

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

QUALITY CERTIFICATE

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No. 80 - 000010

Customer:	Customer Item No:	Customer Order No:
Drawing No - Rev:	Customer Specification Number	Quantity:
Item Designation / Material Descrip	tion:	
West Product Id:		
West SAP No	Master Lot #:	

Date: QA Department Name/Plant:



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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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Batch / Lot Identification

S.No.	Batch/Lot Number	Manufacturing Date	Batch Specific Information		7		
1							



CORNING | Valor® RTU Vials

with SG EZ-fill® Technology

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"

<u>COMPOUND</u> <u>RESIDUAL</u>

Ethylene Chlorohydrin (ECH)

Ethylene Oxide

No more than 9.0 mg/Dev (GC)

No more than 4.0 mg/Dev (GC)

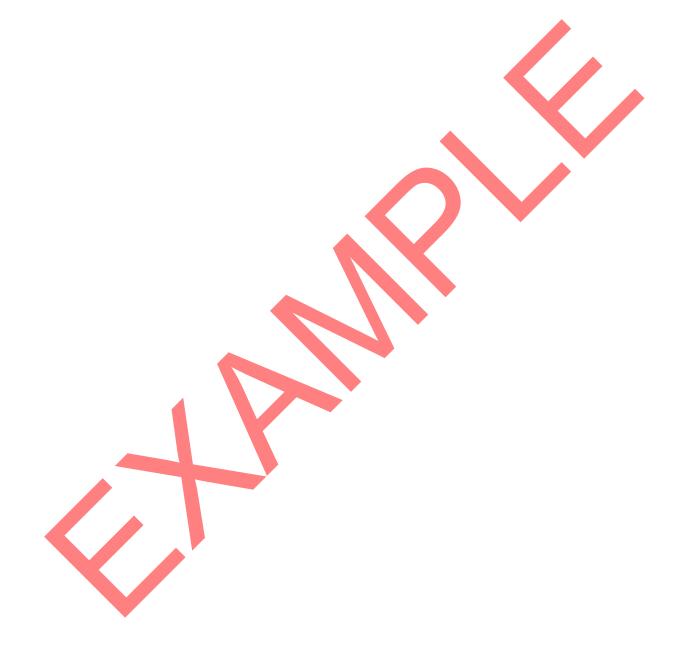
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We certify that the material meets the sterilization process conformance, EN ISO 11135-1 current edition and an SAL of 10^{-6} . We certify that the material meets the test of bacterial endotoxins under the LAL method in accordance with USP <85> current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

Quality Manager



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