Centrient Pharmaceuticals Spain S.A.

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Certificate of Analysis

CEFALEXIN MONOHYDRATE

PURILEX ® COMPACTED	**Batch/lot:** B427974	**Batch/lot size:** 3000 KG
Manufacturing date: Sep 2020	**Expiration Date:** Aug 2024	**Release Date:** 15-Sep-2020

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 5,5		5,0
Specific opt. rotation, anhydrous basis	149 to 158	deg	155
Water content by KF	4,0 to 8,0	%w/w	6,0
Assay, anhydrous basis[1]	97,0 to 102,0	%w/w	100,3
Related Substances:7-ADCA	< = 1,0	%w/w	0,05
Related Substances: PHENYLGLYCINE	< = 1,0	%w/w	< 0,02
Related Substances: PG-AMIDE	< = 0,5	%w/w	< 0,02
Rel. Subs.: Delta-2-Cephalexin	< = 1,0	%w/w	< 0,02
Rel. Subst.: CEX-piperazine+ degradants	< = 1,0	%w/w	0,03
Rel. Subst.: ANY OTHER IMPURITY	< = 1,0	%w/w	0,04
Related Substances: TOTAL IMPURITIES	< = 3,0	%w/w	0,16
Bulk Density	> = 0,45	g/ml	0,69
Tapped Density	> = 0,75	g/ml	0,86
Sulphated Ash	< = 0,2	%w/w	Complies if tested**
Residual Acetone	< 0,20	%w/w	0,01

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.

* Expiry date is 2 years for IP grade as per Indian D&C Act.

Our sales order#: 105363
Customer order#: A-2200613

Ship-to SIEMSGLUSS IBERICA S.A. , Parcela 6, Nave 2, , 08620 , Sant Vicenc Dels Horts (Barcelona) , ES

** Checked at regular intervals

[1]Release Specification

Date of Issue: St. Perpetua de Mogoda, October 21, 2020

COA approved with Digital Signature by Judit Fuentes, QA Technician, 14:13:54, 21.10.2020