

Rosuvastatin

(Rosuvastatin calcium)

Therapeutical category:

Cholesterol lowering agent

Characteristics:

A hygroscopic powder

Applications:

A hygroscopic powder suitable for the manufacture of tablets and capsules. The appropriate excipients need to be added. The particle size of the product is designed for optimal dissolution and processability.

This product is part of our PureActives® range.

All our PureActives® statins 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: Rosuvastatin (Rosuvastatin calcium)

Pharmacopeia quality	EP, IP	
Regulatory information	US: FDA: in progress EU: EDQM in progress	India: MoH Canada: HC in progress
Appearance	White or almost white hygroscopic powder	
Assay (anhydrous basis)	Rosuvastatin: 98.0–102.0%	
Water	≤ 6.1%	
Total impurities	≤ 1.0%	
Residual solvents	Acetonitrile ≤ 410 ppm	
Retest period	Minimum 2 years in the original packaging under storage conditions	
Batch size	~225 kg	
Storage conditions	At 2-8°C, protected from light and moisture in airtight container	
Packaging	Primary packaging: polyethylene bag	
	Secondary packaging: thermo-sealed aluminum polyethylene bag	
	Outer packaging: HDPE drum	
	Fixed quantity of 1kg, 5kg, 10 kg or 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

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