West Pharmaceutical Services, Inc.
1028 Innovation Way
Kinston, NC 28504
www.westpharma.com

# QUALITY CERTIFICATE



**No. 80 - 000010**

| | | |
|---|---|---|
| **Customer:** | **Customer Item No:** | **Customer Order No:** |
| **Drawing No - Rev:** | **Customer Specification Number** | **Quantity:** |
| **Item Designation / Material Description:**<br>*West Product Id:* | | |
| **West SAP No** | **Master Lot #:** | |



| | |
|---|---|
| **Date:** | **QA Department Name/Plant:** |

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# QUALITY CERTIFICATE



**No. 802 - 000010**

## Compliance Statements

**West Pharmaceutical Services, Inc. (West) certifies that all the lots of material listed on this certification have been manufactured according to current Good Manufacturing Practices and are made in accordance to the referenced specification along with any conditions that may be noted in the customer specification review. If a customer specification has not been approved by West, the lots of material will be manufactured, inspected, and packaged to the previously agreed customer specification. If a customer specification has not been provided, the applicable West Master Specification will apply.**

**This item is distributed by West; please refer to the attached supplier certificate for product conformance statements.**

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# QUALITY CERTIFICATE



**No. 802 - 000010**

## Batch / Lot Identification

| S.No. | Batch/Lot Number | Manufacturing Date | Batch Specific Information |
|---|---|---|---|
| 1 | | | |

# *Certificate of Compliance*

**INSERT ADDRESS of Finished Goods Manufacturing Site**

**Corning Item Number:** **XXXXX**

**Product Description:** **Corning Valor® RTU Vials with SG EZ-Fill® Technology**
**XX.XX x X.XX x XX.XX XXBB, chemically strengthened, externally coated, terminally sterilized**

**Lot Number:** **XXXXXXXX**

**Start Date of Sterilization**: DD-MM-YYYY

**TSE/BSE:**
This product does not contain materials of animal origin.

**Tubing:** **Item Code XXXXX**
Location: City, State, Country
Arsenic is not introduced in the glass batch preparation formula. **Test results:** NON-DETECTABLE
Content of Pb, Cd, Hg, Cr VI is considerably below the combined limit values of 100 ppm (parts per million) by weight for US CONEG / TPCH and 94/62/EC regulations. Pb, Cd, Hg, Cr VI compounds are not introduced to the glass.

**Converting:** **Item Code XXXXX**
Location: City, State, Country
Converted lots comply with the prescribed internal limits for hydrolytic resistance following method in USP <660> (Surface Glass Test). The heavy metal content extracted from Valor vials in accelerated development testing were well below USP <232> limits.

**Chemical Strengthening and Coating** **Item Code: XXXXX**
**Location: City, State, Country**

**Specifications:**
The above mentioned lot has been produced in compliance with cGMP per ISO 15378:2017. Vial dimensions are sampled during incoming acceptance testing per ANSI/ASQ Z1.4 S-2; critical dimensions per applicable drawings are controlled to an AQL of 0.4, and other toleranced dimensions are controlled to an AQL of 4 or 10 for tooled controlled angles. Each manufacturing lot is sampled and tested in accordance with Standard Operation Procedures and has been released by Quality Assurance for conformance with specifications including ion exchange, external coating, manual visual inspection per ISO 2859-1 and ANSI/ASQ Z1.4 General Level 2 Single Normal sampling plans, Hydrolytic Resistance per EP 3.2.1 (Test A. Surface Test) and USP <660> (Surface Glass Test) limits for Type I glass. The glass tubing conforms to JP 7.01 Test for Glass Containers for injections, (3) Soluble Alkali test, Method 1.

The components and packaging material included in this shipment meet the material and formulation specified; materials and lots were evaluated using process control methods for it's manufacture and have been approved for the inspection process in compliance with the specification of product classification of defects and acceptable quality levels. The glass vials were subject to a terminal ethylene oxide sterilization process..

The vials meet the permitted maximum residual levels of ethylene oxide in accordance with standard EN ISO 10993-7:2008/AMD 1:2019 "Ethylene Oxide Sterilization Residuals"

| COMPOUND | RESIDUAL |
|---|---|
| Ethylene Chlorohydrin (ECH) | No more than 9.0 mg/Dev (GC) |
| Ethylene Oxide | No more than 4.0 mg/Dev (GC) |

We certify that the material meets the sterilization process conformance, EN ISO 11135-1 current edition and an SAL of $10^{-6}$.
We certify that the material meets the test of bacterial endotoxins under the LAL method in accordance with USP <85> current edition resulting in no more than 0.125 UE / mL.

Quality Manager