Doc No – Ab/TDS/CT-09

Rev No : 05 Date 11/2019

TECHNICAL DATA SHEET

Abdos Labtech Pvt. Ltd.

Racked Centrifuge Tube Conical Bottom, Paper

Valid for Cat. No. Paper Rack: P10409 (15ml), P10410 (50ml)

Racked Non Sterile: P10411 (15ml), P10413 (Amber 15ml),
P10415 (50ml), P10417 (Amber 50 ml),

Racked Sterile: P10412 (15ml), P10414 (Amber 15ml),
P10416 (50ml), P10418 (Amber 50 ml)

1. Description/Specification

1.1 Description:

Disposable PP/PS Tube, HDPE Cap & Paper rack, DNase, RNase, Human DNA, ATP & Pyrogen Free, CE certified

1.2 Design:

1.2.1 Tube: Cylindrical Upper and conical Bottom

1.2.2 Tube Cap: Separate Threaded HDPE Cap

1.2.3 Rack: 25 cavity for 50 ml tube & Cavity for 15 ml tube in Zigzag Fashion.

1.3 Performance Specifications:

1.3.1 Volume: **P10409** (15 ml Rack), **P10410** (50 ml Rack), **P10411** (15 ml Natural Racked), **P10412** (15ml Natural Racked Sterile), **P10413** (15 ml Amber Racked) **P10414 (**15 ml Amber sterile**), P10415** (50 ml Natural Racked), **P10416** (50ml Natural Racked sterile), **P10417** (50ml Amber Racked), **P10418** (50ml Sterile Amber Racked).

1.4 Material:

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

Rack- Paper Rack, Confirm US FDA 21CFR

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

DOMINIQUE DUTSCHER SAS

ABDOS

Shiv Ganga Industrial Estate,
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1.4.3 Complies with requirement accordance with article of regulation (EC) No. 1907/2006 and its amendments.

1.4.4 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

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

1.4.6 Material 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 according to ELV Direction 2000/53/EC, EU CONEG & it's following amendments. It is safe use in contact with food stuff, Pharmaceuticals & drinking water.

1.5 Color:

Tube color- Translucent (Natural), and Amber, **Cap color-** Blue

Racked Color: White

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.

1.8 Quality control:

DNase, RNase, Human DNA, ATP & Pyrogen Free

Testing of various characteristics in accordance with the valid Specification

1.9 Other information:

Recommended for single use only

Pack Size: **P10409 & P10410-** 10 pcs/case

P10411, P10412, P10413 & P10414 – 750 Pcs (25X 30 Racks) case

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P10415, P10416, P10417 & P10418 – 400 Pcs (25X 16 Racks) case

2. Basic Features

2.1 Temperature range: Tube:-80^{0}C to +121^{0}C (PP), -40^{0}C to + 90^{0}C (PS)

2.2 Autoclavability: Only PP is Autoclavable at 15 psi and 121^{0}C for 20 minutes

2.3 Centrifugation: 18,000 RCF (Rated with Double Distilled water at 25^{0}C for 30 minutes) **(Only PP Tubes)**

2.4 Leak Test at 635 mm Hg: No leakage

2.5 Chemical resistance: See website.

Autoclaving Guideline for Plastics

All plastic consumables are autoclavable at 121^{0}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^{0}C before removing product.

Quality Assurance Incharge
Abdos Labtech Pvt. Ltd.

ABDOS LABTECH PVT. LTD. ROORKEE

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