



#### GENERAL CONFORMITY CERTIFICATE

Ohm Laboratories Inc., certifies, based on reasonable testing program and pursuant to 15 U.S.C. § 2063, that the product referred in this certificate is in compliance with applicable CPSC – enforced laws & regulations, as described below.

#### 1. Atorvastatin Calcium Tablets, 40mg x 90 count

Child Resistant Closure – 38 mm sourced from Mold Rite Plastics (source of CRC specified as per the certificate available).

Bottle – 100 cc bottle sourced from Shriji Polymers (India) Ltd.

# 2. The CPSC product safety regulation to which this product is being certified: Regulations for special packaging required under the Poison Prevention Packaging Act (16)

CFR part 1700).

- 3. Special Note: The full CPSC 16 C.F.R. 1700.15 & 1700.20 child resistant package safety testing was performed on a Shriji Polymers (India) Ltd. 75 cc bottle and Mold Rite Plastics 38mm CRC closure. Additionally, a partial CPSC 16 C.F.R. 1700.15 & 1700.20 child resistant package safety testing was performed on a Shriji Polymers (India) Ltd. 100 cc bottle and Mold Rite Plastics 38mm CRC closure.
  - **a.** The Mold Rite Plastics 38mm CRC closure tested was the same for the full and partial testing.
  - **b.** The partial CPSC 16 C.F.R. 1700.15 & 1700.20 child resistant package safety testing was performed on a Shriji Polymers (India) Ltd. 100 cc bottle and Mold Rite Plastics 38mm CRC closure consisted of 24 unit child testing, 50 unit senioradult resecuring testing, and 50 unit senior-adult resecuring child portion of the testing.
  - c. The Shriji Polymers (India) Ltd. 75 cc bottle is manufactured by the same company, using the exact same materials, with the same neck finish as the 100 cc bottle
  - **d.** The Shriji Polymers (India) Ltd. 75 cc bottle is considered to be the worst case scenario.

### 4. Ohm Laboratories, a Sun Pharma Company

14 Terminal Road

New Brunswick, NJ 08901

(732)514-4419

#### 5. Test Results Maintained by:

Daniel Orlandi, Sr Manager, Manufacturing, Science and Technology Group Ohm Laboratories, a Sun Pharma Company

14 Terminal Road

New Brunswick, NJ 08901

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### 6. Date and Place of Product Manufacturing:

January 2018, Terminal Road - NJ

## 7. Compliance Testing Date & Location:

38mm-400 PDT Embossed CRC on a 75 cc Round Bottle

Test # SUN17-07SC 50 Unit Sequential Child Protocol Test September 25 – October 12, 2017

Approved: October 12, 2017

Test # SUN17-07A

100 unit Senior-Adult Resecuring Protocol Test

October 9 - November 3, 2017

Approved: January 3, 2018

Test # SUN17-07C

100 unit Senior-Adult Resecuring Protocol Test - Child Portion of SUN17-07A

December 12 - January 23, 2018

Approved: January 23, 2018

38mm-400 PDT Embossed CRC on a 100 cc Round Bottle

Test # SUN17-08SC

24 Unit Child Mini Test

September 28 – October 13, 2017

Approved: October 13, 2017

Test # SUN17-08A

50 unit Senior-Adult Resecuring Mini Test

November 21 – December 5, 2017

Approved: December 5, 2017

Test # SUN17-08C

50 unit Senior-Adult Resecuring Mini Test - Child Portion of SUN17-08A

January 9 – January 25, 2018

Approved: January 25, 2018

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02/01/18

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