NEWCHEM

CERTIFICATE OF ANALYSIS

DEXAMETHASONE SODIUM PHOSPHATE

Batch: **NR1666**

Manuf. date: **11/2011**
Retest date: **11/2013**
Expiration date: **11/2014**

Tests	Specifications	Results
GENERAL TESTS		
Appearance	White or almost white very hygroscopic powder	Complies
Solubility	Complies	Complies
Identification B (EP)	Positive	Positive
Identification C (EP)	Positive	Positive
Identification A (USP)	Positive	Positive
Identification B (USP)	Positive	Positive
Appearance of solution	Clear and not more than B7	Complies
Colour of solution 400 nm	NMT 0,100 UA	0,009 AU
Colour of the solution (650 nm)	NMT 0.010 AU	0,002 AU
Specific rotation	+75° - +83° on anhydrous, ethanol-free substance	+78 °
Specific rotation (USP)	+74° - +82° on anhydrous, ethanol-free substance	+78 °
pH (EP/USP)	7.5 - 9.5	8,4 pH
Inorganic phosphates (EP; USP)	NMT 1.0 %	Complies
Water content (KF)	NMT 10.0%	3,6 %
Ethanol (GC)	NMT 3.0%	1,7 %
Ethanol and water	NMT 13.0%	5,3
ASSAY		
UV Assay (EP)	97.0%-103.0% on anhydrous, ethanol-free substance	99,6 %
Assay HPLC (USP)	97.0% - 102.0% water-free and alcohol-free basis	99,3 %
RESIDUAL SOLVENTS		
Isopropyl alcohol	NMT 1500 ppm	413 ppm
Methanol	NMT 3000 ppm	N.D.
Acetone	NMT 2500 ppm	N.D.
Ethyl acetate	NMT 500 ppm	N.D.

Complies with cEP and cUSP

Store at refrigerated conditions (+ 2 °C - + 8 °C)

Verona, 17/11/2011

Approved by QA/QC Director

NEWCHEM spa **www.newchemspa.com**
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RESIDUAL SOLVENTS		
Dichloromethane	NMT 300 ppm	N.D.
Tetrahydrofuran	NMT 360 ppm	N.D.
IMPURITIES		
Impurity A	NMT 0.50 %	N.Q.
Impurity B	NMT 0.50 %	0,09 %
Impurity C	NMT 0.15%	N.Q.
Impurity D	NMT 0.15%	N.D.
Impurity E	NMT 0.15%	N.Q.
Any other impurity	NMT 0,10%	0,08 %
Total impurities	NMT 1,0 %	0,2 %

FAGRON IBÉRICA, S.A.U
Corresponde al lote de Fagron:
1K25 - 833
16.7.13 Director Técnico

Complies with cEP and cUSP

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Verona, 17/11/2011

Approved by QA/QC Director

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