

Technical Data Sheet

Doc No – Ab/TDS/Cryo-25

Rev No : 04 Date 10/2021-22

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, 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.

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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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 °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: 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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