

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, 4mg x 100 count

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

Bottle – 75 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. Special Note: The full CPSC 16 C.F.R. 1700.15 & 1700.20 child resistant package safety testing was performed on a Drug Plastics Group 100cc bottle and Drug Plastics Group 38mm CRC closure.

- a. The Drug Plastics Group 38mm CRC closure tested with the Drug Plastics Group 100cc bottle is the exact same closure as with the Drug Plastics Group 75cc bottle.
- b. The Drug Plastics Group 100 cc bottle is manufactured by the same company, using the exact same materials, and has the same neck finish as the 75 cc bottle.

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:

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

7. 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

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

Prepared By:  03/22/18
Daniel Orlandi – Sr Manager, Manufacturing, Science and Technology Group

Approved By:  03/22/18
Frank Piechota – Manager, Quality Assurance

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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, 4mg x 100 count

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

Bottle – 75 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. 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:


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

BirdDog Marketing Group, LLC
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Prepared By:  03/12/18
David Iacobone – Sr Scientist, Manufacturing, Science and Technology Group

Approved By:  03/12/18
Frank Piechota – Manager, Quality Assurance