

# Technical Data Sheet

Doc No – Ab/TDS/CT-10

Rev No : 05 Date 11/2019

## TECHNICAL DATA SHEET

**Abdos Labtech Pvt. Ltd.**

**Centrifuge Tubes Conical bottom, PS/HDPE**

**Valid For Cat. No. P10419, P10421**

### **1. Description/Specification**

#### **1.1 Description:**

Disposable **PS** (Polystyrene) centrifuge tube, 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

#### **1.3 Performance Specifications:**

**1.3.1** Volume : **P10419** (15ml Sterile), **P10421** (15ml Racked Sterile)

#### **1.4 Material:**

**1.4.1** **Tube:** Polystyrene (PS), **Cap-**HDPE

**1.4.2** Polystyrene (PS), Hydrophobic, confirm US FDA 21CFR

**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, 7<sup>th</sup> edition (2011) & its supplements 7.5 (07/2012) monographs 3.2.2 Plastic container and closures for Pharmaceutical use

**1.4.5** 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.



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## 1.5 Color:

**Tube color-** Translucent (Natural),

**Cap 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-sterilized 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: 500pieces/case & 750pieces/case

## 2. Basic Features

**2.1 Temperature range:** Tube:  $-80^{\circ}\text{C}$  to  $+90^{\circ}\text{C}$

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

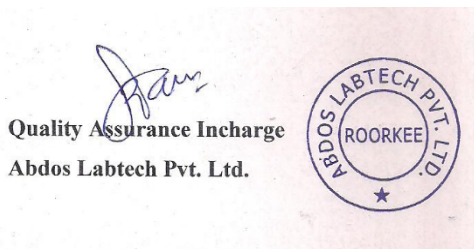
**2.3 Centrifugation:** 2500 RCF (Rated with Double Distilled water at  $25^{\circ}\text{C}$  for 30 minutes)

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

**2.5 Chemical resistance:** See website.

### Autoclaving Guideline for Plastics

Polystyrene can't be autoclaved.



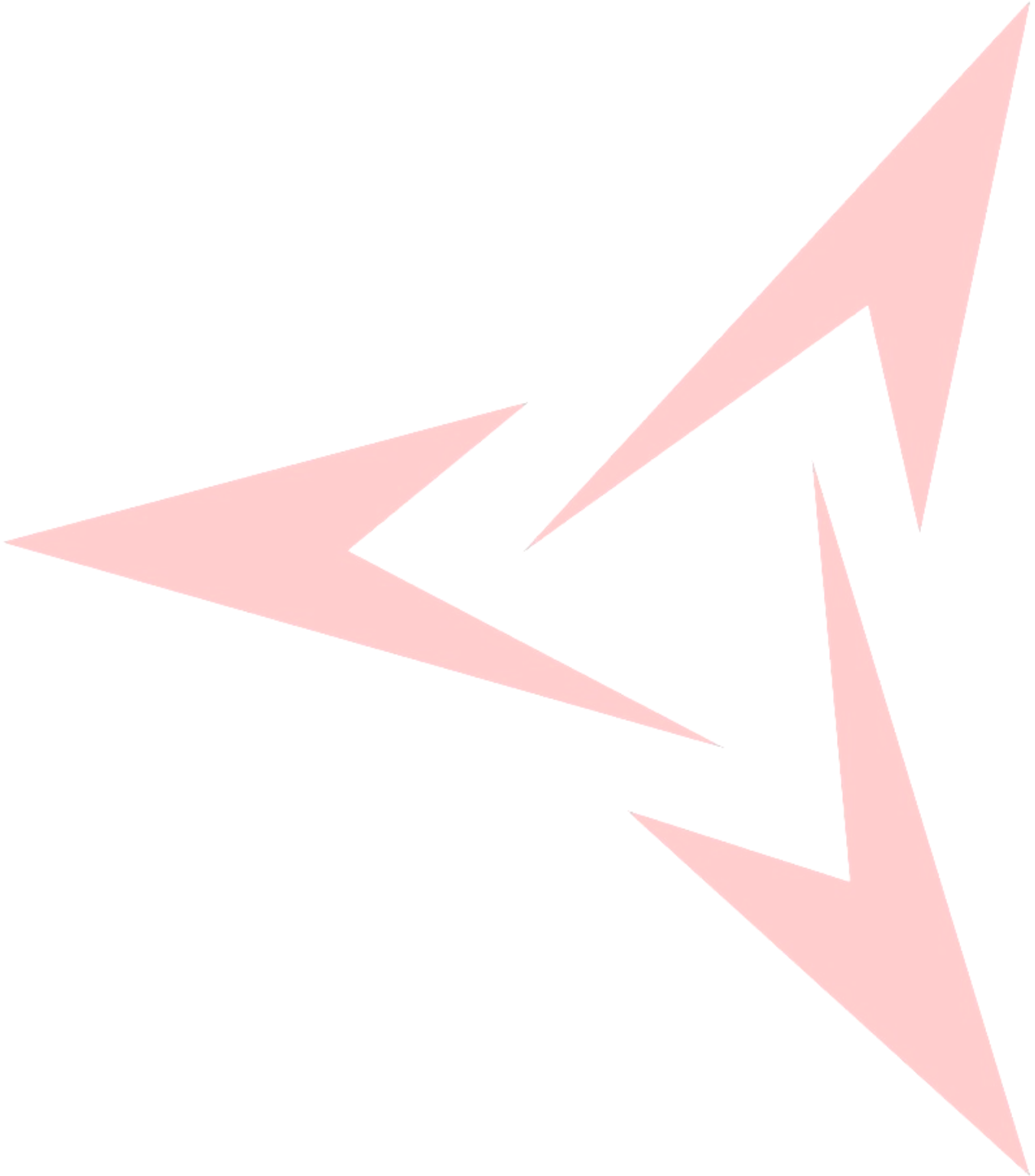
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