

# Technical Data Sheet

Doc No – Ab/TDS/CC-102

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## TECHNICAL DATA SHEET

**Abdos Labtech Pvt. Ltd.**

**Biofill Bottle Top Filtration System, PES**

**Valid for Cat. No. P21101, P21102, P21103, P21104, P21105, P21106, P21107, P21018, P21019, P21090, P21091, P21092, P21093, P21094, P21095, P21096, P21097, P21098**

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

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

**1.1 Description:** Biofill Bottle Top Funnel & Biofill Bottle Top Funnel Filtration System, PES, DNase, RNase, Cytotoxicity & Pyrogen Free, STERILE

1.1.1 BIOFILL Bottle Top Filtration System is available as a Full Assembly or as a bottle top Funnel. ABDOS BIOFILL Bottle Top Filtration Systems are disposable, sterile, vacuum operated systems for the sterile preparation of buffers, tissue culture media, microbiological media, and other biological fluids. Systems are available with asymmetric 0.1 µm, 0.22 µm & 0.45 µm PES membranes. ABDOS PES membrane has low protein binding and is surfactant free.

1.1.2 BIOFILL Filtration system is designed for sterilization or clarification of aqueous laboratory fluids. The filters are gamma radiated & manufactured in clean room plant.

1.1.3 The complete system is composed of a polystyrene filter funnel and receiver bottle, a SECURE grasp cap, and a vacuum hose adapter. Systems are also available with 15 ml and 50 ml polypropylene centrifuge tubes.

1.1.4 Filtration funnels are compatible with the Quick Connect pedestal system, a cradle ring for use with existing lab stands, & vacuum hose adapters. Quick-Connect pedestal offers one-time vacuum connection and one-handed operation. Quick Connect Pedestal are sold separately.

#### **1.1.5 Materials of Construction:**

Filter Housing and Bottle: Polystyrene

Membrane: Polyethersulfone (PES)

Cap: Polypropylene

### **1.2 Design: Bottle Top, GL-45**



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## 1.3 Performance Specifications:

Code	Description	Funnel Capacity (ml)	Receiver Capacity (ml)	Filter Pore Size(µm)	Membrane Diameter (mm)	No. Per Case
<b>P21090</b>	250ml, 0.2 µm High Flow PES Bottle Top Filter Full Assembly, Sterile	250	250	0.2	66	12
<b>P21091</b>	500ml, 0.2 µm High Flow PES Bottle Top Filter Full Assembly, Sterile	500	500	0.2	90	12
<b>P21092</b>	1000mL, 0.2 µm High Flow PES Bottle Top Filter Full Assembly, Sterile	1000	1000	0.2	90	12
<b>P21093</b>	250ml, 0.45 µm High Flow PES Bottle Top Filter Full Assembly, Sterile	250	250	0.45	66	12
<b>P21094</b>	500ml, 0.45 µm High Flow PES Bottle Top Filter Full Assembly, Sterile	500	500	0.45	90	12
<b>P21095</b>	1000ml, 0.45 µm High Flow PES Bottle Top Filter Full Assembly, Sterile	1000	1000	0.45	90	12
<b>P21096</b>	250ml, 0.1 µm High Flow PES Bottle Top Filter Full Assembly, Sterile	250	250	0.1	66	12
<b>P21097</b>	500ml, 0.1 µm High Flow PES Bottle Top Filter Full Assembly, Sterile	500	500	0.1	90	12
<b>P21098</b>	1000ml, 0.1 µm High Flow PES Bottle Top Filter Full Assembly, Sterile	1000	1000	0.1	90	12
<b>P21101</b>	250ml Funnel Only with 0.2 um PES Membrane	250	GLSize/ Thread 45	0.2	66	24
<b>P21102</b>	500ml Funnel Only with 0.2 um PES Membrane	500	GLSize/ Thread 45	0.2	66	24
<b>P21103</b>	1000ml Funnel Only with 0.2 um PES Membrane	1000	GLSize/ Thread 45	0.2	90	24
<b>P21104</b>	250ml Funnel Only with 0.1 um PES Membrane	250	GLSize/ Thread 45	0.1	90	24
<b>P21105</b>	500ml Funnel Only with 0.1 um PES Membrane	500	GLSize/ Thread 45	0.1	66	24

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	um PES Membrane					
<b>P21106</b>	1000ml Funnel Only with 0.1 um PES Membrane	1000	GLSize/ Thread 45	0.1	90	24
<b>P21107</b>	250ml Funnel Only with 0.45 um PES Membrane	250	GLSize/ Thread 45	0.45	90	24
<b>P21108</b>	500ml Funnel Only with 0.45 um PES Membrane	500	GLSize/ Thread 45	0.45	90	24
<b>P21109</b>	1000ml Funnel Only with 0.45 um PES Membrane	1000	GLSize/ Thread 45	0.45	90	24

## 1.4 Material:

1.4.1 Made up of Polyethersulfone (PES), Polypropylene (PP) & Polystyrene (PS), confirm US FDA 21CFR

1.4.2 Complies with the requirement of European Pharmacopoeia, Plastic Containers and closures for Pharmaceutical use.

1.4.3 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.

1.4.4 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

1.4.5 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.

**1.5 Color:** Transparent (Natural color)

## 1.6 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.

## 1.7 Other information

1.7.1 Temperature Range: Operating Range: 4<sup>0</sup> to 37<sup>0</sup>C

1.7.2 Unit Storage: -4<sup>0</sup> to 50<sup>0</sup>C

1.7.4 Crystal Clear Bottles

1.7.5 High Visibility, raised graduations for easy readings



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## 1.7.6 Finger Grips

## 1.7.7 Wide stable base

## 1.7.8 Membrane Bubble Point:

Each membrane pore size was certified according to procedure to determine the water bubble point.

0.1µm Pore Size	29.9 psi (2.1bar)
0.2µm Pore Size	62.4 psi (4.3 Bar)
0.45µm Pore Size	43.5 psi (3.0 Bar)

## 1.8 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, SAL 10<sup>-6</sup>

## 1.9 Basic Features

### 1.9.1 Autoclavability: NO

### 1.9.2 Conveniently sold presterilized

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

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

## 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.

## 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.

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STERILE R



30°C



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