Quality.Reliability.Sustainability.

# Centrient Pharmaceuticals Spain S.A.

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## Certificate of Analysis

CEFALEXIN MONOHYDRATE

| | | |
|---|---|---|
| PURILEX ® COMPACTED | **Batch/lot:** B427863 | **Batch/lot size:** 3175 KG |
| **Manufacturing date:** Feb 2020 | **Expiration Date:** Jan 2024 | **Release Date:** 02-Mar-2020 |

| Tests | Specifications | Units | Results |
|---|---|---|---|
| Appearance | White-almost white powder with granules | | Complies |
| Solubillty | 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 | 154 |
| Water content by KF | 4,0 to 8,0 | %w/w | 5,6 |
| Assay, anhydrous basis[1] | 97,0 to 102,0 | %w/w | 99,4 |
| Related Substances:7-ADCA | < = 1,0 | %w/w | 0,03 |
| 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 | 0,04 |
| Rel. Subst.: ANY OTHER IMPURITY | < = 1,0 | %w/w | 0,05 |
| Related Substances: TOTAL IMPURITIES | < = 3,0 | %w/w | 0,17 |
| Bulk Density | > = 0,45 | g/ml | 0,66 |
| Tapped Density | > = 0,75 | g/ml | 0,87 |
| Sulphated Ash | < = 0,2 | %w/w | Complies if tested** |
| Residual Acetone | < 0,2 | %w/w | < 0,1 |

**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#: 101333
Customer order#: A-2200247

** Checked at regular intervals

[1]Release Specification

**Date of Issue: St. Perpetua de Mogoda, April 09, 2020**

COA approved with Digital Signature by Nuria Roig, QA Assistant - Spain, 11:39:06, 09.04.2020