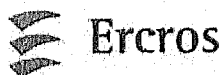


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CONTROL DE CALIDAD - QUALITY CONTROL
CERTIFICADO DE ANALISIS - CERTIFICATE OF ANALYSIS

División
Farmacia

PRODUCTO PRODUCT ERYTHROMYCIN ✓		FECHA DE FABRICACION MANUFACTURING DATE 03-08-2016
LOTE BATCH BM 556 ✓	PESO DE LOTE 1000 Kg BATCH WEIGHT	FECHA DE REANALISIS RETEST DATE 03-08-2021 ✓
ESPECIFICACION SPECIFICATION EP 8.0		FECHA DE CONTROL TEST DATE 08-08-2016

DETERMINACION / DETERMINATION	ESPECIFICACION / SPECIFICATION	RESULTADOS / RESULTS
DESCRIPTION	(Pag. 1/2) WHITE OR SLIGHTLY YELLOW POWDER OR COLOURLESS OR SLIGHTLY YELLOW CRYSTALS, SLIGHTLY HYGROSCOPIC	CONFORMS Kg
IDENTIFICATION (IR)	POSITIVE	POSITIVE
SOLUBILITY	SLIGHTLY SOLUB. IN WATER, FREELY SOLUB. IN ETHANOL 96% SOLUBLE IN METHANOL	CONFORMS
CRYSTALLINITY	CONFORMS	CONFORMS
OPTICAL ROTATION (A.B.)	-78° - -71°	-77.1 °
WATER	NMT. 6.5 %	1.4 %
LIMIT OF THIOCYANATE	NMT. 0.3 %	0.01 %
SULPHATED ASH	NMT. 0.2 %	0.04 %
RESIDUAL SOLVENTS		
ACETONE	NMT. 300 ppm	N.D. ppm.
METHYLENE CHLORIDE	NMT 600 ppm.	333 ppm.
XILENE	NMT 2170 ppm.	164 ppm.
ASSAY HPLC (a.b.)	93.0 - 102.0 %	99.0 %
CONFORME 08 AGO 2016		Ercros, S.A. Div. Farmacia

ERITROMICINA GRANUL

01-09-2016 94113



Lote: 0060052

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OBSERVACIONES
OBSERVATIONS

INFORME DE CONTROL
CONTROL REPORT

V.º B.º JEFE DE CONTROL CALIDAD
QUALITY CONTROL MANAGER

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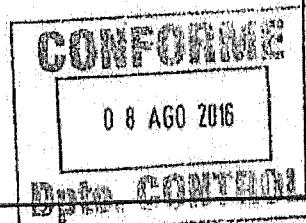


CONTROL DE CALIDAD - QUALITY CONTROL
CERTIFICADO DE ANALISIS - CERTIFICATE OF ANALYSIS

División
Farmacia

PRODUCTO / PRODUCT ERYTHROMYCIN		FECHA DE FABRICACION / MANUFACTURING DATE 03-08-2016
LOTE / BATCH BM 556	PESO DE LOTE / BATCH WEIGHT 1000 Kg	FECHA DE REANALISIS / RETEST DATE 03-08-2021
ESPECIFICACION / SPECIFICATION EP 8.0		FECHA DE CONTROL / TEST DATE 08-08-2016

DETERMINACION / DETERMINATION	ESPECIFICACION / SPECIFICATION	RESULTADOS / RESULTS
(Pag. 2/2)		
RELATED SUSTANC. (HPLC)		
ERYTHROMYCIN F	NMT. 3.0 %	0.63 %
3-N-DESMETHYLERYTHROMYC. A	NMT. 3.0 %	0.58 %
ERYTHROMYCIN E	NMT. 3.0 %	1.2 %
ANHYDROERYTHROMYCIN A	NMT. 3.0 %	0.30 %
ERYTHROMYCIN A ENOL ETHER	NMT. 3.0 %	0.03 %
PSEUDOERYTHR. A ENOL ETHER	NMT. 3.0 %	0.01 %
ERYTHROMYCIN A 3-N-OXIDE	NMT. 1.0 %	0.06 %
ERYTHROMYCIN G	NMT. 0.4 %	0.08 %
IMP. RRT 0.45min	MAX. 0.3 %	N.D. %
IMP. RRT 0.62min	MAX. 0.3 %	0.10 %
UNSPECIFIED IMPURITIES	MAX. 0.1 %	0.10 %
TOTAL SUM OF IMPURITIES	NMT. 7.0 %	3.1 %
ERYTHROMYCIN B	NMT. 5.0 %	0.41 %
ERYTHROMYCIN C	NMT. 5.0 %	0.69 %
DISTRIB. PARTICLE SIZE		
METHOD LASER (LS13320)	d10 MAX. 15 µm	1.1 µm
BECKMAN COULTER	d50 MAX. 40 µm	10.0 µm
(Dry Powder System)	d90 MAX. 80 µm	23.9 µm



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