METAPHARMACEUTICAL IND SL
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ERITROMICINA BASE (EUR. PH.)

PRODUCT CODE: 0540	CAS Nº: 114-07-8	ANALYSIS Nº: 036/21	
MANUFACTURER BATCH:	BM 574	CERTIFICATE ID:	30.975
SUPPLIER BATCH:	----	MANUFACTURING DATE:	26/08/2020
METAPH BATCH:	0130221	RETEST DATE:	26/08/2025

ATTRIBUTES	SHOULD BE	IS
Appearance	White or slightly yellow powder ot colourless or slightly yellow crystals, slightly hygroscopic	White powder slightly hygroscopic
Solubility	Slightly soluble in water (the solubility decreases as the temperature rises), freely soluble in ethanol (96 %), soluble in methanol	Complies (*)
Identification A	Complies	Complies
Related substances		
Impurity C	=< 3.0 %	< 0.20 %
Impurity A	=< 2.0 %	< 0.20 %
Impurity B	=< 2.0 %	< 0.20 %
Impurity D	=< 1.0 %	< 0.20 %
Impurity E	=< 1.0 %	Not Detected
Impurity F	=< 1.0 %	< 0.20 %
Impurity H	=< 1.0 %	0.35 %
Impurity M	=< 1.0 %	< 0.20 %
Impurity L	=< 0.4 %	< 0.20 %
Any other impurity	=< 0.4 %	< 0.20 %
Total of impurities	=< 7.0 %	0.35 %
Thiocyanate	=< 0.3 %	0.007 %
Water	=< 6.5 %	1.8 %
Sulfated ash	=< 0.2 %	< 0.01 %
Assay		
Erythomycin A+B+C	93.0 - 102.0 %	95.0 %
Erythromycin B	=< 5.0 %	0.41 %
Erythromycin C	=< 5.0 %	1.7 %
Residual solvents [In-house]		(*) (**)
Acetone	=< 300 ppm	30 ppm
Methylene chloride	=< 600 ppm	90 ppm
Xylene	=< 2170 ppm	463 ppm
Particle size		(*)
D10	< 15 µm	5.2 µm
D50	< 40 µm	22.9 µm
D90	< 80 µm	56.9 µm

COMPLIES WITH

European Pharmacopoeia 10.0

REMARKS

Erythromycin is subjected to the requirements of the ICH Q3D "Elemental Impurities".

Absence of N-nitrosamines impurities has been ensured after a risk evaluation according to ICH Q9, ICH M7 and in accordance with guidelines EMA/428592/2019 Rev 2 and EMA/189634/2019.

Analysis date: 29/03/2021
Signature: Ferran Gonzalez de Rivera Rier
Conclusion: Complies
Original certificate available upon request

Manufacturer: 40000704
ERCROS INDUSTRIAL S.A.
Paseo del Deleite s/n.
28300 ARANJUEZ
MADRID(España)

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(*) Data adapted from the certificate of analysis of the manufacturer.
(**) According to the requirements of guides EMA/CHMP/ICH/82260/2006.

Certificates of residual solvents, allergens, non-GMO and BSE-TSE, among others, are available upon request.

All methods of analysis are validated by official pharmacopoeias or are validated by internal methods of the manufacturer, which can be obtained at specific request. The above information does not exempt from the obligation to identify the product before use.

STORAGE

Keep the container tightly closed in a cool, dry place and protected from light.

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