Doc No – Ab/TDS/Cryo-26

Rev No : 06 Date 11/2019

# TECHNICAL DATA SHEET

**Abdos Labtech Pvt. Ltd.**

**Storage Vial, PP**

**Valid for Cat. No. P60119, P60106, P60107, P60119A, P60119A1, P60106A, P60106A1, P60107A, P60107A1,P60120**

## 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: Cylindrical External Threads with Self standing, Round Bottom

1.2.3 Cap: separate Cap with threads

**1.3 Performance Specifications:**

1.3.1 Vial Volume: 1.0 ml (P 60119 – Natural, P60119A- amber, P60119A1- Tr. Amber)

1.3.2 Vial Volume: 2.0 ml (P 60106 – Natural, P60106A- amber, P60106A1- Tr. Amber)

1.3.3 Vial Volume: 5.0 ml (P 60107 – Natural, P60107A- amber, P60107A1- Tr. Amber)

1.3.4 Vial Volume: 2.0 ml (P 60120 – Natural, Sterile)

**1.4 Material:**

1.4.1 Polypropylene (PP), Hydrophobic, Complies with requirement of directive 2002/72/EC and requirement of FDA Regulation 21 CFR 177.1520. olefins polymers.

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

1.4.3 Complies with the requirement of European Pharmacopoeia, 7$^{th}$ 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

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ABDOS

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**Regd. Office:**
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& it's following amendments. It is safe use in contact with food stuff, Pharmaceuticals & drinking water.

**1.5 Color:**

Translucent, For Light Sensitive material – Amber & Transparent Amber color

**1.6 Quality control:**

DNase, RNase, Human DNA, ATP & Pyrogen Free, IVD certified

Testing of various characteristics in accordance with the valid specification

**1.7 Other information:**

Recommended for single use only

**Vial Pack Size :**

**For 5.0ml** 1000 pieces/case ( 4 Pouch x 250pcs tube + 1pouch x 1000pcs cap) = 1 case

**For 2.0ml** 1000 pieces/case ( 2 Pouch x 500pcs tube + 1pouch x 1000pcs cap) = 1 case

**For 1.0ml** 1000 pieces/case ( 2 Pouch x 500pcs tube + 1pouch x 1000pcs cap) = 1 case

**1.8. Basic Features**

**1.8.1 Temperature range:** Tube : -80 $^0$C to + 121 $^0$C

**1.8.2 Autoclavability :** Autoclavable at 15 psi and 121 $^0$C for 20 minutes

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

**1.8.4 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

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