Technical Data Sheet

Doc No – Ab/TDS/Cryo-29 Rev No : 04 Date 01/2021

TECHNICAL DATA SHEET

Abdos Labtech Pvt. Ltd.

Cryo Box, system – 100 Place PC

Valid for Catalog No. P20611, P20615

1. Description/Specification

1.1 Description:

Reusable PC (Polycarbonate) cryo box

Used in Ultra low temperature for both internal & External thread cryogenic vials

1.2 Design:

Square Box with Transparent Marked Lid.

1.3 Performance Specification:

1.3.1 Capacity: 2.0 ml x 100 Places

1.3.2 Universal fit for 1.8 ml & 2.0 ml Cryo Tube respectively.

1.4 Material:

1.4.1 Polycarbonate (PC)

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.



Shiv Ganga Industrial Estate,RegdPlot no.1 Lakeshwari, Bhagwanpur,13A, GRoorkee – 247667 Uttrakhand, IndiaKolkatAn ISO 9001 ,13485, 14001 & CE CertifiedA Division of AbdosGST :

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CIN: U85100WB2008PTC123903

GST: 05AAGCA8605A1Z7

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1.4.7 Free from Heavy metals, RoHS Free according to meets relevant requirements of EU regulations1935/2004/CE ,2002/95/EC as amended, UE 10/2011 as amended. EU CONEG & 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:

Box : White, Yellow, Blue Color

Lid : Transparent (Natural) with Indication Mark for each Place which is printed on Top Lid

Intermediate Grill: White color, Blue color & Yellow color

Three colors available for better color coding

1.6 Sterilization:

Can be autoclaved at 15 psi, 121°C for 20 minutes

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:

Writing surface has Number Square for easy sample identification

2. Basic Features

2.1 Made up of High pure virgin Polycarbonate (PC)

2.1 Temperature range: -196° C to $+121^{\circ}$ C (Can Withstand in the vapor Phase of liquid nitrogen)

2.2 Autoclavability: Yes, Autoclavable at 15 psi and 121°C for 20 minutes

2.3 Easy Reference: Transparent lids allow for easy viewing of samples & location



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2.4 Self Draining: Each Box includes Drain hole in Base and Air vents in the Lid, Minimizing condensation.

- 2.5 Manufactured in Aseptic Environment
- 2.6 Chemical resistance: see website (<u>www.abdoslifesciences.com</u>)

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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