

# Technical Data Sheet

Doc No – Ab/TDS/LH-89-II

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## 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 and Pyrogen Free

#### **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

1.4.2 Complies with requirement of Directive 2002/72/EC and requirement of FDA Regulation 21 CFR 177.1520. olefins polymers & 21CFR section '177.1640

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, 7<sup>th</sup> edition (2011) & its supplements 7.5 (07/2012) monographs 3.2.2 Plastic Containers and closures for Pharmaceutical use.



**Shiv Ganga Industrial Estate,**  
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**An ISO 9001 & 13485 Certified**  
A Division of Abdos

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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 Materials 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.

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:

DNase, RNase, and Pyrogen Free

Testing of various characteristics in accordance with the valid Specification

## 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

**1.81 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.



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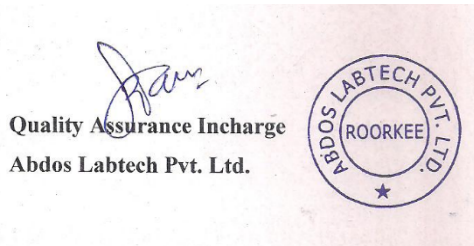
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## Autoclaving Guideline for Plastics (Only for PP RIA Vial)

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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