



ERITROMICINA BASE (EUR. PH.)

PRODUCT CODE: 0540	CAS Nº: 114-07-8	ANALYSIS Nº: 005/24
MANUFACTURER BATCH: BM586	CERTIFICATE ID: 40.712	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 03/04/2023	
METAPH BATCH: 0060124	RETEST DATE: 03/04/2028	

ATTRIBUTES	SHOULD BE	IS
Appearance	White or slightly yellow powder or 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 %	0.5 %
Impurity A	=< 2.0 %	0.1 %
Impurity B	=< 2.0 %	0.1 %
Impurity D	=< 1.0 %	0.1 %
Impurity E	=< 1.0 %	< 0.05 %
Impurity F	=< 1.0 %	< 0.05 %
Impurity H	=< 1.0 %	< 0.05 %
Impurity L	=< 0.4 %	0.1 %
Any other impurity	=< 0.4 %	< 0.4 % (#)
Total of impurities	=< 7.0 %	2.0 %
Thiocyanate	=< 0.3 %	0.1 %
Water	=< 6.5 %	1.5 %
Sulfated ash	=< 0.2 %	0.04 %
Assay		
Erythromycin A+B+C	93.0 - 102.0 %	100.4 %
Erythromycin B	=< 5.0 %	1.1 %
Erythromycin C	=< 5.0 %	2.1 %

COMPLIES WITH

European Pharmacopoeia 11.0

REMARKS

(#) Impurities detailed underneath:

RT (20.30 min) = 0.4 %

RT (22.67 min) = 0.3 %

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

(*) Data adapted from the manufacturer's certificate of analysis.

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.

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.

Analysis date: 15/03/2024

Signature: Albert Sánchez López (QP)

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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STORAGE

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

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