



Purimox[®] for direct compression

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

This product is part of our PureActives[®] range.

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.



Key parameters: Purimox[®] for direct compression

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Pharmacopeia quality	USP, EP, IP, FEUM	
Regulatory information	EU: EDQM USA: FDA Canada: HC South Korea: KFDA Mexico: COFEPRIS	Taiwan: DoH India: MoH Bangladesh: MoH Russian Federation: DoH 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 800 - 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

For more information, please visit www.dsm-sinochem.com or e-mail: info@dsm-sinochem.com or contact us at one of the addresses below:

Singapore (HQ)

sales@dsm-sinochem.com

Europe/North America

Delft, The Netherlands

sales.ea@dsm-sinochem.com

Asia Pacific / Middle East / Africa China

Gurgaon, India

sales.amea@dsm-sinochem.com

Beijing, P.R. China

sales.china@dsm-sinochem.com

Mexico & Latin America

Ramos Arizpe, Mexico

sales.mla@dsm-sinochem.com

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