

Technical Data Sheet

Doc No – Ab/TDS/LH-83

Rev No: 08 Date 10/2021-22

TECHNICAL DATA SHEET

Abdos Labtech Pvt. Ltd.

Sample Container, PP/HDPE

Valid for Cat. No. P40101, P40102, P40103, P40104, P40105, P40106, P40107, P40108, P40109, P40110, P40112, P40113

1. Description/Specification

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

1.2 Design:

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

1.2.3 Cap: separate Threaded HDPE Cap

1.2.4 Caps with spoon

1.3 Performance Specifications:

Code	Capacity	Cap Colour	Height (mm)	No./Case
P40101	60ml Bulk Non STR	Blue, Red & White	55	400
P40102	60ml STR Individual	Blue, Red & White	55	350
P40103	120ml Bulk Non STR	Blue, Red & White	76	200
P40104	120ml STR Individual	Blue, Red & White	76	200
P40105	60ml Bulk Non STR Spoon	Blue, Red & White	55	400
P40106	60ml STR Spoon Individual	Blue, Red & White	55	350
P40107	120ml with spoon Non STR	Blue, Red & White	76	200
P40108	120ml spoon STR Individual	Blue, Red & White	76	200
P40109	60ml sterile 10pcs packing	Blue, Red & White	55	450
P40110	120ml sterile 10pcs packing	Blue, Red & White	76	250
P40112	200ml Bulk Non STR	Blue, Red & White	120	150
P40113	200ml STR Individual	Blue, Red & White	120	100



Distribué par **Humeau**

Z.A. Hauts de Couëron - 11 rue des Imprimeurs
CS 24220 - 44220 Couëron - France
t. : +33 (0)2 40 93 53 53
info@humeau.com - www.humeau.com

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GST : 05AAGCA8605A1Z7

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1.4 Material:

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

1.4.1 Polypropylene (PP),Hydrophobic, 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, 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.

1.5 Color:

Container Color - Translucent (Natural)

Cap color- Blue, Red, White & Yellow

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-sterilizes 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. SAL 10^{-6}

1.8 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.



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1.9 Other information

Recommended for single use only. For the sample collection of blood, Serum, Semen , Plasma, Tissues, Wound samples, Urine for the detection of pathogen or genetically diseases etc.

2. Basic Features

2.1 Temperature range: Tube:-30°C to +121°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 (60ml)

2.4 Leak Test at 300 mm Hg: No leakage (120 & 200ml)

2.5 Brimful capacity:

P40101, P40102, P40105, P40106, P40109 (70ml)
P40103, P40104, P40107, P40108, P40110, P40111 (150ml)
P40112, P40113 (250ml)

2.6 Moulded Subdivision of 10ml increment up to 50ml for the code P40101/P40102/P40105/

P40109 /P40106

Moulded Subdivision of 20ml increment up to 100ml for the code P40103, P40104, P40107, P40108, P40110, P40111

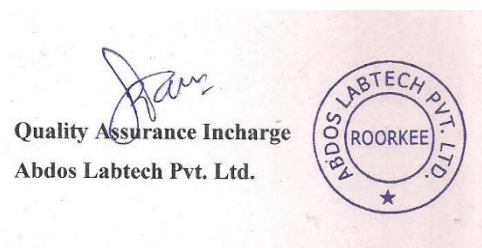
Moulded Subdivision of 20ml increment up to 200ml for the code P40112, P40113

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

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

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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