

Consumer Product Safety Improvement Act General Certificate of Conformity

As required by the Consumer Product Safety Improvement Act, the following certifies the product referenced meets all applicable testing standards.

Alkermes Drug Product: LYBALVI[®] (olanzapine and samidorphan) tablets

Alkermes NDC Numbers: 7-count bottle, 10 mg/10 mg tablet, 65757-652-40 7-count bottle, 10 mg/10 mg tablet, 65757-652-41 (Samples) 30-count bottle, 10 mg/10 mg tablet, 65757-652-42 90-count bottle, 10 mg/10 mg tablet, 65757-652-44

Consumer Product Safety regulations to which the above-referenced product is being certified: Child-resistant packaging requirements under the Poison Prevention Packaging Act. The applicable CPSC regulations are codified at 16 CFR Parts 1700 and 1701.

Drug Product Package Packaging Testing Per Drug Plastics & Glass Co., Inc.:

-24 mm SecurRx[®] Child-Resistant Closure, Test Number DPG14-05C

-33 mm SecurRx[®] Child-Resistant Closure, Test Number DPG11-12C & DPGRQ0006507

Date of testing: 13 May 2014 to 06 Jun 2014 (24 mm SecurRx[®] CRC) Date of testing: 03 Nov 2011 to 18 Nov 2011 (33 mm SecurRx[®] CRC)

Third party testing laboratory and location of testing:

Bird Dog Marketing Group, LLC 3125 Nolt Road, Lancaster, PA 17601, USA 1-717-615-9022

Place of manufacture and contact information for the individual maintaining test result records: Director, Quality Assurance Alkermes, Inc. 265 Olinger Circle, Wilmington, OH 45177 1-937-382-5642 QA.CPSIA@alkermes.com

Alkermes products are marked with a unique

lot number which can used to identify the date of manufacturing by contacting the Director, Quality Assurance.

Date when this product was manufactured:

U.S. Manufacturer of product:

Alkermes, Inc. 852 Winter Street Waltham, MA 02451-1420 1-937-382-5642



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