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 drug products after the addition of appropriate excipients. 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.

PureActives®

Key parameters: Atorvastatin
(Atorvastatin calcium trihydrate)

Pharmacopeia quality	USP, EP, IP, BP	
Regulatory information	US: DMF (no. 29520) EU: CEP 2010-366, Written Confirmation (WC)) China: IDL (SFDA) Taiwan: TFDA (MF20(1830)) Korea: MFDS	Canada: DMF (MF 2016- 114) India: MoH Bangladesh: MoH Ukraine: MoH Russia: MoH Belarus: MoH
Appearance	White to off-white crystalline powder	
Assay (anhydrous basis)	Atorvastatin: 97.0–102.0%	
Water	3.5 - 5.5%	
Total impurities	≤1% (not including impurity E)	
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 - 500 kg	
Storage conditions	Below 30°C	
Packaging	Primary packaging: LDPE 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, and/or absent

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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