Doc No-Ab/TDS/BC-142

Rev No: 06 Date 04/2023-24

TECHNICAL DATA SHEET

Abdos Labtech Pvt. Ltd.

Narrow Mouth Bottle, HDPE

Valid for Catalog No. P11151, P11152, P11153, P11154, P11155, P11156, P11157, P11158, P11159

SRN (Single Registration Number): IN-MF-000022272

1. Description/Specification

1.1 Description:

Narrow Mouth Bottle, HDPE

- 1.1.1 These bottles come with inner thread for superior sealing and better security.
- 1.1.2 These bottles are used for packing, shipping and storage purposes.
- 1.1.3 Superior chemical resistance.
- 1.1.4 Complete emptying is guaranteed through inclination of shoulders.
- 1.1.5 Suitable for storage of low-density liquids.

1.2 Raw material:

- **1.2.1 Body:** HDPE (High Density polyethylene)
- **1.2.2 Cap: PP** (Polypropylene)

1.3 Material:

1.3.1 High Density polyethylene (HDPE), Hydrophobic, confirm US FDA 21CFR

1.3.2 Complies with the requirement of European Pharmacopoeia, Plastic Containers and closures for pharmaceutical use.

1.3.3 The product has passed the USP testing including class VI tests, Materials has successful passed the biological tests according to ISO 10993 external communication devices for indirect blood contact for Prolonged period.

1.3.4 Free from Heavy metals, RoHS Free according to meets relevant requirements of EU regulations1935/2004/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.

1.3.5 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.



Abdos Labtech Private Limited (A Divison of Abdos Group) (An ISO 9001,13485,14001,18385,GMP & CE certified company) Shiv Ganga Industrial Estate Plot No-1, Lakheswari, Bhagwanpur, Roorkee-247667, (UK) INDIA

Registered office 13A Government Place East, 2nd Floor Kolkata West Bengal – 700069 CIN: U85100WB2008PTC123903 Corporate Office 319, 3rd Floor, DLF Tower A, DDA Dist. Centre Jasola, New Delhi - 110025 Ph. No: +91- (0) 1332235277 Email:labtech@abdosindia.com Web: <u>www.abdoslifesiences.com</u> GST: 05AAGCA8605A1Z7

1.4 Quality Control:

1.4.1 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.

1.4.2 Can be used at a temperature below 0° C.

Code	Capacity (ml)	Mouth Diameter (mm)	Height (mm)	No. per Case
P11151	60	17.5	82.4	72
P11152	125	21	97.6	72
P11153	250	21	130.7	72
P11154	500	24.6	165.5	48
P11155	4	12.2	39	72
P11156	8	17.5	42.3	72
P11157	15	17.5	56.1	72
P11158	30	17.5	60	72
P11159	1000	52.1	221.5	24

1.5 DIMENSIONAL SPECIFICATIONS:

1.6 GENERAL FEATURES:

СЕ	Yes		
Autoclavability	No		
Translucence	Yes		
Resistant	To be effected by radiations		
Sterilization	NA		
Temperature	$From - 40^{\circ}C to + 80^{\circ}C$		
Leak Proof	Yes		

1.7 Chemical resistance: See website (<u>www.abdoslifesciences.com</u>)

1.7.1 Manufactured in Aseptic Environment



Abdos Labtech Private Limited (A Divison of Abdos Group) (An ISO 9001,13485,14001,18385,GMP & CE certified company) Shiv Ganga Industrial Estate Plot No-1, Lakheswari, Bhagwanpur, Roorkee-247667, (UK) INDIA

Registered office 13A Government Place East, 2nd Floor Kolkata West Bengal – 700069 CIN: U85100WB2008PTC123903 Corporate Office 319, 3rd Floor, DLF Tower A, DDA Dist. Centre Jasola, New Delhi - 110025 Ph. No: +91- (0) 1332235277 Email:labtech@abdosindia.com Web: <u>www.abdoslifesiences.com</u> GST: 05AAGCA8605A1Z7

1.8 Other Information (not applicable if neglected):

1.8.1 Fair resistance; exposure (30 days) to the chemical does not cause any damage.

1.8.2 Sufficient resistance; exposure causes damage of poor importance, which sometimes is only temporary.

1.8.3 Poor resistance; exposure to chemical is not allowed, or causes immediate permanent damage.

Results of testing with reference materials are to be considered as indication: in case of specific use it is recommended to carry out preliminary testing.

