

# Technical Data Sheet

Doc No – Ab/TDS/CC-98

Rev No : 03 Date 04/2023-24

## TECHNICAL DATA SHEET

**Abdos Labtech Pvt. Ltd.**

**Roller Bottles, PS**

**Valid for Catalog No. P21060, P21061, P21062, P21063, P21064, P21065, P21066, P21067, P21068, P21069**

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

### 1. Description/Specification

**1.1 Description:** Roller Bottles, PS, DNase, RNase, Human DNA, ATP , Pyrogen Free

**1.2 Design:** Bottles

#### 1.3 Performance Specification:

**1.3.1** ABDOS Roller bottles are made from the highest quality Polystyrene suitable for high yield of cell growth and multiplication.

**1.3.2** These bottles are available in 3 volumes of 1000ml, 2000ml, and 5000ml with wide cell growth area of 490cm<sup>2</sup>, 850cm<sup>2</sup>, 1900cm<sup>2</sup> for adhesions and huge growth volume for cell suspension.

**1.3.3** These bottles are designed with large knurls on the cap for easy grip and to prevent slip during process.

**1.3.4** These bottles have silk-printed graduation for easy identification.

**1.3.5** Suitable for all the general instruments and automation used in tissue/ cell culture technique.

Code	Capacity (ml)	Cap Style	Cell Growth Area (cm <sup>2</sup> )	Media Volume (ml)	Surface Treated	No. Per Case
<b>P21060</b>	1000	Sealed	490	100-150	Yes	24
<b>P21061</b>	1000	Vent	490	100-150	Yes	24
<b>P21062</b>	1000	Sealed	490	100-150	NO	24
<b>P21063</b>	1000	Vent	490	100-150	NO	24
<b>P21064</b>	2000	Sealed	850	180-260	Yes	12
<b>P21065</b>	2000	Vent	850	180-260	Yes	12
<b>P21066</b>	2000	Sealed	850	180-260	NO	12
<b>P21067</b>	2000	Vent	850	180-260	NO	12
<b>P21068</b>	5000	Sealed	1900	300-400	Yes	12
<b>P21069</b>	5000	Vent	1900	300-400	Yes	12



Abdos Labtech Private Limited  
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## 1.4 Material:

1.4.1 Made up with Polystyrene (PS), 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 successfully 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 regulations 1935/2004/CE, 2002/95/EC as amended, UE 10/2011 as amended. EU CONEG & its 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** : Green

## 1.6 Sterilization:

Sterile catalog number from this lot have been pre-sterilized 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  $10^{-6}$

## 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 Made up of Polystyrene (PS)

1.8.2 Temperature range:  $-10^{\circ}\text{C} + 70^{\circ}\text{C}$

1.8.3 Autoclavability: NO

1.8.4 Chemical resistance: See website ([www.abdoslifesciences.com](http://www.abdoslifesciences.com))

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

## Autoclaving Guideline for Plastics

All plastic consumables are autoclavable at  $121^{\circ}\text{C}$  for 20 minutes, 15 psi/1atm. Do not use a dry cycle as this may cause deformation or weakening of the plastic. Allow temperature within the autoclave to return to at least  $50^{\circ}\text{C}$  before removing product.



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
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## 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.  
Do Not use in liquid nitrogen.

**STERILE R**  30°C

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 Electronic IFU

Quality Manager

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