Technical Data Sheet

Doc No – Ab/TDS/MRB-135-I

Rev No: 02Date 01/2021

TECHNICAL DATA SHEET

Abdos Labtech Pvt. Ltd.

Polywire Rack Full, Delrin

Valid for Cat. No. P20725, P20726, P20727, P20728, P20729

1. Description/Specification:

1.1 Description:

Polywire Racks full, Delrin

- 1.1.1 Polywire racks are durable, molded in a single continuous piece so no assembly required and there are no detachable pieces.
- 1.1.2 Manufactured from Delrin® which is very tough, highly resistant to acids, bases solvents and heat.

1.2 Design:

Ergonomic design for easy handling, Racks have precise grid and vials.

1.3 Performance Specifications:

Code	Tubes (mm)	Places	L x W x H (mm)	No. per Case
P20725	13	72	104x202x59	4
P20726	16	72	127x250x70	4
P20727	20 (15ml Tube)	40	100x252x83	4
P20728	25	40	120x300x92	4
P20729	30 (50ml Tube)	24	110x282x85	4

1.4 Material:

- 1.4.1 Delrin, Hydrophobic, confirm 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



A Division of Abdos

Shiv Ganga Industrial Estate,

Plot no.1 Lakeshwari, Bhagwanpur, Roorkee – 247667 Uttrakhand, India Regd. Office:

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

An ISO 9001 ,13485, 14001 & CE Certified **GST**: 05AAGCA8605A1Z7

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P: +91 (0) 1332 235277

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- 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 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
- 1.4.7 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: White, Blue, Red

1.6 Sterilization:

NA

1.7 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.

1.8 Other information

Reusable, can be used in wide temperature range

1.9. Basic Features

1.9.1 Temperature range: -40° C to $+140^{\circ}$ C

1.9.2 Autoclavability: Yes, Autoclavable at 15 psi and 121°C for 20 minutes

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

1.9.4 Manufactured in Aseptic Environment

Autoclaving Guideline for Plastics

All plastic consumables are autoclavable at 121°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°C before removing product.



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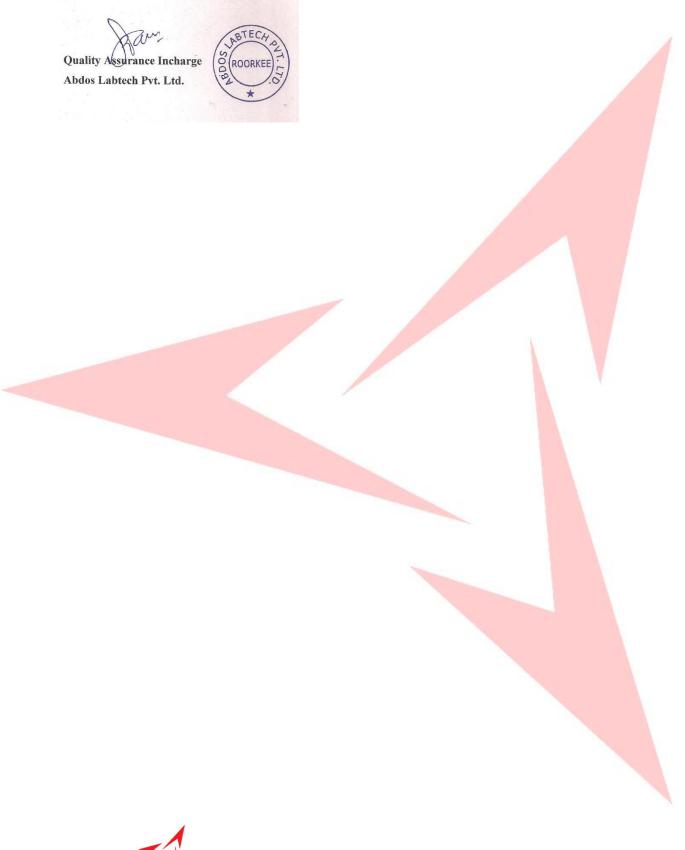
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