

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, 80mg x 90 count

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

Bottle – 175 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. 175 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. 175 cc bottle and Mold Rite Plastics 38mm CRC closure consisted of 24 unit child testing, 50 unit senior-adult resealing testing, and 50 unit senior-adult resealing – 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 175 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 (732)514-4483

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 175 cc Round Bottle


Test # SUN17-09SC
24 Unit Child Mini Test
October 11 – October 18, 2017
Approved: October 18, 2017

Test # SUN17-09A
50 unit Senior-Adult Resecuring Mini Test
December 12 – January 17, 2018
Approved: January 17, 2018

Test # SUN17-09C
50 unit Senior-Adult Resecuring Mini Test – Child Portion of SUN17-09A
January 8 – January 22, 2018
Approved: January 22, 2018

BirdDog Marketing Group, LLC
166 Farmington Lane
Lancaster, PA 17601 USA
Tel (717) 581 – 6602
Fax (717) 581 – 1762

Prepared By:  02/01/18
David Jacobone – Sr Scientist, Manufacturing, Science and Technology Group

Approved By:  02/02/18
Frank Piechota – Manager, Quality Assurance