

# 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® 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:

**Singapore (HQ)**  
[sales@dsm-sinochem.com](mailto:sales@dsm-sinochem.com)

**Europe/North America**  
Delft, The Netherlands  
[sales.ea@dsm-sinochem.com](mailto:sales.ea@dsm-sinochem.com)

**Asia Pacific / Middle East / Africa** **China**  
Gurgaon, India  
[sales.amea@dsm-sinochem.com](mailto:sales.amea@dsm-sinochem.com)

**Mexico & Latin America**  
Ramos Arizpe, Mexico  
[sales.mla@dsm-sinochem.com](mailto:sales.mla@dsm-sinochem.com)

**Copyright © 2016 DSM Sinochem Pharmaceuticals.** All rights reserved. Although diligent care has been used to ensure that the information provided herein is accurate, nothing contained herein can be construed to imply any representation or warranty as to the accuracy, currency or completeness of this information nor can it be construed to imply any other representation or warranty of any kind, including the implied warranties of merchantability, fitness for a particular purpose or non-infringement.

The content of this document is subject to change without further notice. Please contact us for the latest version of this document or further information. Product offers are explicitly not made in respect of those jurisdictions where valid third party patent rights related to such products are in force. In such jurisdictions the advertised products are only offered for regulatory purposes insofar allowed under local provisions like the Bolar provisions in the US and 2004/27/EC in Europe.

VAPFS 21.08.2017