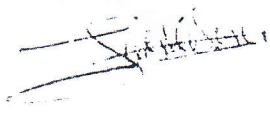


**Ercros****CONTROL DE CALIDAD - QUALITY CONTROL**
CERTIFICADO DE ANALISIS - CERTIFICATE OF ANALYSISDivisión
Farmacia

PRODUCTO / PRODUCT SODIUM FUSIDATE		FECHA DE FABRICACIÓN / MANUFACTURING DATE 22-02-2015	
LOTE / BATCH FST 539	PESO DE LOTE / BATCH WEIGHT 289 Kg	FECHA DE REANÁLISIS / RE-TEST DATE 22-08-2017	
ESPECIFICACIÓN / SPECIFICATION EP 7.3		FECHA DE CONTROL / TEST DATE 25-02-2015	

DETERMINACIÓN / DETERMINATION	ESPECIFICACIÓN / SPECIFICATION	RESULTADOS / RESULTS
DESCRIPTION	(Pag. 1/2) WHITE OR ALMOST WHITE. CRYSTALLINE POWDER	CONFORMS
IDENTIFICATION (IR)	POSITIVE	POSITIVE
IDENTIFICATION (Na)	POSITIVE	POSITIVE
SOLUBILITY	FREELY SOLUBLE IN WATER, AND IN ETHANOL	CONFORMS
OPTICAL ROTATION (A.B.)	5° - 8°	7.1 °
WATER	NMT. 2.0 %	0.24 %
APPARENCE OF SOLUTION	NMT. B6	CONFORMS
pH	7.5 - 9.0	8.3
RESIDUAL SOLVENTS		
ACETONE	NMT. 150 ppm	N.D. ppm.
METHANOL	NMT 200 ppm.	N.D. ppm.
METHYL ISOB. KETONE	NMT 1000 ppm.	125 ppm.
METHYLENE CHLORIDE	NMT 25 ppm.	N.D. ppm.
XYLENE	NMT 125 ppm.	N.D. ppm.
ASSAY (a.b.)	97.5 - 101.0 %	100.1 %

OBSERVACIONES
OBSERVATIONSFAGRON GMBH ET CO. KG
NETHERLANDS
BI 150586INFORME DE CONTROL
CONTROL REPORT
V.º B.º JEFE DE CONTROL CALIDAD
QUALITY CONTROL MANAGER

G



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

División
Farmacia

SODIUM FUSIDATE		22-02-2015
FST 539	289 Kg	22-08-2017
EP 7.3		25-02-2015

DETERMINACION / DETERMINATION	ESPECIFICACION / SPECIFICATION	RESULTADO / RESULT
(Pag. 2/2)		
RELATED SUSTANC. (HPLC)		
IMP. A	NMT. 0.3 %	N.D. %
IMP. B	NMT. 0.4 %	N.D. %
IMP. C	NMT. 0.2 %	N.D. %
IMP. E	NMT. 0.10%	N.D. %
IMP. D	NMT. 0.2 %	N.D. %
IMP. N	NMT. 0.2 %	N.D. %
IMP. F	NMT. 0.2 %	0.02 %
IMP. G	NMT. 0.7 %	0.12 %
IMP. H	NMT. 0.10%	0.06 %
IMP. I	NMT. 0.2 %	N.D. %
IMP. J	NMT. 0.10%	N.D. %
IMP. O	NMT. 0.10%	N.D. %
IMP. K	NMT. 0.2 %	N.D. %
IMP. L	NMT. 0.5 %	N.D. %
IMP. M	NMT. 1.0 %	0.40 %
UNSPECIFIED IMPURITIES	NMT. 0.10%	N.D. %
TOTAL IMPURITIES	NMT. 2.0 %	0.60 %

ELABORADO POR:
ANALIZADO POR:

FAGRON GMBH ET CO KG
NETHERLANDS
BI 150586

INFORME DE CONTROL
S. CONTROLADO

Vº Bº JEFE DE CONTROL CALIDAD
QUALITY CONTROL MANAGER