

# Technical Data Sheet

Doc No–Ab/TDS/BC-145

Rev No: 06 Date 04/2023-24

## TECHNICAL DATA SHEET

**Abdos Labtech Pvt. Ltd.**

**Wide Mouth Bottle, PP**

**Valid for Catalog No. P11160, P11161, P11162, P11163, P11164, P11163S, P11169**

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

### **1. Description/Specification**

#### **1.1 Description:**

Wide Mouth Bottle Graduated, PP

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

#### **1.2 Raw material:**

**1.2.1 Body: PP** (Polypropylene)

**1.2.2 Cap: PP** (Polypropylene)

#### **1.3 Material:**

1.3.1 Polypropylene (PP), 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 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.

1.3.5 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  
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(An ISO 9001,13485,14001,18385,GMP & CE certified company)  
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## 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.

## 1.5 DIMENSIONAL SPECIFICATIONS:

Code	Capacity (ml)	Mouth Diameter (mm)	Height (mm)	No. per Case
P11160	30	21.2	58.9	72
P11161	60	24.8	81	72
P11162	125	32	94.5	72
P11163	250	32.2	126.7	72
P11164	500	47.5	163.2	48
P11163 S	250	32.2	126.7	48
P11169	1000	61.5	196.8	24

## 1.6 GENERAL FEATURES:

CE	Yes
Autoclavability	Yes
Translucence	Yes
Resistant	To be effected by radiations
Sterilization	Gamma
Temperature	From 0°C to 121°C
Leak Proof	Yes

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

1.7.1 Manufactured in Aseptic Environment

1.8 Other Information (not applicable if neglected):



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**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.

## 1.9 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.

## Autoclaving Guideline for Plastics

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.

### 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<sup>0</sup>C at 15 psi for 20 minutes.

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## 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.

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