# Technical Data Sheet

Doc No – Ab/TDS/Cryo-21

Rev No: 06 Date 01/2021

## TECHNICAL DATA SHEET

Abdos Labtech Pvt. Ltd.

Freezing Tubes Sterile, PP

Valid for Cat. No. P60102, P60103

## 1. Description/Specification

**1.1 Description:** Freezing Cryo vials, DNase, RNase, Human DNA, ATP & Pyrogen Free, IVD certified

## 1.2 Design:

- 1.2.1 Vials: Cylindrical External Threads with Self standing, Round Bottom (PP)
- 1.2.3 Cap: separate Cap with threads (HDPE)

## 1.3 Performance Specifications:

- 1.3.1 Vial Volume: 1.8 ml and  $4.5 \pm 0.1$  ml
- 1.3.2 Vial Size: 11.80 x 45.7 mm (P60102), 11.80 x 86.5 mm (P60103),

Cap Size : 13.2 mm (φ)

## 1.3.3 Graduation and writing surface:

- 1.3.3.1 Large Printed Graduation
- 1.3.3.2 White Patch for easy writing on the tube

### 1.4 Material:

- 1.4.1 **Tube**: Polypropylene (PP), Hydrophobic **Cap**-HDPE
- 1.4.2 Polypropylene (PP), Hydrophobic, confirm US FDA 21CFR
- 1.4.3 Complies with requirement accordance with article of regulation (EC) No. 1907/2006 and its amendments.
- 1.4.4 Complies with the requirement of European Pharmacopoeia, 7<sup>th</sup> edition (2011) & its supplements 7.5 (07/2012) monographs 3.2.2 Plastic Containers and closures for Pharmaceutical use.
- 1.4.5 The product has passed the USP testing including class VI tests & has been assigned the FDA Drug master file DMF 12123
- 1.4.6 Materials has successful passed the biological tests according to ISO 10993 external communication devices for indirect blood contact for Prolonged period.



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**An ISO 9001 ,13485, 14001 & CE Certified**A Division of Abdos **GST :** 05AAGCA8605A1Z7

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CIN: U85100WB2008PTC123903

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- 1.4.7 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
- 1.4.8 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:

Translucent (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 Other information:

Recommended for single use only

**Vial Pack Size:** 1000 pieces/case (P60102) & 500 pieces/case (P60103)

- 2. Basic Features
- **2.1 Temperature range:** Tube: -80  $^{0}$ C to + 121  $^{0}$ C (Can withstand in liquid nitrogen with standard procedure, recommended to store in vapor phase of liquid nitrogen).
- **2.2 Autoclavability:** Autoclavable at 15 psi and 121 <sup>o</sup>C for 20 minutes
- 2.3 Leak Test at 635 mm Hg with Cap fitted: No leakage
- **2.4** Manufactured in Clean room ISO Class 8 (100,000)
- **2.5 Chemical resistance:** see website (www.abdoslifesciences.com)



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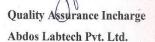
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### **Autoclaving Guideline for Plastics**

ROORKE

All plastic consumables are autoclavable at 121°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°C before removing product.





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