

Certificate of Conformity

VWR Catalogue Number	See List
Description	Round Carboys with Narrow neck and purple screw caps
Country of Origin	Manufactured in India
Date of Issue (yyyy-mm-dd)	2022-11-04

LDPE carboys

Catalogue Number	Capacity [L]	Type	Neck I – Ø [mm]	Thread [mm]
216-1704	10	Non Sterile	65	83
216-1918	15	Non Sterile	65	83
216-1706	20	Non Sterile	65	83
216-1908	25	Non Sterile	65	83
216-1738	50	Non Sterile	65	83

HDPE carboys

Catalogue Number	Capacity [L]	Type	Neck I – Ø [mm]	Thread [mm]
216-1736	10	Non Sterile	65	83
216-1737	20	Non Sterile	65	83
216-1729	20	Sterile	65	83
216-2180	50	Non Sterile	65	83

PP carboys

Catalogue Number	Capacity [L]	Type	Neck I – Ø [mm]	Thread [mm]
216-1703	10	Non Sterile	65	83
216-1701	20	Non Sterile	65	83
216-1702	50	Non Sterile	65	83

Replacement Caps

Catalogue Number	Description	Cap Size [mm]	Colour
216-1840	Cap for narrow mouth VWR® carboys	83	Purple
216-1841	Cap for wide mouth VWR® carboys	100	Purple

Quality System Compliance

Products are manufactured under the **ISO 9001:2015 & ISO 13485:2016** standard. Products are inspected and controlled through whole production processing in accordance with current applicable product specifications and QC SOP.

QC Testing

Representative products samples are collected and inspected in accordance with current applicable QC requirements.

Test Name	Test Reference	Accuracy	Result
Leak Test	QWI-QC-04	General Insp. Level-1, AQL -1.5	Leak Proof
Autoclaving	QWI-QC-07	General Insp. Level-1, AQL -1.5	NA
Dimensional	QSF-QCIR-03	General Insp. Level-1, AQL -1.5	Within Tolerance

For Carboys Cap

Test Name	Test Reference	Accuracy	Result
Leak Test	QWI-QC-19	General Insp. Level-1, AQL -1.5	Leak Proof
Autoclaving	QWI-QC-07	General Insp. Level-1, AQL -1.5	PASS
Dimensional	QSF-QC-23	General Insp. Level-1, AQL -1.5	Within Tolerance

Product Specifications

Material	Carboy High Density Polyethylene (HDPE), Low Density Polyethylene (LDPE) or Polypropylene (PP)		
	Closure Polypropylene		
	Above material is 100% Virgin, Compliance with FDA 21 CFR, USP Class VI passed. Closure with Food grade colour.		
Temperature Resistance	High Density Polyethylene	-80 °C to +120 °C	
	Low Density Polyethylene	-80 °C to +80 °C	
	Polypropylene	0 °C to +135 °C	

Sterilization	Product labelled as sterile is Gamma irradiated as per ISO 11137 and meets a minimum requirement of 10 ⁻⁶ SAL with a minimum specified dose of 15 kGy.
ATP Assay	Not Applicable.
DNase & RNase Free	Not Applicable.
BSE/TSE	No use of any raw material produced from or substances derived from animal origin. The manufacturing process of the product does not use any ingredient of animal origin and no material derived from or exposed to animals affected by or under quarantine for transmitting Animal Bovine Spongiform Encephalopathy/Spongiform Encephalopathy (BSE)/(TSE).
Cytotoxicity	Not Applicable.
Non-Pyrogenic Statement	Not Applicable.
Latex Statement	This product is not made from natural rubber latex.
BPA Statement	Bisphenol are not used in the manufacture of the raw material and are not expected to be present.
DEHP Statement	Please see RoHS information below.
RoHS	No substances (Lead, Cadmium, Mercury, Hexavalent Chromium (Cr6+), Poly Brominated Biphenyls (PBB), Poly Brominated Diphenyl ethers (PBDE), Bis(2-Ethyhexyl) Phthalate (DEHP), Benzyl Butyl Phthalate (BBP), Dibutyl Phthalate (DBP), Diisobutyl Phthalate (DIBP)) are used in manufacturing the raw materials and final product. No routinely analyse is performed.
REACH Statement	No substances as listed on >Substance of Very High Concern< candidate list published 2022-06-10 are used in manufacturing of the raw materials used to produce this product. No routinely analyse is performed.
Extractable and Leachable	The product has been manufactured using drug master file listed and USP class VI passed virgin raw material and without adding any additives, resulting in high purity and avoiding any extractable or leachable. Pb, Cr, Co, Ni, As, Ca, Na, Zn and Hg found below detection level as tested.

Storage Conditions

Room temperature.

Shelf Life

5 years from date of manufacturing for sterile products, which is not applicable for non-sterile products.

Disclaimer: VWR states that this declaration will not discharge the user from their obligation to ensure the product is suitable for the intended use. The purpose of the product is for use in laboratory only.

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