



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 230001

Product:	ERYTHROMYCIN
Lot:	230001
Expiry date:	10/08/2027
Reference:	Cumple PhEur11.0
Synonyms:	
Formula:	C37H67NO13
Molecular weight:	733,95 g/mol

Assay	Result	Specification	
Identification	Conform (A)	Test PhEur (A)	
Organoleptic properties	Conform	PhEur	
Related substances (HPLC)	Conform	Test PhEur	
Thiocyanate	0,03 %	<= 0,3 %	=
Water	1,1 %	<= 6,5 %	
Sulphated ashes	0,13 %	<= 0,2 %	=
Purity (A+B+C) (HPLC)	94,6 % sps	93,0 - 102,0 % sps	
Erythromycin B	0,4 % sps	<= 5,0 % sps	
Erythromycin C	1,5 % sps	<= 5,0 % sps	
Elemental impurities	Conform	Test PhEur	#
Nitrosamine impurities	Conform	Test PhEur	#
Impurity A	< 0,20 %	<= 2,0 %	
Impurity B	0,8 %	<= 2,0 %	
Impurity C	2,0 %	<= 3,0 %	
Impurity D	0,5 %	<= 1,0 %	
Impurity E	< 0,20 %	<= 1,0 %	
Impurity F	< 0,20 %	<= 1,0 %	
Impurity H	0,3 %	<= 1,0 %	
Impurity L	< 0,20 %	<= 0,4 %	
Any other impurity	0,3 %	<= 0,4 %	
Total impurities	4,1 %	<= 7,0 %	
Residual solvent: acetone	< 5000 ppm	<= 5000 ppm	#
Residual solvent: methylene chloride	< 600 ppm	<= 600 ppm	#
Residual solvent: xylene	< 2170 ppm	<= 2170 ppm	#

Organoleptic characteristics: White or slightly yellow powder or colourless or slightly yellow crystals, slightly hygroscopic. Slightly soluble in water, freely soluble in ethanol (96 per cent), soluble in methanol.

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 26/01/2023

Judgement:
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F01003 ERCROS, S.A.

Manufacturer batch: BM583

Product	Name	Capacity	Batch
1128693	ERITROMICINA	5 g	230001-E-2
1128693	ERITROMICINA	5 g	230001-E-3
1128693	ERITROMICINA	5 g	230001-E-4
1128693	ERITROMICINA	5 g	230001-E-6
1128694	ERITROMICINA	10 g	230001-F-2
1128694	ERITROMICINA	10 g	230001-F-4
1128695	ERITROMICINA	25 g	230001-G-1
1128695	ERITROMICINA	25 g	230001-G-2
1128695	ERITROMICINA	25 g	230001-G-3
1128695	ERITROMICINA	25 g	230001-G-4
1128696	ERITROMICINA (INACTIVO)	5 kg	230001-Q-2
1128697	ERITROMICINA	100 g	230001-J-2
1128697	ERITROMICINA	100 g	230001-J-4
1128698	ERITROMICINA	250 g	230001-N-2
1128698	ERITROMICINA	250 g	230001-N-3
1128698	ERITROMICINA	250 g	230001-N-4
1128698	ERITROMICINA	250 g	230001-N-6
1200153	ERITROMICINA	1 kg	230001-P-1
1200153	ERITROMICINA	1 kg	230001-P-2
1200153	ERITROMICINA	1 kg	230001-P-3
1370056	ERITROMICINA (FLB)	5 g	230001-E-1
1370056	ERITROMICINA (FLB)	5 g	230001-E-5
1370057	ERITROMICINA (FLB)	10 g	230001-F-1
1370057	ERITROMICINA (FLB)	10 g	230001-F-3
1370059	ERITROMICINA (FLB) (INACTIVO)	100 g	230001-J-1
1370059	ERITROMICINA (FLB) (INACTIVO)	100 g	230001-J-3
1370060	ERITROMICINA (FLB)	250 g	230001-N-1
1370060	ERITROMICINA (FLB)	250 g	230001-N-5

This certificate is not initialled as it is computer processed, it is validated with the originals available at Acofarma.

Original manufacturer's certificate available on request.

(#) Parameter controlled by the manufacturer

(=) UE certificate

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Date of edition: 20/04/2026

