

Technical Data Sheet

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TECHNICAL DATA SHEET

Abdos Labtech Pvt. Ltd.

MaxiRCF Trace Metal Free Centrifuge Tubes, PP/HDPE

Valid For Cat. No. P10480, P10481, P10482, P10483, P10484, P10485, P10486, P10487, P10488,
P10464

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

1. Description/Specification

1.1 Description:

High Purity Virgin Polypropylene (PP) centrifuge tube, DNase, RNase, Human DNA, ATP, Pyrogen Free, Trace Heavy Metals Free, IVD & CE certified

1.2 Design:

1.2.1 Tube: Cylindrical Upper and conical Bottom/Self Stand

1.2.2 Tube Cap: Separate Threaded HDPE Cap

1.3 Performance Specifications:

Code	Capacity	Outer Diameter(mm)	Height (mm)	No./Case
P10480	15ml Bulk	16.5	121	500
P10481	15ml	16.5	121	500
P10482	15ml Sterile	16.5	121	500
P10483	50ml Bulk	29.2	116	500
P10484	50ml	29.2	116	500
P10485	50ml Sterile	29.2	116	500
P10486	50ml Self Stand (Bulk)	29.2	117.3	500
P10487	50ml Self Stand	29.2	117.3	500
P10488	50ml Self Stand (Sterile)	29.2	117.3	500
P10464	50ml Conical Racked	29.2	116	500 (25x20)



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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

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- Natural

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-sterilized and dosimetrically released based on ANSI/AAMI/ISO 11137 *Sterilization of healthcare products Requirements for validation 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

1.9.1 Recommended for single use only

1.9.2 Pack Size: 500pieces/case

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

2. Basic Features

2.1 Temperature range: Tube:-80°C to +121°C

2.2 Autoclavability: Yes, Autoclavable at 15 psi and 121°C for 20 minutes

2.3 Centrifugation: 20,000 RCF (15ml), 20,000 RCF (50ml conical) & 7,000 RCF (50ml self stand)



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2.4 Leak Test at 635 mm Hg: No leakage

2.5 SAL 10^{-6}

2.6 Chemical resistance: See website, www.abdoslifesciences.com

2.7 Trace Metals included in testing are (<1ppb): Zinc, Iron, Boron, Copper, Manganese, Aluminum, Silicon, Nickel, Vanadium, Phosphorus, Cobalt, Chromium, Lithium, Selenium, Cadmium, Mercury, Arsenic & Lead, Silver (19)

Autoclaving Guideline for Plastics

All plastic consumables are autoclavable at 121⁰C for 20 minutes, 15 psi/1atm. Do not use 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.

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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Electronic IFU



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Quality Manager

Abdos Labtech Private Limited

Employee Code 30110



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