

Technical Data Sheet

Doc No – Ab/TDS/Cryo-28

Rev No : 03 Date 11/2019

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	Dimensions
P20601	1 & 2 ml
P20601A	1 & 2 ml
P20602	1 & 2 ml
P20602A	1 & 2 ml
P20603	5 ml
P20603A	5 ml

1.4 Material:

1.4.1 Polycarbonate (PC)

1.4.2 Complies with requirement accordance with article of regulation (EC) No. 1907/2006 and its amendments, confirm US FDA 21 CFR.

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.



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An ISO 9001 & 13485 Certified
A Division of Abdos

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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 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, Yellow, & Blue

1.6 Graduation and writing surface:

1.6.1 Large Printed Graduation

1.7 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.

1.8 Quality control:

Testing of various characteristics in accordance with the valid Specification

1.9 Other information

Reusable

2. Basic Features

2.1 Temperature range: -196⁰C to +121⁰C

2.2 Autoclavability: Yes, Autoclavable at 15 psi and 121⁰C for 15 minutes

2.3 Chemical resistance: See website.



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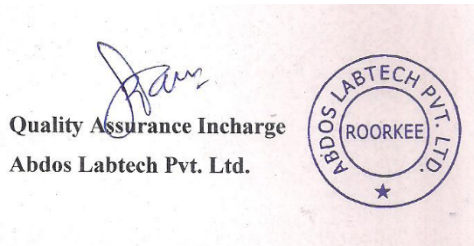
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Autoclaving Guideline for Plastics

All plastic consumables are autoclavable at 121⁰C 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 50⁰C before removing product.



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