

Technical Data Sheet

Doc No – Ab/TDS/Cryo-26

Rev No : 07 Date 01/2021

TECHNICAL DATA SHEET

Abdos Labtech Pvt. Ltd.

Storage Vial, PP

Valid for Cat. No. P60119, P60106, P60107, P60119A, P60119A1, P60106A, P60106A1, P60107A, P60107A1, P60120, P60107S

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, without Printed

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)

1.3.5 Vial Volume: 5.0 ml (P 60107S – Natural, Sterile)

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, 7th 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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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 & its 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, For Light Sensitive material – Amber & Transparent Amber color

1.6 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.

1.7 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 or Assembled with Cap & Tube

For 2.0ml 1000 pieces/case (2 Pouch x 500pcs tube + 1pouch x 1000pcs cap) = 1 case or Assembled with Cap & Tube

For 1.0ml 1000 pieces/case (2 Pouch x 500pcs tube + 1pouch x 1000pcs cap) = 1 case or Assembled with Cap & Tube

1.8. Basic Features

1.8.1 Temperature range: Tube : -80 °C to + 121 °C

1.8.2 Autoclavability : Autoclavable at 15 psi and 121 °C for 20 minutes

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

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

1.8.5 Chemical resistance: see website (www.abdoslifesciences.com)



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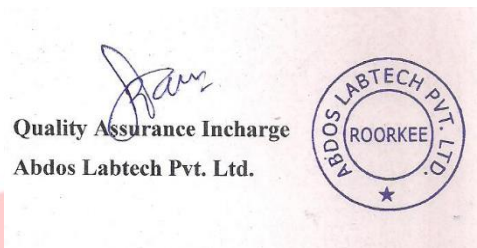
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2.0 Sterilization: For P60120 & P60107S

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}

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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