DSM Sinochem Pharmaceuticals

Rosuvastatin
(Rosuvastatin calcium)

Therapeutical 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® 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.

PureActives

Key parameters: Rosuvastatin
(Rosuvastatin calcium)

Pharmacopeia quality	EP, IP, BP	
Regulatory information	US: FDA: in progress EU: CEP 2015-090, EUGMP Written Confirmation (WC) China: in progress Taiwan: in progress Korea: in progress	Canada: DMF India: MoH Bangladesh: MoH Ukraine: in progress Russia: in progress Belarus: 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 Acetic acid ≤5000ppm Tert-Butylmethyl ether (MTBE) ≤ 5000pmm	
Retest period	Minimum 2 years in the original packaging under storage conditions	
Batch size	200 - 400kg	
Storage conditions	Below 25°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 10 kg or 25 kg packed in each bag	

* Actual results: below 10% of ICHQ3C limits

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:

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VAPFS 21.08.2017