

## Statement of GMP Compliance

AndersonBrecon Inc., an Illinois Corporation doing business as "PCI of Illinois" located in Rockford, Illinois, is engaged in the packaging and labeling of pharmaceutical products. AndersonBrecon Inc., is registered with the U.S. Food and Drug Administration as follows:

|                                                 |                                                                                                                                     |
|-------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------|
| FDA Facility Establishment Identifier (FEI No.) | 1421377                                                                                                                             |
| DUNS number                                     | 05-321-7022                                                                                                                         |
| Last Satisfactory FDA Inspection                | March 20-24, 2017 (No FDA 483 Issued)                                                                                               |
| Location of Facility                            | AndersonBrecon Inc.<br>4545 Assembly Drive<br>Rockford, IL 61109, USA                                                               |
| Authorized Official                             | Sheri Mace<br>Executive Director, Quality                                                                                           |
| Contact Information                             | Phone: (815) 484- 2167<br>Fax: (815) 484-8901<br>E-mail: <a href="mailto:Sheri.Mace@pciservices.com">Sheri.Mace@pciservices.com</a> |

AndersonBrecon Inc. certifies that the methods and controls used for the packaging of the drug product are in conformance with all applicable requirements of the U.S. Food, Drug, and Cosmetic Act and specifically the Code of Federal Regulations, Title 21, Parts 210 and 211 for Current Good Manufacturing Practices, and with all applicable local and state regulations.

|                     |                                                                   |
|---------------------|-------------------------------------------------------------------|
| Dosage Forms:       | -Solid Dosage, Semi-Solid Dosage<br>-Liquid Dosage, Powder Dosage |
| Packaging operation | Primary/Secondary/Tertiary Packaging & Labeling                   |

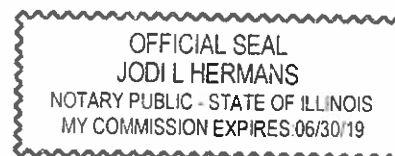
Under Section 306(a)(2) and (b)(1) AndersonBrecon Inc., hereby certifies that we have not and will not use in any capacity the services of any person debarred under section 306 of the U.S. Federal Food Drug and Cosmetic Act in connection with this application.

Kathryn Cavanaugh  
Kathryn Cavanaugh  
Regulatory Affairs Specialist

4/12/17  
Date

State of Illinois  
County of Winnebago

Signed and attested before me on 4/12/17 (date) by  
Kathryn Cavanaugh (name/s of person/s).



Jodi L Hermans  
(Signature of Notary Public)



4/12/2017

To Whom it May Concern:

The undersigned, Kathryn Cavanaugh, Regulatory Affairs Specialist at AndersonBrecon Inc., with packaging facilities located at 4545 Assembly Drive, Rockford, Illinois 61109 USA, attest that the Food and Drug Administration (FDA) located in the United States no longer issues paper forms as proof of drug establishment registrations, but instead uses the FDA website data as proof of a site's current registration/licensing. This information has been queried and retrieved from the FDA website, as shown in the attached document.

Sincerely,

*Kathryn Cavanaugh*

Kathryn Cavanaugh, Regulatory Affairs Specialist

State of Illinois  
County of Winnebago  
Signed and attested before me on 4/12/17 (date) by  
Kathryn Cavanaugh (name/s of person/s).

*Jodi L Hermans*  
(Signature of Notary Public)

