

# Technical Data Sheet

Doc No – Ab/TDS/CW-08

Rev No : 03

## TECHNICAL DATA SHEET

Abdos Labtech Pvt. Ltd.

**Racked Centrifuge Tube Conical Bottom, Paper**

**Valid for Cat. No. ESP Rack: P10409 (15ml), P10410 (15ml)**

**Racked Non Sterile: P10411 (15ml), P10413 (Amber 15ml),  
P10415 (15ml), 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 & EPS rack, DNase, RNase and Pyrogen Free

#### **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-** Expanded Polystyrene (ESP), Confirm US FDA 21CFR

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



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1.4.3 Complies with the requirement of European Pharmacopoeia, 7<sup>th</sup> edition (2011) & its supplements 7.5 (07/2012) monographs 3.2.2 Plastic container and closures for Pharmaceutical use

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

1.4.5 Material has Successful Passed the biological tests according to ISO 10993 external Communication devices for indirect blood contact for Prolonged period.

1.4.6 Polystyrene meets the standard of U.S. Food and Drug Administration, The European Commission/European Food Safety Authority and Hong Kong Food and Environmental Hygiene Department for use in Packaging to Store and Serve Food.

## 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, and 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** – 50 Pcs X 2 Racks/case

**P10415, P10416, P10417 & P10418** – 25 Pcs X 2 Racks/case



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## 2. Basic Features

**2.1 Temperature range:** Tube:  $-80^{\circ}\text{C}$  to  $+121^{\circ}\text{C}$  (PP),  $-40^{\circ}\text{C}$  to  $+90^{\circ}\text{C}$  (PS)

**2.2 Autoclavability:** Only PP are Autoclavable at 15 psi and  $121^{\circ}\text{C}$  for 20 minutes


**2.3 Centrifugation:** 15,000 RCF (Rated with Double Distilled water at  $25^{\circ}\text{C}$  for 30 minutes)  
(Only PP Tubes)

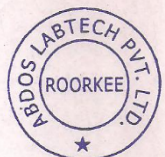
**2.4 Leak Test at 635 mm Hg:** No leakage

**2.5 Chemical resistance:** See website.

### Autoclaving Guideline for Plastics

All plastic consumables are autoclavable at  $121^{\circ}\text{C}$  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  $50^{\circ}\text{C}$  before removing product.

  
Quality Assurance Incharge  
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