Technical Data Sheet

Doc No – Ab/TDS/CT-07

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TECHNICAL DATA SHEET

Abdos Labtech Pvt. Ltd.

Self-Standing Centrifuge Tubes, PP/HDPE

Valid For Cat. No. P10423, P10424, P10450, P10432, P10449

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

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)

1.2.2 Tube Cap: Separate Threaded HDPE Cap

1.3 Performance Specifications:

| Code | Capacity (ml) | OD (mm) | Height (mm) | Sterile | Colour | No./Case |
|--------|---------------|------------|-------------|---------|--------|----------|
| P10432 | 50 Bulk | 29.2 | 117.3 | NO | Blue | 500 |
| P10423 | 50 | 29.2 | 117.3 | NO | Blue | 500 |
| P10449 | 50 | 29.2 | 117.3 | NO | Red | 500 |
| P10424 | 50 | 29.2 | 117.3 | YES | Blue | 500 |
| P10450 | 50 | 29.2 | 117.3 | YES | Red | 500 |

1.4 Material:

- 1.4.1 Tube Polypropylene (PP) & 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 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



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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- 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
- 1.6.3 Printed Max Freze Level Indicator with Red Colour

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:-80^oC to +121^oC
- 2.2 Autoclavability: Yes, Autoclavable at 15 psi and 121°C for 20 minutes
- **2.3 Centrifugation:** 7000 RCF (Rated with Double Distilled water at 10^oC 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)
- *Depending on the quality of Centrifuge and compatibility of Rotor.

Autoclaving Guideline for Plastics

All plastic consumables are autoclavable at 121°C 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 50°C before removing product.



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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

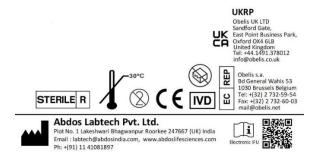
For each tube inserted in the rotor, add a tube of equal weight directly opposite it.

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.



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