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, 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.

DOMINIQUE DUTSCHER SAS

ABDOS

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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-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: 500pieces/case & 750pieces/case

2. Basic Features

2.1 Temperature range: Tube:-80^{0}C to +90^{0}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^{0}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.

Quality Assurance Incharge
Abdos Labtech Pvt. Ltd.

ABDOS LABTECH PVT. LTD. ROORKEE

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