Technical Data Sheet

Doc No – Ab/TDS/Cryo-28

Rev No: 04 Date 01/2021

TECHNICAL DATA SHEET

Abdos Labtech Pvt. Ltd.

Cryo Box, PC

Valid For Cat. No. P20601, P20601A, P20602, P20602A, P20603, P20603A

1. Description/Specification

1.1 Description:

Reusable Cryo Box

1.2 Design:

Transparent lid permit viewing design having 25 & 81 Places

1.3 Performance Specifications:

Code	Capacity	Places
P20601	1 & 2 ml	25(5x5)
P20601A	1 & 2 ml	25(5x5)
P20602	1 & 2 ml	81(9x9)
P20602A	1 & 2 ml	81(9x9)
P20603	5 ml	81(9x9)
P20603A	5 ml	81(9x9)

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



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- 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 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:

White, Yellow, & Blue

1.6 Graduation and writing surface:

1.6.1 Large Printed Graduation

1.7 Sterilization:

NA

1.8 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.

1.9 Other information

Reusable

- 2. Basic Features
- **2.1 Temperature range:** -196° C to $+121^{\circ}$ C
- 2.2 Autoclavability: Yes, Autoclavable at 15 psi and 121°C for 15 minutes
- 2.3 Manufactured in Aseptic Environment
- **2.4 Chemical resistance:** see website (<u>www.abdoslifesciences.com</u>)



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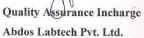
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Autoclaving Guideline for Plastics

All plastic consumables are autoclavable at 121°C for 15 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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