Certificate of Conformity

Article no.	Retrace Code/Batch/Lot no.
225328	0000000843

Article description
0.3 ML LVI VIAL, AMB ABC W/PATCH

Additional Information:

In accordance with applicable ISO 9001, cGMP's, and Company requirements, DWK Life Sciences, LLC hereby certifies with respect to the manufactured item described above (collectively, the "Product") that:

1. 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.
2. **Glass:** We certify that glass product will meet the following:

   a) **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.
   b) **Arsenic Extraction** - Product will meet the requirements as described in the current revisions of USP <660> and EP3.2.1 Pharmacopeias for Arsenic Extraction.
   c) **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.
   d) **Amber Glass** - Product conforms to the light transmission limits specified in the current version of the USP and EP Pharmacopeias.
   e) **Hydrolytic Resistance** - when indicated above this product conforms to the current version of USP <660> Surface Test and EP 3.2.1.A – Test for surface hydrolytic resistance.
   f) **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.
   g) **Transmissible and Bovine Spongiform Encephalopathy (TSE/BSE)**- We certify that containers made from glass and accompanying plastic caps are free of any nonconforming animal derivatives.
3. **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.
4. **Rubber:** We certify that product made from rubber has been manufactured under controlled conditions and is in compliance with all applicable procedures and specifications.
5. **Aluminum:** We certify that product made from aluminum has been manufactured under controlled conditions and is in compliance with all applicable procedures and specifications.

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

Certified by: Donna L. Bauer
Quality Inspector

Date: 2019-03-05

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