



Purimox[®] Powder Extra Dry

Amoxicillin Trihydrate, powder extra dry



Therapeutical category:

Oral, broad spectrum penicillin



Characteristics:

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



Applications:

The product is suitable for the manufacture of dosage forms based on association with clavulanate/clavulanic acid and water-sensitive formulations. The extra dry grade increases stability and reduces the degradation of the product.

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[®] Powder Extra Dry

Amoxicillin Trihydrate, powder extra dry

Pharmacopeia quality	USP, EP, IP, FEUM	
Regulatory information	USA: FDA EU: EDQM Canada: HC South Korea: KFDA Ukraine: MoH Australia: TGA	Taiwan: DoH India: MoH Bangladesh: MoH Russian Federation: DoH Mexico: COFEPRIS
Appearance	White to almost white crystalline powder	
Assay (anhydrous basis)	Amoxicillin: 97.5 - 102.0%	
pH	3.5 - 5.5	
Water activity	≤ 0.3	
Tapped bulk density	≥ 0.28 g/ml	
Total impurities	≤ 2.0%	
Residual solvents	Not used in the process	
Dimethylaniline	Not used in the process	
Shelf-life	Minimum 5 years in the original packaging under storage conditions	
Batch size	Approximately 600 - 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

Gurgaon, India

sales.amea@dsm-sinochem.com

China

Beijing, P.R. China

sales.china@dsm-sinochem.com

Mexico & Latin America

Ramos Arizpe, Mexico

sales.mla@dsm-sinochem.com

Copyright © 2017 DSM Sinochem Pharmaceuticals. All rights reserved. Although diligent care has been used to ensure that the information provided herein is accurate, nothing contained herein can be construed to imply any representation or warranty as to the accuracy, currency or completeness of this information nor can it be construed to imply any other representation or warranty of any kind, including the implied warranties of merchantability, fitness for a particular purpose or non-infringement.

The content of this document is subject to change without further notice. Please contact us for the latest version of this document or further information. Product offers are explicitly not made in respect of those jurisdictions where valid third party patent rights related to such products are in force. In such jurisdictions the advertised products are only offered for regulatory purposes insofar allowed under local provisions like the Bolar provisions in the US and 2004/27/EC in Europe.

VA22.09.2017