



# Purimox<sup>®</sup> Compacted grade P

*Amoxicillin Trihydrate, compacted grade P*



## 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 based on association with clavulinate/clavulanic acid by direct compression process, after adding relevant excipients. Grade P increases stability of the formulation and reduces tableting cycle time.

### **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<sup>®</sup> Compacted grade P

### *Amoxicillin Trihydrate, compacted grade P*

<b>Pharmacopeia quality</b>	USP, EP, IP, FEUM	
<b>Regulatory information</b>	EU: EDQM Mexico: COFEPRIS Australia: TGA South Korea: KFDA Taiwan: DoH	India: MoH Bangladesh: MoH Ukraine: MoH Canada: HC in progress
<b>Appearance</b>	White to almost white granules	
<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>	≥ 0.70 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 5 years in the original packaging under storage conditions	
<b>Batch size</b>	Approximately 500 – 1600 kg (depending on manufacturing site)	
<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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VA22.09.2017