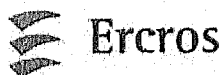


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CONTROL DE CALIDAD - QUALITY CONTROL
CERTIFICADO DE ANALISIS - CERTIFICATE OF ANALYSIS

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 ERITROMICINA GRANUL
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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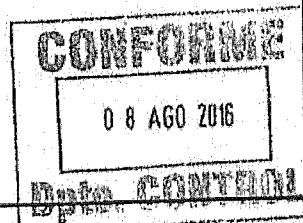


CONTROL DE CALIDAD - QUALITY CONTROL
CERTIFICADO DE ANALISIS - CERTIFICATE OF ANALYSIS

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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