



**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, 15 mg/10 mg tablet, 65757-653-40**  
**7-count bottle, 15 mg/10 mg tablet, 65757-653-41 (Samples)**  
**30-count bottle, 15 mg/10 mg tablet, 65757-653-42**  
**90-count bottle, 15 mg/10 mg tablet, 65757-653-44**

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

Date when this product was manufactured:

Alkermes products are marked with a unique lot number which can be used to identify the date of manufacturing by contacting the Director, Quality Assurance.

U.S. Manufacturer of product:

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



©2021 Alkermes, Inc. All rights reserved.

ALKERMES® is a registered trademark of Alkermes, Inc. and

LYBALVI® is a registered trademark of Alkermes Pharma Ireland Limited, used by Alkermes, Inc., under license.