### **Technical Data Sheet**

Doc No – Ab/TDS/Cryo-25

Rev No: 03 Date 01/2021

### 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 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, 7<sup>th</sup> 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.
- 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 &



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A Division of Abdos **GST**: 05AAGCA8605A1Z7

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CIN: U85100WB2008PTC123903

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it's 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:** White, Blue, Red, Yellow, Green.

1.6 Sterilization:

NA

#### 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

Vial Pack Size: 100 pieces/case

1.9. Basic Features

**1.9.1 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).

1.9.2 Autoclavability: Can be Autoclave

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

**1.9** 4 Chemical resistance: see website (www.abdoslifesciences.com)

#### **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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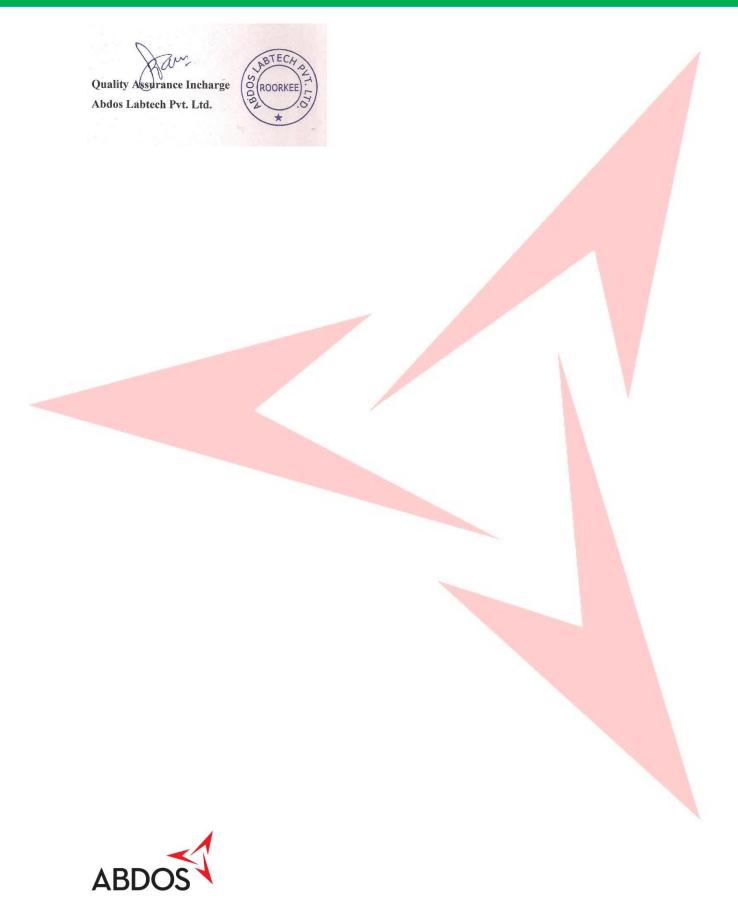
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