

Technical Data Sheet

Doc No – Ab/TDS/LH-76

Rev No: 04

TECHNICAL DATA SHEET

Abdos Labtech Pvt. Ltd.

Sample Container, PP/HDPE

Valid for Cat. No. P40101, P40102, P40103, P40104, P40105, P40106

1. Description/Specification

1.1 Description: Disposable PP/HDPE Sample Container, DNase, RNase and Pyrogen Free

1.2 Design:

1.2.1 Container: Cylindrical Upper end with outer threads Taper towards Bottom

1.2.3 Cap: separate Threaded HDPE Cap

1.3 Performance Specifications:

1.3.1 Volume: **P40101** (50ml), **P40102** (50ml Sterile), **P40103** (100ml). **P40101** (100ml sterile), **P40105** (50ml with spoon), **P40106** (50ml sterile with spoon)

1.4 Material:

Container – Hydrophobic Polypropylene (PP), **Cap-** HDPE

1.4.1 Polypropylene (PP), Hydrophobic

1.4.2 Complies with requirement of European Pharmacopoeia, 7th Edition (2011) & its supplements 7.5 (07/2012) monograph 3.2.2 Plastic container and closures for Pharmaceutical use.

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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 Material has Successful Passed the biological tests according to ISO 10993 external Communication devices for indirect blood contact for Prolonged period.



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1.5 Color:

Container Color - Translucent (Natural),

Cap color- Blue, Red & White

1.6 Graduation and writing surface:

1.6.1 Large Printed Graduation

1.6.2 Frosted Area for easy writing on the container already marked for Name, No. and Date

1.7 Sterilization:

Sterile catalog number from this lot have been pre-sterilized 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, and Pyrogen Free

Testing of various characteristics in accordance with the valid Specification

1.9 Other information

Recommended for single use only

Pack Size: 400 pieces/ case (50ml), 200 pieces/case (100ml), 350 pieces/case (50ml sterile)

2. Basic Features

2.1 Temperature range: Tube: -30°C to $+121^{\circ}\text{C}$

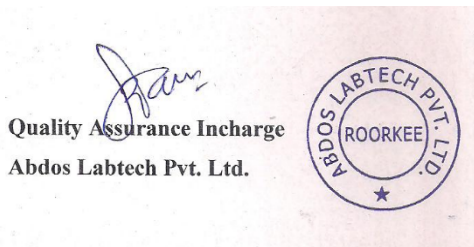
2.2 Autoclavability: Yes, Autoclavable at 15 psi and 121°C for 20 minutes

2.3 Leak Test at 600 mm Hg: No leakage

2.4 Chemical resistance: See website.

Autoclaving Guideline for Plastics

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.

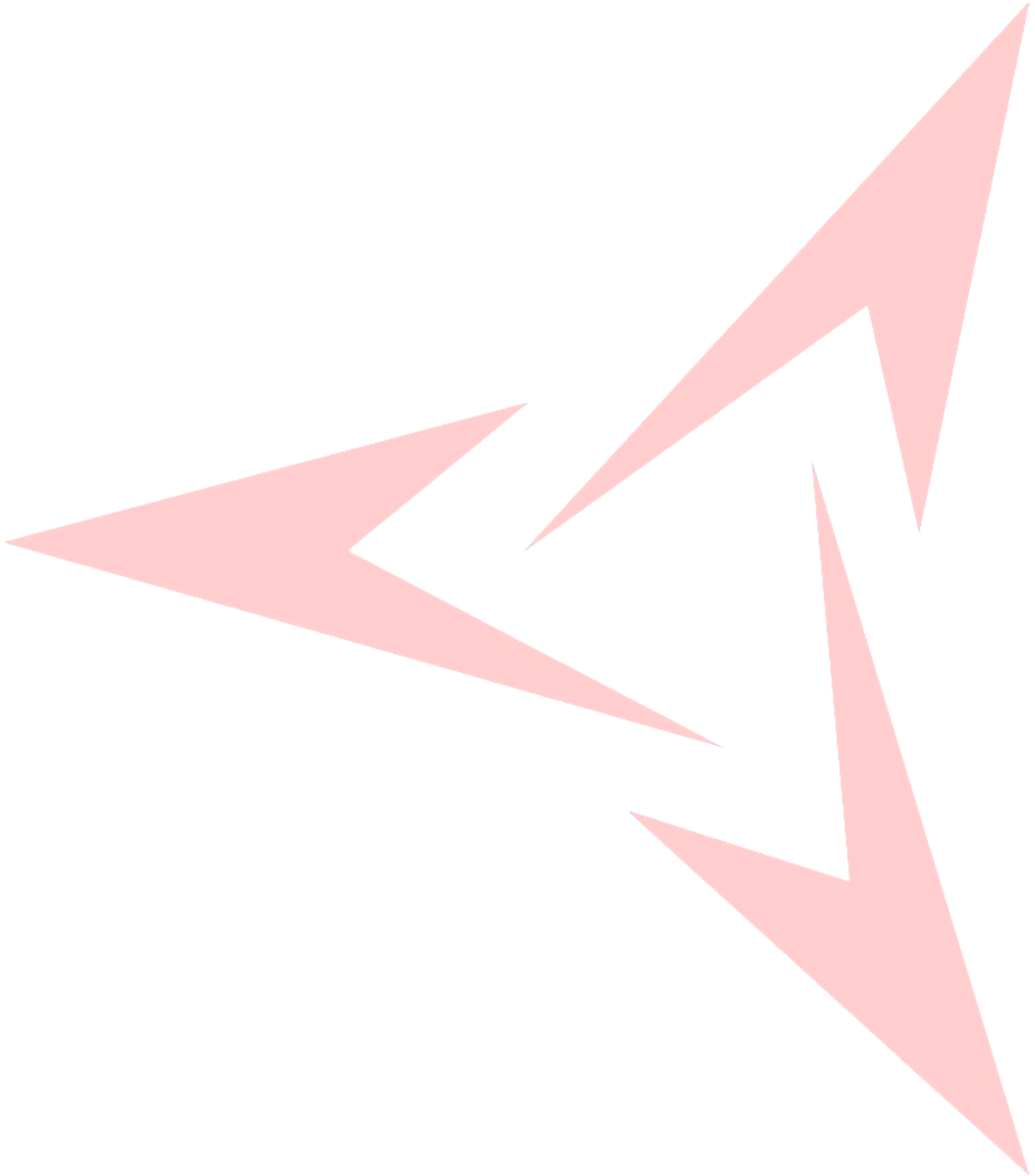


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