



This product is part of our PureActives® range.

# Purimox® Compacted grade DC

## Amoxicillin Trihydrate, compacted grade DC

### Therapeutical category:

Oral, broad spectrum penicillin

### Characteristics:

Granules obtained by means of dry compaction of the crystalline powder without adding any excipients.

No solvents are used in the process resulting in higher purity of the product.



### Applications:

The product is suitable for the manufacture of tablets by the direct compression process, after addition of appropriate excipients. The product is also suited for the manufacture of capsules on high speed machines.

### 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: Purimox<sup>®</sup> Compacted grade DC

### Amoxicillin Trihydrate, compacted grade DC

|                         |   |   |
|-------------------------|---|---|
| Pharmacopeia quality    | USP, EP, IP, FEUM   |   |
| Regulatory information  | EU: EDQM<br>USA: FDA<br>Canada: HC<br>Mexico: COFEPRIS<br>Russian Federation: DoH | India: MoH<br>Bangladesh: MoH<br>South Korea: KFDA<br>Taiwan: DoH<br>Australia: TGA |
| Appearance              | White to almost white granules  |   |
| Assay (anhydrous basis) | Amoxicillin: 97.5 - 102.0%  |   |
| pH                      | 3.5 - 5.5   |   |
| Water                   | 11.5 - 14.5%  |   |
| Tapped bulk density     | 0.7–0.9 g/ml  |   |
| Total impurities        | ≤ 2.0%  |   |
| Residual solvents       | Not used in the process   |   |
| Dimethylaniline         | Not used in the process   |   |
| Shelf-life              | Minimum 4 years in the original packaging under storage conditions                |   |
| Batch size              | Approximately 1600 - 5500 kg (depending on manufacturing site)                    |   |
| Storage conditions      | Below 25°C, protected from light and moisture                                     |   |
| Packaging               | Primary packaging: polyethylene bag   |   |
|                         | Secondary packaging: thermo-sealed aluminum polyethylene bag                      |   |
|                         | Outer packaging: corrugated box or HDPE drum                                      |   |
|                         | Fixed quantity of 25 kg packed in each bag  |   |

#### Contact and information

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