Doc No – Ab/TDS/CT-08

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TECHNICAL DATA SHEET

Abdos Labtech Pvt. Ltd.

Individually Wrap Centrifuge Tubes, PP/HDPE

Valid For Cat. No. P10425, P10426, P10427, P10451, P10452, P10453

1. Description/Specification

1.1 Description:

Disposable PP/HDPE centrifuge tube, DNase, RNase, Human DNA, ATP & Pyrogen Free, CE certified

1.2 Design:

1.2.1 Tube: Cylindrical Upper and conical Bottom with self-stand (skirted) & Conical Bottom

1.2.2 Tube Cap: Separate Threaded HDPE Cap

1.3 Performance Specifications:

1.3.1 Volume: **P10425** (15ml Sterile), **P10426** (50ml Sterile), **P10427** (50ml Self Stand Sterile), **P10451** (15ml Sterile Red), **P10452** (50ml Sterile Red), **P10453** (50ml Self Stand Sterile Red),

1.4 Material:

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

1.4.2 Polypropylene (PP), 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

DOMINIQUE DUTSCHER SAS

ABDOS

Shiv Ganga Industrial Estate,
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& it's following amendments. It is safe use in contact with food stuff, Pharmaceuticals & drinking water.

1.5 Color:

Tube color- Translucent (Natural) **Cap color-** Blue/Red

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 (Conical Bottom), 450pieces/case (Self Stand),

2. Basic Features

2.1 Temperature range: Tube:-80^{0}C to +121^{0}C

2.2 Autoclavability: Yes, Autoclavable at 15 psi and 121^{0}C for 20 minutes

2.3 Centrifugation: 3500 RCF Self Stand & 18000 RCF Conical (Rated with Double Distilled water at 10^{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

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.

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