

Technical Data Sheet

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TECHNICAL DATA SHEET

Abdos Labtech Pvt. Ltd.

Tissue Culture Treated Plates, PS

Valid for Cat. No. P21020, P21021, P21022, P21023, P21024, P21025, P21026

1. Description/Specification

1.1 Description: Tissue Culture Treated Plates, PS, DNase, RNase, Human DNA, ATP , Pyrogen Free, CE & IVD certified

1.2 Design: Plates

1.3 Performance Specifications:

Code	Cell Growth Area (cm ³)	Bottom Shape	No.of Well	Media Volume (ml)	No. Per Case
P21020	9.5	Flat	6	1.9-2.9	50
P21021	3.6	Flat	12	0.76-1.14	50
P21022	1.9	Flat	24	0.38-0.57	50
P21023	0.88	Flat	48	0.19-0.28	50
P21024	0.32	Flat	96	0.1-0.2	100
P21025	0.32	U	96	0.1-0.2	100
P21026	0.32	V	96	0.1-0.2	100

1.4 Material:

1.4.1 Petri Dish made up of Hydrophobic Polystyrene (PS), Confirm with 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



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CIN : U85100WB2008PTC123903

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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: 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 Plates are designed with low profile & low evaporation rate ensuring no loss of samples.

1.7.2 Small feet on the bottom corners of each plate eliminate scraping of the microscopic lens.

1.7.3 Plates are been treated with vacuum plasma to assures uniform growth.

1.7.4 Easy to peel open and individually wrapped blister pack with lot no. for traceability.

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}

1.9 Basic Features

1.9.1 Autoclavability: NO

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

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

1.9.4 Temperature range: -10°C + 90°C




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