Technical Data Sheet

Doc No - Ab/TDS/CT-05

Rev No : 09 Date 04/2023-24

TECHNICAL DATA SHEET

Abdos Labtech Pvt. Ltd.

Centrifuge Tubes Conical bottom, PS/HDPE

Valid For Cat. No. P10419, P10421

SRN (Single Registration Number): IN-MF-000022272

1. Description/Specification

1.1 Description:

Disposable PS (Polystyrene) centrifuge tube, DNase, RNase, Human DNA, ATP & Pyrogen Free, CE

& IVD certified

1.2 Design:

1.2.1 Tube: Cylindrical Upper and 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
P10419	15	16.5	121	YES	Blue	500 (Bulk)
P10421	15	16.5	121	YES	Blue	500(25pcsx20racks)

1.4 Material:

1.4.1 Tube - Polystyrene (PS) & Cap- High Density Polyethylene (HDPE) confirm US FDA 21CFR

1.4.2 Complies with the requirement of European Pharmacopoeia, Plastic Containers and closures for Pharmaceutical use.

1.4.3 The product has passed the USP testing including class VI tests. Materials has successful passed the biological tests according to ISO 10993 external communication devices for indirect blood contact for Prolonged period.

1.4.4 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



Abdos Labtech Private Limited (A Divison of Abdos Group) (An ISO 9001,13485,14001,18385,GMP & CE certified company) Shiv Ganga Industrial Estate Plot No-1, Lakheswari, Bhagwanpur, Roorkee-247667, (UK) INDIA

Registered office 13A Government Place East, 2nd Floor Kolkata West Bengal – 700069 CIN: U85100WB2008PTC123903 Corporate Office 319, 3rd Floor, DLF Tower A, DDA Dist. Centre Jasola, New Delhi - 110025 Ph. No: +91- (0) 1332235277 Email:labtech@abdosindia.com Web: <u>www.abdoslifesiences.com</u> GST: 05AAGCA8605A1Z7

Technical Data Sheet

1.4.5 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- NaturalCap color- Blue

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

2. Basic Features

2.1 Temperature range: Tube:- 10° C to + 70° C

2.2 Autoclavability: NO, PS material can't be Autoclavable at doing such may cause deformation of shape.

2.3 Centrifugation: 2500 RCF (Rated with Double Distilled water at 25^oC for 30 minutes)

2.4 Leak Test at 635 mm Hg: No leakage

2.5 These racks are made of eco-friendly paper to hold 25 pieces of CT 15 & 50ml.

- 2.6 Manufactured in Clean room ISO Class 8 (100,000)
- 2.7 Chemical resistance: see website (www.abdoslifesciences.com)

 $\label{eq:comparison} * Depending on the quality of Centrifuge and compatibility of Rotor.$

Autoclaving Guideline for Plastics

Polystyrene can't be autoclaved.



Abdos Labtech Private Limited (A Divison of Abdos Group) (An ISO 9001,13485,14001,18385,GMP & CE certified company) Shiv Ganga Industrial Estate Plot No-1, Lakheswari, Bhagwanpur, Roorkee-247667, (UK) INDIA

Registered office 13A Government Place East, 2nd Floor Kolkata West Bengal – 700069 CIN: U85100WB2008PTC123903 Corporate Office 319, 3rd Floor, DLF Tower A, DDA Dist. Centre Jasola, New Delhi - 110025 Ph. No: +91- (0) 1332235277 Email:labtech@abdosindia.com Web: www.abdoslifesiences.com GST: 05AAGCA8605A1Z7

Technical Data Sheet

Instruction for Use

Product can be used for food contact also. Storage temp. Max 30°C Before using the product check crackness, pouch punctured etc. Check all the information printed on pouches or boxes. Always wear gloves while handling specimen. Ensure all sample tubes are evenly filled For each tube inserted in the rotor, add a tube of equal weight directly opposite it.

WARNING

DO NOT store strong oxidizing agents.

DO NOT place any plastic labware in a flame.

DO NOT mix any chemicals that may result in a thermic reaction, which can cause product failure Wear a face shield and / or safety goggles if you have to work anywhere near a centrifuge that's in use. **Do not bump, jar, or move the centrifuge while the rotor is spinning**. Make sure you don't have the cord dangling from a table edge where someone could catch their foot in it and pull down the centrifuge Consult local fire codes prior to storage of flammable liquids.





Abdos Labtech Private Limited (A Divison of Abdos Group) (An ISO 9001,13485,14001,18385,GMP & CE certified company) Shiv Ganga Industrial Estate Plot No-1, Lakheswari, Bhagwanpur, Roorkee-247667, (UK) INDIA

Registered office 13A Government Place East, 2nd Floor Kolkata West Bengal – 700069 CIN: U85100WB2008PTC123903 Corporate Office 319, 3rd Floor, DLF Tower A, DDA Dist. Centre Jasola, New Delhi - 110025 Ph. No: +91- (0) 1332235277 Email:labtech@abdosindia.com Web: www.abdoslifesiences.com GST: 05AAGCA8605A1Z7