

Technical Data Sheet

Doc No – Ab/TDS/CT-06

Rev No: 04 Date 01/2021

TECHNICAL DATA SHEET

Abdos Labtech Pvt. Ltd.

PureRight Individually Wrap Centrifuge Tubes, PP/HDPE

Valid For Cat. No. P10425, P10426, P10427, P10451, P10452, P10453

1. Description/Specification

1.1 Description:

Disposable PP/HDPE centrifuge tube, DNase, RNase, Human DNA, ATP & Pyrogen Free, CE & IVD certified

1.2 Design:

1.2.1 Tube: Cylindrical Upper and conical Bottom with self-stand (skirted) & Conical Bottom

1.2.2 Tube Cap: Separate Threaded HDPE Cap

1.3 Performance Specifications:

Code	Capacity (ml)	OD (mm)	Height (mm)	Sterile	Colour	No./Case
P10425	15	16.5	121	YES	Blue	500
P10451	15	16.5	121	YES	Red	500
P10426	50	29.2	116	YES	Blue	500
P10452	50	29.2	116	YES	Red	500
P10427	50	29.2	117.3	YES	Blue	450
P10453	50	29.2	117.3	YES	Red	450

1.4 Material:

1.4.1 **Tube:** Polypropylene (PP), Hydrophobic **Cap**-HDPE

1.4.2 Polypropylene (PP), Hydrophobic, confirm US FDA 21CFR

1.4.3 Complies with requirement accordance with article of regulation (EC) No. 1907/2006 and its amendments.



Shiv Ganga Industrial Estate,
Plot no.1 Lakeshwari, Bhagwanpur,
Roorkee – 247667 Uttarakhand, India
An ISO 9001 ,13485, 14001 & CE Certified
A Division of Abdos

Regd. Office:
13A, Government Place (East)
Kolkata – 700069, India
GST : 05AAGCA8605A1Z7

P : +91 (0) 1332 235277
E : labtech@abdosindia.com
W: www.abdoslifesciences.com
CIN : U85100WB2008PTC123903

Technical Data Sheet

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 & 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:

Tube color- Translucent (Natural)

Cap color- Blue/Red

1.6 Graduation and writing surface:

1.6.1 Large Printed Graduation

1.6.2 White Patch for easy writing on the tube

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. SAL 10^{-6}

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

Recommended for single use only



Shiv Ganga Industrial Estate,
Plot no.1 Lakeshwari, Bhagwanpur,
Roorkee – 247667 Uttarakhand, India
An ISO 9001 ,13485, 14001 & CE Certified
A Division of Abdos

Regd. Office:
13A, Government Place (East)
Kolkata – 700069, India
GST : 05AAGCA8605A1Z7

P : +91 (0) 1332 235277
E : labtech@abdosindia.com
W: www.abdoslifesciences.com
CIN : U85100WB2008PTC123903

Technical Data Sheet

2. Basic Features

2.1 Temperature range: Tube:-80⁰C to +121⁰C

2.2 Autoclavability: Yes, Autoclavable at 15 psi and 121⁰C for 20 minutes

2.3 Centrifugation: 7000 RCF Self Stand & 18000 RCF Conical (Rated with Double Distilled water at 10⁰C for 30 minutes)


2.4 Leak Test at 635 mm Hg: No leakage

2.5 Manufactured in Clean room ISO Class 8 (100,000)

2.6 Chemical resistance: see website (www.abdoslifesciences.com)

Autoclaving Guideline for Plastics

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


Quality Assurance Incharge
Abdos Labtech Pvt. Ltd.



ABDOS

Shiv Ganga Industrial Estate,
Plot no.1 Lakeshwari, Bhagwanpur,
Roorkee – 247667 Uttarakhand, India

An ISO 9001 ,13485, 14001 & CE Certified

A Division of Abdos

Regd. Office:
13A, Government Place (East)
Kolkata – 700069, India

GST : 05AAGCA8605A1Z7

P : +91 (0) 1332 235277
E : labtech@abdosindia.com
W: www.abdoslifesciences.com
CIN : U85100WB2008PTC123903