

# WHEATON Industries Inc.

1501 North 10th Street  
Millville, NJ 08332  
1.800.225.1437

## Certificate of Compliance

<b>Certification Date:</b> 11/3/16	<b>Lot/Batch #:</b> SAMPLE C OF C FOR CUSTOMER- NO BATCH/LOT AVAILABLE AT THIS TIME.
<b>Customer:</b> Dutscher	<b>PO #:</b> SAMPLE C OF C FOR CUSTOMER- NO PURCHASE ORDER # AVAILABLE AT THIS TIME.
<b>Wheaton Item #:</b> 224706	<b>Customer Item #:</b> SAMPLE C OF C- NOTE: ACTUAL C OF C SENT WITH SHIPMENT WILL INCLUDE CUSTOMERS PART NUMBER IF AVAILABLE TO WHEATON.
<b>Description:</b> 16 mL E-C Vial, Glass Type I Clr, No Cap	<b>Qty Shipped:</b> 000000 PCS/CASES
<b>USP/EP Test A Compliant (see note 2.e):</b> <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	

**Additional Information:** SAMPLE CERTIFICATE ONLY

### Certificate of Compliance:

In accordance with applicable cGMP's, and Company requirements, Wheaton Industries, Inc. hereby certifies with respect to the Wheaton manufactured item described above (collectively, the "Product") that:

- Product has been given appropriate visual, and/or mechanical and/or electronic inspection and the results of these inspections indicate that the product meets all agreed upon contractual specifications at the time of its shipment.
- Glass:** We certify that glass product will meet the following:
  - TYPE I Borosilicate Glass** - Product meets the requirements for the glass grain test limits for Type I Glass when tested according to the current revisions of the USP <660> and EP3.2.1 Pharmacopeias.
  - Arsenic Extraction** - Product will meet the requirements as described in the current revisions of USP <660> and EP3.2.1 Pharmacopeias for Arsenic Extraction.
  - TYPE III Soda Lime Glass** - Product meets the requirements for the glass grain test limits according to the current revisions of the USP <660> and EP3.2.1 Pharmacopeias.
  - Amber Glass** - Product conforms to the light transmission limits specified in the current revision of the USP and EP Pharmacopeias.
  - Hydrolytic Resistance** when indicated above this product conforms to the current revisions USP <660> Surface Test and EP 3.2.1.A - Test for surface hydrolytic resistance.
  - Heavy Metals** are not intentionally added to the glass compositions. Thus Contents of lead, cadmium, mercury and hexavalent chrome are in compliance with the limit values of 100 parts per million by weight for US (TPCH and CONEG) and EC regulations.
  - Transmissible and Bovine Spongiform Encephalopathy (TSE/BSE)** We certify that containers made from glass are free of any nonconforming animal derivatives.
- Plastic:** We certify that product made from resin material has been manufactured under controlled conditions and is in compliance with all applicable procedures and specifications.
- Rubber:** We certify that product made from rubber has been manufactured under controlled conditions and is in compliance with all applicable procedures and specifications.
- Aluminum:** We certify that product made from aluminum has been manufactured under controlled conditions and is in compliance with all applicable procedures and specifications.

### Certificate of Compliance authorized by:



**Date:** 11/3/16

**Quality Inspector**

In the event of questions regarding this C of C, please contact the **Customer Service Department** at (800) 225-1437.