



This product is part of our PureActives® range.

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.

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: Atorvastatin (Atorvastatin calcium trihydrate)

Pharmacopeia quality	USP, EP, IP, BP	
Regulatory information	EU: CEP 2010-366, Written Confirmation (WC) US: DMF (no. 29520) Canada: DMF (MF 2016- 114) Russia: MoH Ukraine: MoH Belarus: MoH	India: MoH Bangladesh: MoH China: IDL (SFDA) Taiwan: TFDA (MF20(1830) Korea: MFDS
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	

Contact and information

For more information, please visit www.centrient.com or e-mail: info@centrient.com or contact us at one of the addresses below:

Rotterdam (HQ)
sales@centrient.com

Europe/North America
Delft, The Netherlands
sales.ea@centrient.com

Asia Pacific / Middle East / Africa
Gurgaon, India
sales.amea@centrient.com

China
Beijing, P.R. China
sales.china@centrient.com

Mexico & Latin America
Ramos Arizpe, Mexico
sales.mla@centrient.com

Copyright © 2019 Centrient 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 2019