Doc No – Ab/TDS/CC-101

Rev No: 05 Date 04/2023-24

# TECHNICAL DATA SHEET

Abdos Labtech Pvt. Ltd.

Media Bottles, PETG & PET

Valid for Catalog No. P21180, P21181, P21182, P21183, P21184, P21186, P21187, P211888, P21189, P21170, P21171, P21172, P21173, P21174, P21176, P21177, P21178, P21179, P21192, P21193, P21194, P21195, P21196

SRN (Single Registration Number): IN-MF-000022272

# 1. Description/Specification

1.1 Description: Media Bottles, PETG/PET, DNase, RNase, Human DNA, ATP, Pyrogen Free

**1.2 Design:** Square Bottles

# 1.3 Performance Specification:

- **1.3.1** ABDOS Media Bottle is manufactured with high quality PETG/PET that complies US FDA 21 CFR, free from heavy metals. Non-pyrogenic and non-cytotoxic to protect cells.
- **1.3.2** The Cap of the bottle is Screw cap made with HDPE (High Density Polypropylene), free of heavy metal.
- **1.3.3** These bottles come with embossed graduation on two sided.
- 1.3.4 These bottles are compatible to work in Temperature range from -80 °C to +60 °C
- **1.3.5** Volume range available from 60, 125, 250, 500 & 1000ml. Square shape easy to hold and saves shelf & counter space.

Code	Capacity (ml)	Сар	No. Per Case
P21180	Media Bottle, 60ml, Sterile, PETG	Yes	192
P21181	Media Bottle, 125ml, Sterile, PETG	Yes	96
P21182	Media Bottle, 250ml, Sterile, PETG	Yes	60
P21183	Media Bottle, 500ml, Sterile, PETG	Yes	48
P21184	Media Bottle, 1000ml, Sterile, PETG	Yes	24
P21186	Media Bottle, 125ml, Sterile, PET	Yes	96
P21187	Media Bottle, 250ml, Sterile, PET	Yes	224
P21188	Media Bottle, 500ml, Sterile, PET	Yes	120
P21189	Media Bottle, 1000ml, Sterile, PET	Yes	40



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Code	Capacity (ml)	Cap	No. Per Case
P21170	Media Bottle, 60ml, Non- Sterile, PETG	Yes	192
P21171	Media Bottle, 125ml, Non- Sterile, PETG	Yes	96
P21172	Media Bottle, 250ml, Non- Sterile, PETG	Yes	60
P21173	Media Bottle, 500ml, Non- Sterile, PETG	Yes	48
P21174	Media Bottle, 1000ml, Non- Sterile, PETG	Yes	24
P21176	Media Bottle, 125ml, Non- Sterile, PET	Yes	96
P21177	Media Bottle, 250ml, Non- Sterile, PET	Yes	224
P21178	Media Bottle, 500ml, Non- Sterile, PET	Yes	120
P21179	Media Bottle, 1000ml, Non- Sterile, PET	Yes	40

Code	Capacity (ml)	Cap	No. Per Case
P21192	Media Bottle, 60ml, Sterile, PETG	Yes	192
P21193	Media Bottle, 125ml, Sterile, PETG	Yes	80
P21194	Media Bottle, 250ml, Sterile, PETG	Yes	60
P21195	Media Bottle, 500ml, Sterile, PETG	Yes	48
P21196	Media Bottle, 1000ml, Sterile, PETG	Yes	40

### 1.4 Material:

- 1.4.1 **Bottle**: Polyethylene terephthalate glycol (PETG) & Polyethylene terephthalate (PET), Hydrophobic **Cap**-HDPE, High Density Polypropylene, Hydrophobic, confirm US FDA 21CFR
- 1.4.2 Complies with the requirement of European Pharmacopoeia, Plastic Containers and closures for Pharmaceutical use.
- 1.4.3 The product has passed the USP testing including class VI tests ,Materials has successful passed the biological tests according to ISO 10993 external communication devices for indirect blood contact for Prolonged period.
- 1.4.4 Free from Heavy metals, RoHS Free according to meets relevant requirements of EU regulations1935/2004/CE ,2002/95/EC as amended, UE 10/2011 as amended. EU CONEG & it's following amendments. It is safe use in contact with food stuff, Pharmaceuticals & drinking water
- 1.4.5 Product is manufactured without the use of Raw Materials of animal origin. Therefore BSE/TSE issue does not concern this product to the best of our Knowledge. No materials containing latex or natural rubber are used in the Manufacturing, handling & packaging process for this product.



1.5 Color: Natural

#### 1.6 Sterilization:

Sterile catalog number from this lot have been pre-sterilizes and dosimetrically released based on ANSI/AAMI/ISO 11137 *Sterilization of healthcare products-Requirements for validation and routine control-Radiation sterilization.* The product has been sterilized with Co-60 Gamma Radiation. SAL 10<sup>-6</sup>

# 1.7 Quality control:

Product are manufactured, inspected and found to be in compliance with product & quality specification requirements as documented in ISO 9001:2015 & 13485:2016 Quality Management System. Testing of various characteristics in accordance with the valid specification, inspection reviewed & signed for product release.

## 1.8 Basic Features

**1.8.1 Bottle**: PETG/PET Hydrophobic Cap- HDPE

**1.8.2 Temperature range:**  $-80^{\circ}$ C to  $+60^{\circ}$ C

**1.8.3** Autoclavability: NA, Available in Gamma Sterile & Non Sterile options.

**1.8.4 Chemical resistance:** See website (www.abdoslifesciences.com)

**1.8.5** Manufactured in Clean room ISO Class 8 (100,000)

## **Instruction for Use**

Product can be used for food contact also.

Storage temp. Max 30°C

Before using the product check crackness, pouch punctured etc.

Check all the information printed on pouches or boxes.

Always wear gloves while handling specimen.

#### **WARNING**

**DO NOT** store strong oxidizing agents.

**DO NOT** place any plastic labware in a flame.

**DO NOT** mix any chemicals that may result in a thermic reaction, which can cause product failure Consult local fire codes prior to storage of flammable liquids.



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Quality Manager

Abdos Labtech Private Limited

Employee Code 30110











1000 ml

500 ml

250 ml

125 ml

60 ml



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