



CONTROL DE CALIDAD - QUALITY CONTROL
CERTIFICADO DE ANALISIS - CERTIFICATE OF ANALYSIS

División
Farmacia

PRODUCTO PRODUCT		ERYTHROMYCIN		FECHA DE FABRICACION MANUFACTURING DATE		03-04-2023					
LOTE BATCH		BM 586		PESO DE LOTE BATCH WEIGHT		500 Kg		FECHA DE REANALISIS RETEST DATE		03-04-2028	
ESPECIFICACION SPECIFICATION				EP 11.0 / USP-NF 2022				FECHA DE CONTROL TEST DATE		20-04-2023	

DETERMINACION / DETERMINATION	ESPECIFICACION / SPECIFICATION	RESULTADOS / RESULTS
DESCRIPTION	WHITE OR SLIGHTLY YELLOW POWDER OR COLOURLESS OR SLIGHTLY YELLOW CRYSTALS, SLIGHTLY HYGROSCOPIC	CONFORMS
IDENTIFICATION IR IDENTIFICATION HPLC	POSITIVE POSITIVE	POSITIVE POSITIVE
SOLUBILITY	SLIGHTLY SOLUBLE IN WATER, FREELY SOLUBLE IN ETHANOL 96% SOLUBLE IN METHANOL	CONFORMS
CRYSTALLINITY	CONFORMS	CONFORMS
LIMIT OF THIOCYANATE	NMT. 0.3 %	0.02 %
OPTICAL ROTATION	-78° - -71°	-75.2°
WATER	NMT. 6.5 %	0.76 %
SULPHATED ASH	NMT. 0.2 %	0.04 %
RESIDUAL SOLVENTS ACETONE METHYLENE CHLORIDE XYLENE	NMT. 300 ppm NMT. 600 ppm NMT. 2170 ppm	121 ppm. N.D. ppm. 170 ppm.
PARTICLE SIZE (MALVERN)	d10. UNDER 15 µm d50 UNDER 40 µm d90 UNDER 80 µm	9.1 µm 21.9 µm 53.2 µm

OBSERVACIONES
OBSERVATIONS

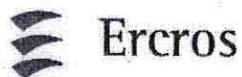
METAPHARMACEUTICAL

N DE LOTE:

0060124

INFORME DE CONTROL
CONTROL REPORT

V.º B.º RESPONSABLE DE CONTROL CALIDAD
QUALITY CONTROL RESPONSIBLE



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DETERMINACION / DETERMINATION	ESPECIFICACION / SPECIFICATION	RESULTADOS / RESULTS
RELATED SUBSTANCES HPLC		
ERYTHROMYCIN F (Imp.A)	NMT. 2.0 %	<LQ %
N-DEMETHYL ERYT.A (Imp.B)	NMT. 2.0 %	0.56 %
ERYTHROMYCIN E (Imp.C)	NMT. 3.0 %	2.2 %
ANHYDRO ERYT. A (Imp.D)	NMT. 1.0 %	N.D. %
ERY. A ENOL ETHER (Imp.E)	NMT. 1.0 %	0.04 %
PSEUDO A ENOL ET. (Imp.F)	NMT. 1.0 %	N.D. %
N-OXYDE ERYT. A (Imp.H)	NMT. 1.0 %	N.D. %
N-FORMYL ERYTH. A (Imp.L)	NMT. 0.4 %	0.07 %
UNKNOWN IMPURITY	NMT. 0.2 %	<LQ %
ANY OTH. IMP. (I, J, K, N, M)	NMT. 0.4 %	N.D. %
TOTAL IMPURITIES	NMT. 7.0 %	2.9 %
ASSAY (A+B+C) a.b.HPLC	93.0 - 102.0 %	96.8 %
ERYTHROMYCIN B (a.b.)	NMT. 5.0 %	0.49 %
ERYTHROMYCIN C (a.b.)	NMT. 5.0 %	1.2 %
MICROBIOLOGICAL CONTAMIN.		
TYMC	NMT 100 Cfú/g	30 Cfú/g
TAMC	NMT 1000 Cfú/g	<1000 Cfú/g
CONFORME 20 ABR 2023		Ercros, S.A. Div. Farmacia

OBSERVACIONES
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