Doc No – Ab/TDS/Cryo-24

Rev No : 03 Date 11/2019

TECHNICAL DATA SHEET

Abdos Labtech Pvt. Ltd.

Cryo Vial Internal Threaded Sterile with Silicon Seal, PP

Valid for Cat. No. P60108, P60109, P60110, P60112, P60113

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 Internal Thread

1.2.3 Cap: Separate Cap with threads (PP) along with Silicon Washer

1.3 Performance Specifications:

1.3.1 Vial Volume: 1.0 ml, 1.8 ml and 4.5 ($\pm$ 0.1 ml)

1.3.2 Vial Size :

Code	Capacity (mm)	Outer Diameter (mm)	Height	No. Per Case	Self Standing	Bottom
P60108	1.0	12.3	41.2	1000	Yes	Star Foot
P60109	1.8	12.3	47.5	1000	Yes	Star Foot
P60110	1.8	12.3	46.2	1000	No	Round
P60112	4.5	12.3	90.3	500	Yes	Star Foot
P60113	4.5	12.3	89	500	No	Round

1.4 Material:

1.4.1 Polypropylene (PP), Hydrophobic, confirm US FDA 21CFR

1.4.2 Complies with requirement accordance with article of regulation (EC) No. 1907/2006 and its amendments.

DOMINIQUE DUTSCHER SAS

ABDOS

Shiv Ganga Industrial Estate,
Plot no.1 Lakeshwari, Bhagwanpur,
Roorkee – 247667 Uttrakhand, India
An ISO 9001 & 13485 Certified
A Division of Abdos

Regd. Office:
13A, Government Place (East)
Kolkata – 700069, India
CIN : U85100WB2008PTC123903
GST : 05AAGCA8605A1Z7

P : +91 (0) 1332 235277
E : labtech@abdosindia.com
W: www.abdoslifesciences.com

1.4.3 Complies with the requirement of European Pharmacopoeia, 7th edition (2011) & its supplements 7.5 (07/2012) monographs 3.2.2 Plastic Containers and closures for Pharmaceutical use.

1.4.4 The product has passed the USP testing including class VI tests & has been assigned the FDA Drug master file DMF 12123

1.4.5 Materials has successful passed the biological tests according to ISO 10993 external communication devices for indirect blood contact for Prolonged period.

1.4.6 Free from heavy metals according to ELV Direction 2000/53/EC, EU CONEG & it's following amendments. It is safe use in contact with food stuff, Pharmaceuticals & drinking water.

1.5 Color:

Translucent

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.

1.7 Quality control:

DNase, RNase, Human DNA, ATP & Pyrogen Free

Testing of various characteristics in accordance with the valid Process.

1.8 Other information:

Recommended for single use only

2. Basic Features

2.1 Temperature range : Tube : -196 ^{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 ^{0}C for 20 minutes (Caps & Vials)

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

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

2.5 These Cryo Vials have silicon washer 'O' ring for secure seal.

DOMINIQUE DUTSCHER SAS

ABDOS

Shiv Ganga Industrial Estate,
Plot no.1 Lakeshwari, Bhagwanpur,
Roorkee – 247667 Uttrakhand, India
An ISO 9001 & 13485 Certified
A Division of Abdos

Regd. Office:
13A, Government Place (East)
Kolkata – 700069, India
CIN : U85100WB2008PTC123903
GST : 05AAGCA8605A1Z7

P : +91 (0) 1332 235277
E : labtech@abdosindia.com
W: www.abdoslifesciences.com

2.6 Star Foot Bottom base helps in single hand operation.

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

2.8 No dicolorization after sterilizing.

2.9 Chemical resistance: See website.

Autoclaving Guideline for Plastics

All plastic consumables are autoclavable at 121^{0}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^{0}C before removing product.

Quality Assurance Incharge
Abdos Labtech Pvt. Ltd.

ABDOS LABTECH PVT. LTD. ROORKEE

DOMINIQUE DUTSCHER SAS

ABDOS

Shiv Ganga Industrial Estate,
Plot no.1 Lakeshwari, Bhagwanpur,
Roorkee – 247667 Uttrakhand, India
An ISO 9001 & 13485 Certified
A Division of Abdos

Regd. Office:
13A, Government Place (East)
Kolkata – 700069, India
CIN : U85100WB2008PTC123903
GST : 05AAGCA8605A1Z7

P : +91 (0) 1332 235277
E : labtech@abdosindia.com
W: www.abdoslifesciences.com