

Technical Data Sheet

Doc No – Ab/TDS/CC-99

Rev No: 01 Date 10/2021-22

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, P21099, P21100

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



Shiv Ganga Industrial Estate,

Plot no.1 Lakeshwari, Bhagwanpur,
Roorkee – 247667 Uttarakhand, India

An ISO 9001 ,13485, 14001 & CE Certified

A Division of Abdos

Regd. Office:

13A, Government Place (East)
Kolkata – 700069, India

GST : 05AAGCA8605A1Z7

P : +91 (0) 1332 235277

E : labtech@abdosindia.com

W: www.abdoslifesciences.com

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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
P21090	250ml, 0.2 μm High Flow PES Bottle Top Filter Full Assembly, Sterile	250	250	0.2	66	12
P21091	500ml, 0.2 μm High Flow PES Bottle Top Filter Full Assembly, Sterile	500	500	0.2	90	12
P21092	1000mL, 0.2 μm High Flow PES Bottle Top Filter Full Assembly, Sterile	1000	1000	0.2	90	12
P21093	250ml, 0.45 μm High Flow PES Bottle Top Filter Full Assembly, Sterile	250	250	0.45	66	12
P21094	500ml, 0.45 μm High Flow PES Bottle Top Filter Full Assembly, Sterile	500	500	0.45	90	12
P21095	1000ml, 0.45 μm High Flow PES Bottle Top Filter Full Assembly, Sterile	1000	1000	0.45	90	12
P21096	250ml, 0.1 μm High Flow PES Bottle Top Filter Full Assembly, Sterile	250	250	0.1	66	12
P21097	500ml, 0.1 μm High Flow PES Bottle Top Filter Full Assembly, Sterile	500	500	0.1	90	12
P21098	1000ml, 0.1 μm High Flow PES Bottle Top Filter Full Assembly, Sterile	1000	1000	0.1	90	12
P21099	50ml centrifuge Tube and Funnel , 0.2 μm High Flow PES Membrane, Sterile	50	50	0.2	40	24
P21100	15ml centrifuge Tube and Funnel , 0.2 μm High Flow PES Membrane, Sterile	15	15	0.2	40	24



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P21101	250ml Funnel Only with 0.2 um PES Membrane	250	GLSize/ Thread 45	0.2	66	24
P21102	500ml Funnel Only with 0.2 um PES Membrane	500	GLSize/ Thread 45	0.2	66	24
P21103	1000ml Funnel Only with 0.2 um PES Membrane	1000	GLSize/ Thread 45	0.2	90	24
P21104	250ml Funnel Only with 0.1 um PES Membrane	250	GLSize/ Thread 45	0.1	90	24
P21105	500ml Funnel Only with 0.1 um PES Membrane	500	GLSize/ Thread 45	0.1	66	24
P21106	1000ml Funnel Only with 0.1 um PES Membrane	1000	GLSize/ Thread 45	0.1	90	24
P21107	250ml Funnel Only with 0.45 um PES Membrane	250	GLSize/ Thread 45	0.45	90	24
P21108	500ml Funnel Only with 0.45 um PES Membrane	500	GLSize/ Thread 45	0.45	90	24
P21109	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)

1.4.2 Confirm with US FDA Title 21CFR section '177.1655 of US Food and Drug Administration, regarding use of polystyrene in food contact application.

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.



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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: 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: 4⁰ to 37⁰C

1.7.2 Unit Storage: -4⁰ to 50⁰C

1.7.4 Crystal Clear Bottles

1.7.5 High Visibility, raised graduations for easy readings

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-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



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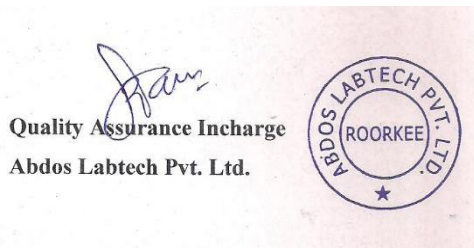
1.9 Basic Features

1.9.1 Autoclavability: NO

1.9.2 Conveniently sold presterilized

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

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



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