Information relating to the resistances of plastic materials to temperatures, sterilization and washing treatments, have been made as per reports of the raw materials' producers, following the data published in the literature and the experience gained in the use of products.

WARNING

DO NOT store strong oxidizing agents.

DO NOT place any plastic labware in a flame.

DO NOT mix any chemicals that may result in a thermic reaction, which can cause product failure Consult local fire codes prior to storage of flammable liquids in carboys/bottles/aspirators. Consult OSHA guidelines prior to handling or lifting filled carboys/bottles/aspirators.

If applicable: Using the spigot as a handle can ruin the threads and causing the spigot not to seal properly.

Cleaning:

Bottles/Aspirators/Carboys need to be cleaned by hand using a non-abrasive, neutral pH, mild detergent that does not contain a sheeting agent.

Cap and Spigot Cleaning: (if applicable)

- 1. Remove O-ring from cap.
- 2. Disassemble the spigot.
- 3. Spray and wipe the spigot, cap and O-ring with 70% Isopropyl Alcohol.
- 4. Rinse all parts with distilled water.
- 5. Replace O-ring in cap.
- 6. Autoclave cap and spigot at 121°C at 15 psi for 20 minutes.

Instruction for Use

Product can be used for food contact also.

Storage temp. Max 30°C

Before using the product check crackness, pouch punctured etc.

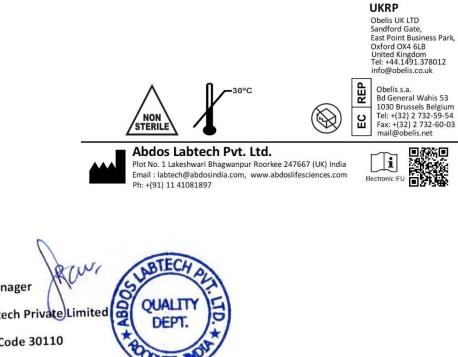
Check all the information printed on pouches or boxes.

Always wear gloves while handling specimen.



Abdos Labtech Private Limited (A Divison of Abdos Group) (An ISO 9001,13485,14001,18385,GMP & CE certified company) Shiv Ganga Industrial Estate Plot No-1, Lakheswari, Bhagwanpur, Roorkee-247667, (UK) INDIA

Registered office 13A Government Place East, 2nd Floor Kolkata West Bengal – 700069 CIN: U85100WB2008PTC123903 Corporate Office 319, 3rd Floor, DLF Tower A, DDA Dist. Centre Jasola, New Delhi - 110025 Ph. No: +91- (0) 1332235277 Email:labtech@abdosindia.com Web: <u>www.abdoslifesiences.com</u> GST: 05AAGCA8605A1Z7









Abdos Labtech Private Limited (A Divison of Abdos Group) (An ISO 9001,13485,14001,18385,GMP & CE certified company) Shiv Ganga Industrial Estate Plot No-1, Lakheswari, Bhagwanpur, Roorkee-247667, (UK) INDIA

Registered office 13A Government Place East, 2nd Floor Kolkata West Bengal - 700069 CIN: U85100WB2008PTC123903 Corporate Office 319, 3rd Floor, DLF Tower A, DDA Dist. Centre Jasola, New Delhi - 110025

Ph. No: +91- (0) 1332235277 Email:labtech@abdosindia.com Web: www.abdoslifesiences.com GST: 05AAGCA8605A1Z7