



This product is part of our PureActives® range.

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.

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.

Quality



Reliability



Sustainability



Key parameters: Rosuvastatin (Rosuvastatin calcium)

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

Contact and information

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