Quality Certificate

VWR® SQUARE PETG MEDIA BOTTLES

As per the manufacturer, the below mentioned product meets the following Criteria.

North American Catalog Number:	89095-292
Lot Number:	060216C
Description:	VWR BOTTLE PETG ST 1000ML PK12
Production Date:	February 16, 2017
Expiration Date:	4 years post sterilization
Date of Irradiation:	Jan 11, 2016
Country of Origin:	Taiwan. Molded with US manufactured resin

Non-Toxin Leaching Resin: This product was manufactured in a class 10,000 cleanroom using FDA compliant SK SKYGREEN S2008 resin. This product is deemed particle free.

Component Materials Toxicity: All component materials have been tested and met the requirements for United States Pharmacopoeia (USP) Class VI Biological Test for Plastics, current edition. The materials also pass the requirements of the MEM elution Cytotoxicity Procedure utilizing WI 38 or MRC5 cell lines. The plastics meet the requirements of the United States Food and Drug Administration (FDA) for food and beverage contact in 21 CFR 177.1640.

Heavy Metals: The resins used in the manufacture of PETG Media Bottle do not require reporting under the Superfund Amendment and Reauthorization Act (SARA) Title III Section 313. They would pass Toxicity Characteristic Leaching Procedure (TCLP) testing.

Lot Criteria: *The manufacturing lot was sampled, tested and released by Quality Assurance at the Manufacturer for the following characteristics:*

Sterilization: Product has been gamma irradiated and dosimetrically released based upon U.S. Association for the Advancement of Medical Instrumentation (AAMI) Recommended practices. Gamma sterilized to SAL 10^{-6}, RNase-free, Dnase free, DNA-free, and Non-pyrogenic.

Pyrogens: An extract from the lot contained < 0.005 EU/ml per the Limulus Amebocyte Lysate (LAL) test method in the FDA Guidelines on Validation Of The Limulus Amebocyte Lysate Test As an End Product Endotoxin Test for Human and Animal Parenteral Drugs, Biological Products, And Medical Devices, December 1987.

Audit Criteria: Audit Criteria tests are conducted on a routine basis as Appropriate for each product configuration manufactured.

Bioburden: Samples were evaluated to determine the viable microbial Bioburden of the product prior to sterilization.

The product above is for research use only, not for invitro diagnosis or parenterals.

Signed:

Linda K. Shine
Manager - Supplier Qualification
Global Compliance
VWR International LLC

Date: 05/08/2018