



# Puridrox<sup>®</sup> Compacted

(Cefadroxil Monohydrate)



## Therapeutical category:

Oral broad-spectrum cephalosporin



## Characteristics:

Granules obtained by means of dry compaction of the crystalline powder without the addition of any excipients. No solvents are used in the process for higher purity with the exception of acetone used for the final product wash.



## Applications:

The product is suitable for the manufacture of capsules after the addition of excipients such as magnesium stearate.

### **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: Puridrox<sup>®</sup> Compacted (Cefadroxil Monohydrate)

<b>Pharmacopeia quality</b>	USP, EP, BP	
<b>Regulatory information</b>	USA: FDA EU: EDQM Canada: HC Bangladesh: MoH	China: CFDA Taiwan: DoH India: MoH South Korea: KFDA
<b>Appearance</b>	White to almost white crystalline powder	
<b>Assay (anhydrous basis)</b>	Cefadroxil: 95.0–102.0%	
<b>pH</b>	4.0 – 6.0	
<b>Water</b>	4.0 – 6.0%	
<b>Tapped bulk density</b>	≥ 0.75 g/ml	
<b>Total impurities</b>	≤ 3.0%	
<b>Residual solvents</b>	Acetone < 0.2% (washing step)	
<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 2,400 kg	
<b>Storage conditions</b>	Below 25°C	
<b>Packaging</b>	Primary packaging: polyethylene bag	
	Secondary packaging: thermo-sealed aluminum polyethylene bag	
	Outer packaging: corrugated box	
	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

Gurgaon, India

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

#### China

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