

Centrient Pharmaceuticals Spain S.A.

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Certificate of Analysis

CEFALEXIN MONOHYDRATE
CEFALEXIN COMPACTED
Batch/lot: B428019
Batch/lot size: 3000 KG
Manufacturing date: Oct 2020
Expiration Date: Sep 2024
Release Date: 06-Nov-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 | 156 |
| Water content by KF | 4,0 to 8,0 | %w/w | 6,3 |
| Assay, anhydrous basis* | 97,0 to 102,0 | %w/w | 99,8 |
| 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 |
| el. Subs.: Delta-2-Cephalexin | < = 1,0 | %w/w | < 0,02 |
| el. Subst.: CEX-piperazine+ degradants | < = 1,0 | %w/w | 0,07 |
| el. Subst.: ANY OTHER IMPURITY | < = 1,0 | %w/w | 0,04 |
| Related Substances: TOTAL IMPURITIES | < = 3,0 | %w/w | 0,23 |
| Bulk Density | > = 0,45 | g/ml | 0,60 |
| Tapped Density | > = 0,75 | g/ml | 0,81 |
| Sulphated Ash | < = 0,2 | %w/w | Complies if tested** |
| Residual Acetone | < 0,20 | %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.
Expiry date is 2 years for IP grade as per Indian D&C Act.
Our sales order#: 107826
Customer order#: A-2210074
**Ship-to SIEMSGLUSS IBERICA S.A. , Parcela 6, Nave 2, , 08620 , Sant Vicenc Dels Horts
Barcelona) , ES**
*** Checked at regular intervals**
Release Specification
Date of Issue: St. Perpetua de Mogoda, February 10, 2021

COA approved with Digital Signature by Judit Fuentes.
QA Technician, 15:10:13, 10.02.2021