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TECHNICAL DATA SHEET

Abdos Labtech Pvt. Ltd.

Centrifuge Tubes Conical Bottom, PP/HDPE

Valid For Cat. No. P10401, P10402, P10403, P10404, P10405, P10406, P10407, P10408, P10430, P10444, P10442, P10441, P10431, P10443

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

1.2.2 Tube Cap: Separate Threaded HDPE Cap

1.3 Performance Specifications:

1.3.1 Volume: **P10401 (**15ml Natural), **P10402** (15ml Sterile), **P10403** (50ml Natural), **P10404** (50ml Sterile), **P10405** (15ml Amber), **P10406** (15ml Sterile Amber), **P10407** (50ml Amber), **P10408** (50ml Sterile Amber), **P10430 (**15ml Blue Bulk), **P10444** (50ml Sterile Red), **P10442**(15ml Sterile Red), **P10441**(15ml Red), **P10431**(50ml Bulk), **P10443**(50ml 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) monograph 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.

DOMINIQUE DUTSCHER SAS

ABDOS

Shiv Ganga Industrial Estate,
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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/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:

DNase, RNase, Human DNA, ATP & Pyrogen Free

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 control- Radiation sterilization.* The product has been sterilized with Co-60 Gamma Radiation.

1.8 Quality control:

Testing of various characteristics in accordance with the valid Specification

1.9 Other information

Recommended for single use only

Pack Size: 500pieces/case

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: 18,000 RCF (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 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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Technical Data Sheet

Quality Assurance Incharge
Abdos Labtech Pvt. Ltd.

ABDOS LABTECH PVT. LTD. ROORKEE

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