

Technical Data Sheet

Doc No – Ab/TDS/Cryo-27

Rev No: 04 Date 02/2022-23

TECHNICAL DATA SHEET

Abdos Labtech Pvt. Ltd.

Cryo Vial External Threaded Sterile, PP

Valid for Cat. No. P60115, P60116, P60117, P60118, P60116A, P60122, P60123

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: Assembled

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

Code	Capacity (ml)	Outer Diameter (mm)	Height	No. Per Case	Self-Standing	Bottom	Brimful Capacity (Approx ml)
P60115	1.0	12.00	41.00	1000	Yes	Star Foot	1.70
P60116	1.8	12.00	48.5	1000	Yes	Star Foot	2.50
P60117	1.8	12.00	47.5	1000	No	Round	2.50
P60118	4.5	11.80	86.5	500	Yes	Star Foot	5.30
P60116A	1.8	12.00	48.5	1000	Yes	Star Foot	2.50
P60122	4.5	11.80	86.5	500	Yes	Star Foot	5.30
P60123	4.5	11.80	86.5	500	Yes	Round Bottom	5.30



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1.4 Material:

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

1.4.5 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:

Translucent (Natural)

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 Other information:

Recommended for single use only

1.9. Basic Features

1.9.1 **Temperature range:** Tube: -196°C to $+121^{\circ}\text{C}$

* Caution: Do not use Abdos Cryogenic Vial in the liquid phase of liquid nitrogen. Improper use may cause liquified nitrogen to be trapped inside the vial and lead to pressure build up resulting in possible explosion or biohazard release. Can be used in vapour phase of liquid nitrogen.

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



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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)

Autoclaving Guideline for Plastics

All plastic consumables are autoclavable at 121⁰C 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 50⁰C before removing product.

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 Assurance Incharge
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P60115

P60116

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