



This product is part of our PureActives® range.

Puriclor® Powder (Cefaclor powder)

Therapeutical category:

Oral broad-spectrum cephalosporin

Characteristics:

A crystalline powder. No solvents are used in the process for higher purity and improved odor of the product.

Applications:

The product is suitable for the manufacture of solid oral dosage forms such as capsules, tablets, powders and granules for oral suspensions, after addition of appropriate excipients.

PureActives, the enzymatic difference

All our PureActives® antibiotic products are produced using our proprietary, sustainable, and environmentally friendly enzymatic technology. They bring our brand promise to life through superior quality, outstanding reliability and leading sustainability performance.

All our manufacturing sites use the best available technology and operate dedicated waste water treatment plants, 24/7 throughout the year. Effluents are regularly sampled and checked for antimicrobial activity.



Quality



Reliability



Sustainability



| Key parameters: Puriclor® Powder (Cefaclor powder) | | | | | | | |
|---|---|----------|-------------|---------------|-------------|-----------------|-------------|
| Pharmacopeia quality | EP, USP, IP, ChP | | | | | | |
| Regulatory information | <table border="1"> <tr> <td>EU: EDQM</td> <td>Korea: KFDA</td> </tr> <tr> <td>India: MoH&FW</td> <td>China: CFDA</td> </tr> <tr> <td>Bangladesh: MoH</td> <td>Taiwan: DoH</td> </tr> </table> | EU: EDQM | Korea: KFDA | India: MoH&FW | China: CFDA | Bangladesh: MoH | Taiwan: DoH |
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| India: MoH&FW | China: CFDA | | | | | | |
| Bangladesh: MoH | Taiwan: DoH | | | | | | |
| Appearance | White or slightly yellow powder | | | | | | |
| Assay (anhydrous basis) | Cefaclor: 96.0–102.0% | | | | | | |
| pH | 3.0 – 4.5 | | | | | | |
| Water | 3.0 - 6.5% | | | | | | |
| Total impurities | ≤ 2.0% | | | | | | |
| Residual solvents | Methanol < 0.3% (residual from side chain production) | | | | | | |
| Dimethylaniline | Not used in the process | | | | | | |
| Shelf-life | Minimum 4 years in the original packaging under recommended storage conditions | | | | | | |
| Batch size | Approximately 1,000 kg | | | | | | |
| Storage conditions | Below 25°C | | | | | | |
| Packaging | Primary packaging: polyethylene bag | | | | | | |
| | Secondary packaging: thermo-sealed aluminum polyethylene bag | | | | | | |
| | Outer packaging: corrugated box | | | | | | |
| | Fixed quantity of 25 kg packed in each bag; 300kg per pallet | | | | | | |

Contact and information

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