

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. Guanfacine ER Tablets, 2mg x 100 count

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

Bottle – 100 cc bottle sourced from Drug Plastics Group

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. Ohm Laboratories, a Sun Pharma Company

14 Terminal Road
New Brunswick, NJ 08901 (732)514-4419

4. 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

5. Date and Place of Product Manufacturing:


Approved for use as of March 2018, Terminal Road - NJ

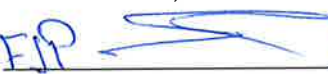
6. Compliance Testing Date & Location:

38 mm SecuRx Pictorial on 100 cc Round Bottle

Test #DPG13-01A
100 unit Senior-Adult Resecuring Protocol Test
January 3 - January 22, 2013
Approved: January 22, 2013

Test #DPG13-01CR
100 unit Senior-Adult Resecuring Protocol Test – Child Portion of #DPG13-01A
January 16 - February 20, 2013
Approved: February 20, 2013

Prepared By:  03/16/18
David Iacobone – Sr Scientist, Manufacturing, Science and Technology Group

Approved By:  03/16/18
Frank Piechota – Manager, Quality Assurance

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. Guanfacine ER Tablets, 2mg x 100 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. The Shriji Polymers (India) Ltd. 100 cc HW bottle external dimensions are the same as the Shriji Polymers (India) Ltd. 100 cc bottle.

- 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 senior-adult resealing testing, and 50 unit senior-adult resealing – child portion of the testing.
- c. The Shriji Polymers (India) Ltd. 100 cc HW bottle is manufactured by the same company, using the exact same materials, has the same external dimensions, and has the same neck finish as the 100 cc bottle.
- d. 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 HW bottle.
- e. The Shriji Polymers (India) Ltd. 75 cc bottle is considered to be the worst case scenario.

4. Ohm Laboratories, a Sun Pharma Company

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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:

Approved for use as of March 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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Prepared By:  03/12/18
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