



# Purimox<sup>®</sup> Fine

*Amoxicillin Trihydrate, fine powder*



## Therapeutical category:

Oral, broad spectrum penicillin



## Characteristics:

A fine crystalline powder. No solvents are used in the process resulting in higher purity of the product.



## Applications:

The product is suitable for manufacturing suspensions and dry powder mixtures for syrups after adding relevant excipients.

### **This product is part of our PureActives<sup>®</sup> range.**

All our PureActives<sup>®</sup> 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.



## Key parameters: Purimox® Fine

### *Amoxicillin Trihydrate, fine powder*

|                                |  |  |
|--------------------------------|--|--|
| <b>Pharmacopeia quality</b>    | USP, EP, IP  |  |
| <b>Regulatory information</b>  | USA: FDA<br>EU: EDQM<br>Canada: HC<br>Korea: KFDA                  | Taiwan: DoH<br>India: MoH<br>Bangladesh: MoH<br>Ukraine: MoH |
| <b>Appearance</b>              | White to almost white crystalline powder                           |  |
| <b>Assay (anhydrous basis)</b> | Amoxicillin: 97.5 - 102.0%   |  |
| <b>pH</b>                      | 3.5 - 5.5  |  |
| <b>Water</b>                   | 11.5 - 14.5%   |  |
| <b>Tapped bulk density</b>     | ≥ 0.40 g/ml  |  |
| <b>Total impurities</b>        | ≤ 2.0%   |  |
| <b>Residual solvents</b>       | Not used in the process  |  |
| <b>Dimethylaniline</b>         | Not used in the process  |  |
| <b>Shelf-life</b>              | Minimum 4 years in the original packaging under storage conditions |  |
| <b>Batch size</b>              | Approximately 3000 - 5500 kg                                       |  |
| <b>Storage conditions</b>      | Below 25°C, protected from light and moisture                      |  |
| <b>Packaging</b>               | 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

For more information, please visit [www.dsm-sinochem.com](http://www.dsm-sinochem.com) or e-mail: [info@dsm-sinochem.com](mailto:info@dsm-sinochem.com) or contact us at one of the addresses below:

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