

# Technical Data Sheet

Doc No – Ab/TDS/Cryo-23

Rev No: 02 Date 01/2021

## TECHNICAL DATA SHEET

**Abdos Labtech Pvt. Ltd.**

**Cryo Vial External Threaded Sterile, PP**

**Valid for Cat. No. P60115, P60116, P60117, P60118**

### **1. Description/Specification**

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

#### **1.2 Design:**

1.2.1 Vials : Available in Star Foot, Round Bottom with External Thread

1.2.3 Cap: Separate Cap with threads.

#### **1.3 Performance Specifications:**

1.3.1 Vial Volume: 1.0 ml, 1.8 ml and 4.5 ( ± 0.1 ml)

##### **1.3.1 Graduation and writing surface:**

1.3.1.1 Large Printed Graduation

1.3.1.2 White Patch for easy writing on the tube

<b>Code</b>	<b>Capacity (mm)</b>	<b>Outer Diameter (mm)</b>	<b>Height</b>	<b>No. Per Case</b>	<b>Self-Standing</b>	<b>Bottom</b>
P60115	1.0	12.00	41.00	1000	Yes	Star Foot
P60116	1.8	12.00	48.5	1000	Yes	Star Foot
P60117	1.8	12.00	47.5	1000	No	Round
P60118	4.5	11.80	86.5	500	Yes	Star Foot

#### **1.4 Material:**

1.4.1 **Tube:** Polypropylene (PP), Hydrophobic **Cap**-HDPE

1.4.2 Confirm US FDA 21CFR



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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.

1.4.7 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 & 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  $10^{-6}$

## 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 Other information:

Recommended for single use only

## 1.9. Basic Features

**1.9.1 Temperature range :** Tube : -196 °C to + 121 °C (Can withstand in liquid nitrogen with standard procedure, recommended to store in vapor phase of liquid nitrogen).



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**1.9.2 Autoclavability:** Autoclavable at 15 psi and 121 °C for 20 minutes (Caps & Vials)

**1.9.3 Leak Test at 635 mm Hg with Cap fitted:** No leakage

**1.9.4** Large White frosted portion for easy writing & silk screen accurate graduation for sample identification.

**1.9.5** These cryo vial are designed for mechanical freezing and screw cap reduces risk of contamination due to handling.

**1.9.6** Star Foot Bottom base helps in single hand operation.

**1.9.7** Secure tamper evident packaging along with self-stand Zipper pouch.

**1.9.8** No discolorization after re sterilizing.

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

**2.0 Chemical resistance:** see website ([www.abdoslifesciences.com](http://www.abdoslifesciences.com))

## Autoclaving Guideline for Plastics

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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