

DSM Sinochem Pharmaceuticals Spain S.A.



Calle Ripolles, 2
Polígono Industrial Urvasa, Sta Perpetua de Mogoda, 08130 Barcelona, Spain
Tel.:34.93.544 30 60, Fax:34.93.560 40 51,34.93.560 03 00

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Certificate of Analysis

CEFADROXIL MONOHYDRATE

PURIDROX® COMPACTED

Manufacturing date: Jul 2014

Batch/lot: B339661

Batch/lot size: 2700 KG

Expiration Date: Jun 2018

Release date: 24-Jul-2014

Tests	Specifications	Units	Results
Appearance	White-almost white powder with granules		Complies
Solubility	Conforms with test		Complies
Identification (IR)	Conforms with test		Complies
Crystallinity	Crystalline		Complies
pH	4.0 to 6.0		5.1
Specific opt. rotation, anhydrous basis	165 to 178	deg	173
Water content by KF	4.2 to 6.0	%w/w	4.9
Assay, anhydrous basis	95.0 to 102.0	%w/w	99.6 99.2
Related Substances:7-ADCA	< = 1.0	%w/w	0.06
Related Substances:pOH-PHENYLGLYCINE	< = 1.0	%w/w	0.03
Rel. Subst.: ANY OTHER UNKNOWN IMPURITY	< = 0.1	%w/w	0.04
Related Substances: TOTAL IMPURITIES	< = 3.0	%w/w	0.18
Bulk Density	> = 0.50	g/ml	0.70
Tapped Density	> = 0.75	g/ml	0.90
Sulphated Ash	< = 0.5	%w/w	Complies if tested**
Residual Acetone	< 0.2	%w/w	Complies if tested**

Pharmacopoeia quality: Complies with the current editions: Ph.Eur, BP, USP, IP.

Manufactured according to ICH Q7 GMP for APIs.

N,N-Dimethylaniline is not used in the manufacturing process of this product or present in any of the raw materials.

DSM order#: 49910

Customer order#: FGB-073-B 2014

Ship-to: SERVIALCOMEX SA , Carrera 106 NO. 15-25, Manzana 7, I , , Bogota , CO

** Checked at regular intervals

Date of issue: St. Perpetua de Mogoda, August 26, 2014

COA Approved with Digital Signature by Elena
Lopez-Boado, Compliance Manager, 14:15:23,
26.08.2014

The material covered by this delivery is produced in accordance with DSM Sinochem Pharmaceuticals manufacturing specifications currently in force for this product grade. DSP certifies that the material supplied conforms to the performance typical for this grade and product description, and has been monitored in accordance with the internal quality control routines employed in our processes. However, the buyer must check the suitability of this grade for the actual application. This certificate does not release the recipient from his obligation to carry out his usual incoming