METAPHARMACEUTICAL

TECHNICAL DATA SHEET

0540-TDS-ENG-2026

ERITROMICINA BASE (EUR. PH.)		
DESCRIPTION DCI: erythromycin	DESCRIPTION DOE: ERITROMICINA	
CAS Nº: 114-07-8	EC Nº: 620-534-3	AEMPS CODE: 1419A
MOL. WEIGHT: 733,94	MOL. FORMULA: C37H67NO13	ARTICLE CODE: 0540

ATTRIBUTES	SHOULD BE
Appearance	White or slightly yellow powder or colourless or slightly yellow crystals, slightly hygroscopic
Solubility	Slightly soluble in water (the solubility decreases as the temperature rises), freely soluble in ethanol (96 %), soluble in methanol
Identification A	Complies
Related substances	
Impurity C	=< 3.0 %
Impurity A	=< 2.0 %
Impurity B	=< 2.0 %
Impurity D	=< 1.0 %
Impurity E	=< 1.0 %
Impurity F	=< 1.0 %
Impurity H	=< 1.0 %
Impurity L	=< 0.4 %
Any other impurity	=< 0.4 %
Total of impurities	=< 7.0 %
Thiocyanate	=< 0.3 %
Water	=< 6.5 %
Sulfated ash	=< 0.2 %
Assay	
Erythomycin A+B+C	93.0 - 102.0 %
Erythromycin B	=< 5.0 %
Erythromycin C	=< 5.0 %

COMPLIES WITH

European Pharmacopoeia 12.2

STORAGE

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

REMARKS

It shows polymorphism.

Erythromycin is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006 - ICH Q3C (R6) "Residual solvents".

Absence of N-nitrosamines impurities has been ensured after a risk evaluation according to ICH Q9, ICH M7 and in

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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.

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