

# Technical Data Sheet

Doc No – Ab/TDS/LH-82-II

Rev No : 06 Date 10/2021-22

## TECHNICAL DATA SHEET

**Abdos Labtech Pvt. Ltd.**

**RIA Vials & Caps (12x40)**

**Valid for Cat. No. Vial- P10305, P10305A, P10305A1, P10306,  
Cap- P10304, P10304A, P10304A1, P10307, P10302**

### **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:**

<b>Ria Vial</b> – 12 x 40 mm (P10305 – PP Natural, P10305A – PP-Amber, P10305A1-PP-Transparent Amber, P10306- PS Natural)
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<b>Ria Vial Cap</b> – (P10304 – HDPE Natural, P10304A-PE Amber, P10304A1-HDPE Transparent Amber, P10307 –PP Natural P10302 – LDPE Natural)
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1.3.1 Volume : 2.8 ml  $\pm$  0.1ml

1.3.2 Size : 12 x 40 mm      Cap Size : 12mm ( $\phi$ )

### **1.4 Material:**

1.4.1 Vial Made up of Hydrophobic Polypropylene (PP, **P10305**) and Polystyrene (PS), **P10306**), Cap made up HDPE, confirm US FDA 21CFR

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, 7<sup>th</sup> 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



**Shiv Ganga Industrial Estate,**  
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Roorkee – 247667 Uttarakhand, India  
**An ISO 9001 ,13485, 14001 & CE Certified**  
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**CIN : U85100WB2008PTC123903**

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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 Other information

Recommended for single use only

**Vial Pack Size:** 500 pieces/case

**Cap Pack Size:** 500 pieces/case

## 1.8 Basic Features

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

Tube :  $10^{\circ}\text{C}$  +  $90^{\circ}\text{C}$  for **PS**

**1.8.2 Autoclavability:** Only **PP** is Autoclavable at 15 psi and  $121^{\circ}\text{C}$  for 20 minutes

**1.8.3 Centrifugation:** **PP**-3,000 RCF, **PS** – 1400 RCF (With Distilled water at  $25^{\circ}\text{C}$ )

**1.8.3 Leak Test at 400 mm Hg:** No leakage

**1.8.4 Chemical resistance:** See website ([www.abdoslifesciences.com](http://www.abdoslifesciences.com))

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



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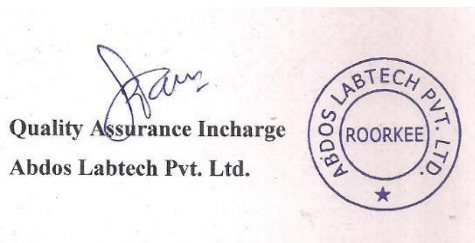
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## Autoclaving Guideline for Plastics (Only for PP RIA Vial)

All plastic consumables are autoclavable at 121<sup>0</sup>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<sup>0</sup>C before removing product.



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