handled in NON-sterile rooms, therefore this product IS NOT STERILE

Silvia Sancho-Tello Ripoll
Technical Director.

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