



# Puricillin® Powder

(Ampicillin Trihydrate, powder)



## Therapeutical category:

Oral, broad spectrum penicillin



## Characteristics:

A crystalline powder. No solvents are used in the process for higher purity and improved smell of the product. Methanol is a residual from raw material and a by-product of an enzymatic reaction.



## Applications:

The product is suitable for the manufacture of granules for suspensions, dry powder mixtures for syrups and tablets after adding relevant excipients.

### **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: Puricillin® Powder

(Ampicillin Trihydrate, powder)

<b>Pharmacopeia quality</b>	USP, EP, IP	
<b>Regulatory information</b>	EU: EDQM Russian Federation: DoH Australia: TGA	India: MoH Bangladesh: MoH Taiwan: in progress
<b>Appearance</b>	White or almost white crystalline powder	
<b>Assay (anhydrous basis)</b>	Ampicillin: 96.0–102.0%	
<b>pH</b>	3.5 - 5.5	
<b>Water</b>	12.0 to 15.0%	
<b>Tapped bulk density</b>	≥ 0.50 g/ml	
<b>Total impurities</b>	≤ 2.0%	
<b>Residual solvents</b>	≤ 3000 ppm	
<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 1500 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:

#### Singapore (HQ)

[sales@dsm-sinochem.com](mailto:sales@dsm-sinochem.com)

#### Europe/North America

Delft, The Netherlands

[sales.ea@dsm-sinochem.com](mailto:sales.ea@dsm-sinochem.com)

#### Asia Pacific / Middle East / Africa China

Gurgaon, India

[sales.amea@dsm-sinochem.com](mailto:sales.amea@dsm-sinochem.com)

Beijing, P.R. China

[sales.china@dsm-sinochem.com](mailto:sales.china@dsm-sinochem.com)

#### Mexico & Latin America

Ramos Arizpe, Mexico

[sales.mla@dsm-sinochem.com](mailto:sales.mla@dsm-sinochem.com)

**Copyright © 2016 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.

VAPFS 2016