Technical Data Sheet

Doc No – Ab/TDS/LH-82-III

Rev No: 04 Date 10/2021-22

TECHNICAL DATA SHEET

Abdos Labtech Pvt. Ltd.

Plastic Test Tube & Cap

Valid for Cat. No. Tube- P10308, P10309, P10310, P10311

Cap- P10312, P10313

1. Description/Specification

1.1 Description: Disposable Vials and Caps, DNase, RNase, Pyrogen Free, CE & IVD

certified

1.2 Design:

1.2.1 Vial: Cylindrical with Round Bottom

1.2.3 Cap: Separate Cap

1.3 Performance Specifications:

1.3.1 Plastic Test Tube

Code	Øxh(mm)	Material	Capacity (ml)	No. Per Case
P10308	13x100	PP	8	500
P10309	13x100	PS	8	500
P10310	16x100	PP	10	500
P10311	16x100	PS	10	500

1.3.2 Plastic Test Tube Cap

Code	Ø x h (mm)	Material	No. Per Case
P10312	13	HDPE	1000
P10313	16	HDPE	1000

1.4 Material:

1.4.1 Polypropylene (PP), Polystyrene (PS), Hydrophobic, Cap made up HDPE confirm US FDA 21CFR



Shiv Ganga Industrial Estate, Plot no.1 Lakeshwari, Bhagwanpur,

Roorkee – 247667 Uttrakhand, India

Regd. Office:

13A, Government Place (East) Kolkata - 700069, India

An ISO 9001,13485, 14001 & CE Certified

A Division of Abdos **GST**: 05AAGCA8605A1Z7 **P**:+91(0)1332235277

E: labtech@abdosindia.com W: www.abdoslifesciences.com

CIN: U85100WB2008PTC123903

Technical Data Sheet

- 1.4.2 Complies with requirement accordance with article of regulation (EC) No. 1907/2006 and its amendments.
- 1.4.3 Complies with the requirement of European Pharmacopoeia, 7th edition (2011) & its supplements 7.5 (07/2012) monographs 3.2.2 Plastic Containers 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 Materials has successful passed the biological tests according to ISO 10993 external communication devices for indirect blood contact for Prolonged period.
- 1.4.6 Free from Heavy metals, RoHS Free according to meets relevant requirements of EU regulations 1935/2004/CE ,2002/95/EC as amended, UE 10/2011 as amended. EU CONEG & it's following amendments. It is safe use in contact with food stuff, Pharmaceuticals & drinking water
- 1.4.7 Product is manufactured without the use of Raw Materials of animal origin Therefore BSE/TSE issue does not concern this product to the best of our Knowledge. No materials containing latex or natural rubber are used in the Manufacturing, handling & packaging process for this product.
- 1.4.8 PS- Material is stable and inert in normal handling & storage conditions.

1.5 Color:

PP – Translucent, and **PS**- Glass Clear Transparent

1.6 Quality Control:

Product are manufactured, inspected and found to be in compliance with product & quality specification requirements as documented in ISO 9001:2015 & 13485:2016 Quality Management System. Testing of various characteristics in accordance with the valid specification, inspection reviewed & signed for product release.

1.7 Basic Features

1.7.1 Temperature range: Tube: -80° C to $+121^{\circ}$ C for **PP**

Tube: $10^{0}\text{C} + 90^{0}\text{C}$ for **PP**

1.7.2 Autoclavability: Only **PP** is Autoclavable at 15 psi and 121^oC for 20 minutes

1.7.3 Centrifugation: PP-3,000 RCF, PS – 1400 RCF (With Distilled water at 25°C)

1.7.3 Leak Test at 350 mm Hg: No leakage

1.7.4 Chemical resistance: See website (www.abdoslifesciences.com)

1.7.5 Manufactured in Clean room ISO Class 8 (100,000)



Shiv Ganga Industrial Estate,

Regd. Office:

Plot no.1 Lakeshwari, Bhagwanpur, Roorkee – 247667 Uttrakhand, India 13A, Government Place (East) Kolkata – 700069, India

GST: 05AAGCA8605A1Z7

An ISO 9001,13485, 14001 & CE Certified

A Division of Abdos

P:+91 (0) 1332 235277
F: lahtech@ahdosindia

E: labtech@abdosindia.com
W: www.abdoslifesciences.com

CIN: U85100WB2008PTC123903

Technical Data Sheet

Autoclaving Guideline for Plastics (Only for PP Plastic test tube)

All plastic consumables are autoclavable at 121°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°C before removing product.

Quality Assurance Incharge Abdos Labtech Pvt. Ltd.





Shiv Ganga Industrial Estate,

Plot no.1 Lakeshwari, Bhagwanpur, Roorkee – 247667 Uttrakhand, India

An ISO 9001,13485, 14001 & CE Certified
A Division of Abdos GST

Regd. Office:

13A, Government Place (East) Kolkata – 700069, India

GST: 05AAGCA8605A1Z7

P:+91 (0) 1332 235277
F:labtech@abdosindia

E: labtech@abdosindia.com
W: www.abdoslifesciences.com
CIN: U85100WB2008PTC123903