

Corning Incorporated - Life Sciences
Avenida Industrial del Norte S/N
Parque Industrial del Norte
Reynosa TAMP 88736 MEX
www.corning.com/lifesciences
Refer to website for regional contact information.

Page: 1 / 1

Product Name	: VIAL CAP INSERT,RBW,NS,BK,50/	Manufacture Date	: 2018-12-07
Catalog Number	: 430499		
Lot ID	: 34118125		
Expiration Date	: Unconfirmed Validity		

Quality Management System - Complies with the current version of the ISO 9001 Standard and the FDA CFR 21 Part 820, current Good Manufacturing Practices (cGMP).

BSE/TSE - Product complies with the latest revision of EMA/410/01 "Note for Guidance on minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products" by virtue of all bovine derived material having been processed per specific conditions of section 6.4 of EMA/410/01.

Non-Pyrogenic - Tested and met the criteria established in the current version of ANSI/AAMI ST 72, "Bacterial Endotoxins - Test methodologies, routine monitoring, and alternatives to batch testing" and USP <85>, "Bacterial Endotoxins Test". The acceptance level for product is ≤ 0.10 EU/ml or ≤ 4 EU/device.

USP Class VI Testing - All material resin is tested, qualified and shown to be non-toxic as established in the Standards USP Class VI Chapter<87>, "Biological reactivity Tests, in Vitro" and Chapter<88>, "Biological Reactivity Tests, in vivo".

DNase/RNase Free - Tested by nuclease assay method and found to be free of detectable DNase/RNase contamination. The assay detection limit is 10^{-7} Kunitz units/uL for DNase and 10^{-9} Kunitz units/uL for RNase.

Quality Control Testing - Representative production samples are collected and inspected in accordance with current applicable product specifications. Inspection records are reviewed and approved by qualified personnel for product release. Key inspections and inline tests are listed below:

Visual Inspection - Pass
Functional Test - Pass

- This product met Corning Incorporated - Life Sciences' high standards of quality at the time of batch/lot release.



JOSE DOMINGUEZ
Quality Manager