

# Rosuvastatin

(Rosuvastatin calcium)

## Therapeutic category:

Cholesterol lowering agent

## Characteristics:

A hygroscopic powder

## Applications:

A hygroscopic powder suitable for the manufacture of drug products. The appropriate excipients need to be added. The particle size of the product is designed for optimal performance.

**This product is part of our PureActives® range.**

All our PureActives® statin 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.



## Key parameters: Rosuvastatin (Rosuvastatin calcium)

<b>Pharmacopeia quality</b>	USP, EP, IP, BP	
<b>Regulatory information</b>	USA: DMF (no.31410) EU: CEP 2015-090, Written Confirmation (WC) China: in progress Taiwan: TFDA (MF20(2574)) Korea: in progress	Canada: DMF (MF 2015-058) India: MoH Bangladesh: MoH Ukraine: MoH Russia: in progress
<b>Appearance</b>	White or almost white hygroscopic powder	
<b>Assay (anhydrous basis)</b>	Rosuvastatin: 97.0-102.0%	
<b>Water</b>	≤6.0%	
<b>Total impurities</b>	≤ 1.0%	
<b>Residual solvents*</b>	Acetonitrile ≤ 410 ppm Acetic acid ≤5000ppm Tert-Butylmethyl ether (MTBE) ≤ 5000ppm	
<b>Retest period</b>	Minimum 3 years in the original packaging under storage conditions	
<b>Batch size</b>	200-300 kg	
<b>Storage conditions</b>	Below 25°C, protected from light and moisture in airtight container	
<b>Packaging</b>	Primary packaging: LDPE polyethylene bag	
	Secondary packaging: black LDPE polyethylene bag	
	Tertiary packaging: thermo-sealed aluminum polyethylene bag	
	Outer packaging: HDPE drum	
	Fixed quantity of 10 kg or 25 kg packed in each bag	

\* Actual results: below 10% of ICHQ3C limits, and/or absent

### 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:

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