

# Atorvastatin

(*Atorvastatin calcium trihydrate*)

## Therapeutic 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® 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.



## Key parameters: Atorvastatin (Atorvastatin calcium trihydrate)

<b>Pharmacopeia quality</b>	USP, EP, IP, BP	
<b>Regulatory information</b>	US: DMF (no. 29520) EU: CEP 2010-366, EU GMP Written Confirmation (WC) China: IDL (SFDA) Taiwan: Taiwan FDA Korea: MFDS	Canada: DMF India: MoH Bangladesh: MoH Ukraine: MoH Russia: in progress Belarus: in progress
<b>Appearance</b>	White to off-white crystalline powder	
<b>Assay (anhydrous basis)</b>	Atorvastatin: 97.0–102.0%	
<b>Water</b>	3.5 - 5.5%	
<b>Total impurities</b>	≤ 1.0%	
<b>Residual solvents*</b>	Tert-Butylmethyl ether (MTBE) ≤ 5000 ppm Methanol: ≤ 3000 ppm	
<b>Retest period</b>	Minimum 5 years in the original packaging under storage conditions	
<b>Batch size</b>	300 - 500 kg	
<b>Storage conditions</b>	Below 30°	
<b>Packaging</b>	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](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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