DSM Sinochem Pharmaceuticals

Atorvastatin
(Atorvastatin calcium trihydrate)

Therapeutical category:

Cholesterol lowering agent

Characteristics:

A crystalline powder

Applications:

A crystalline powder suitable for the manufacture of tablets, capsules and /or suspensions after the addition of appropriate excipients. The particle size of the product is designed for optimal dissolution.

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.

PureActives®

Key parameters: Atorvastatin
(Atorvastatin calcium trihydrate)

Pharmacopeia quality	USP, EP, IP	
Regulatory information	US: FDA EU: EDQM China: SFDA	India: MoH Korea: in progress Brazil: in progress
Appearance	White to off-white crystalline powder	
Assay (anhydrous basis)	Atorvastatin: 98.0–102.0%	
Water	3.5 - 5.5%	
Total impurities	≤ 1.0%	
Residual solvents	Tert-Butylmethyl ether (MTBE) ≤ 5000 ppm Methanol: ≤ 3000 ppm	
Retest period	Minimum 5 years in the original packaging under storage conditions	
Batch size	300 - 350 kg	
Storage conditions	Below 30°, protected from light and moisture	
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:

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