

Technical Data Sheet

Doc No – Ab/TDS/Cryo-27

Rev No : 02

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, DNase, RNase and Pyrogen Free

1.2 Design:

Transparent lid permit viewing design having 100 cavities

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

1.4.2 Complies with the requirement of European Pharmacopoeia, 7th edition (2011) & its supplements 7.5 (07/2012) monographs 3.2.2 Plastic container and closures for Pharmaceutical use

1.4.3 The product has passed the USP testing including class VI tests & has been assigned the FDA Drug master file DMF 12123

1.4.4 Material has Successful Passed the biological tests according to ISO 10993 external Communication devices for indirect blood contact for Prolonged period.



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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-sterilized 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:

DNase, RNase, and Pyrogen Free

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

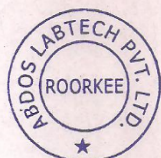
2.2 Autoclavability: Yes, Autoclavable at 15 psi and 121⁰C for 15 minutes

2.3 Chemical resistance: See website.

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.


Quality Assurance Incharge
Abdos Labtech Pvt. Ltd.



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