

Technical Data Sheet

Doc No – Ab/TDS/Cryo-25

Rev No : 02 Date 11/2019

TECHNICAL DATA SHEET

Abdos Labtech Pvt. Ltd.

Cryo Coders for External & Internal Threaded Vials, HDPE

Valid for Cat. No. P60114 W, P60114 B, P60114 R, P60114 Y, P60114 G

1. Description/Specification

1.1 Description: Freezing Cryo vials, DNase, RNase and Pyrogen Free

1.2 Design:

1.2.1 Vials: Cylindrical Cryo Coders for External & Internal Threaded Vials.

1.2.3 Cap: These coders fit onto the top of Abdos skirted foot cryogenic vial closures.

1.3 Performance Specifications:

1.3.1 Coders colour:	P60114 W – White	P60114 B – Blue
	P60114 R - Red	P60114 Y – Yellow
		P60114 G - Green

1.3.2 These provide quick visual identification.

1.4 Material:

1.4.1 High Density Polyethylene (HDPE), Hydrophobic

1.4.2 This material meets the FDA criteria Regulation 21 CFR 177.1520. olefins polymers.

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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An ISO 9001 & 13485 Certified
A Division of Abdos

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1.4.7 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: White, Blue, Red, Yellow, Green.

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 and Pyrogen Free

Testing of various characteristics in accordance with the valid Process.

1.8 Other information:

Recommended for single use only

Vial Pack Size : 100 pieces/case

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).

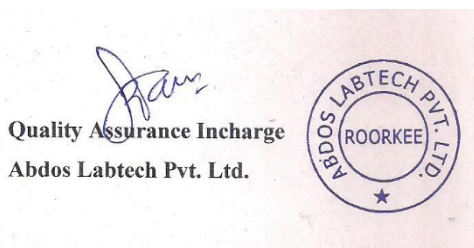
1.9.2 Autoclavability: Autoclavable at 15 psi and 121 °C for 20 minutes

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

1.9 4 Chemical resistance: see website

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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