# Technical Data Sheet

Doc No – Ab/TDS/LH-59

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## TECHNICAL DATA SHEET

Abdos Labtech Pvt. Ltd.

Refill Filter Pipette Tips, Sterile, PP

Valid for Cat. No. P11092, P11093, P11094, P11095, P11096, P11097, P11098, P11099, P11100

## 1. Description/Specification

## 1.1 Description:

- 1.1.1 Refill Filter Pipette Tips, Sterile, DNase, RNase, Human DNA, ATP & Pyrogen Free, CE & IVD certified.
- 1.1.2 Sterile by Gama Radiation.

## 1.2 Design:

Tip: Open Cylindrical Upper and conical Apex with orifice for liquid dispensing. Precise graduation mark for error free pipetting.

Box: Rectangular Paper Box with Tray.

Compatible for use with Multichannel Pipettes

Each wafer comes in individual wrapping.

## 1.3 Performance Specifications:

Code	Capacity (µl)	No./Case	Colour
P11092	0.1-10 (Graduated)	10Racksx96pcs	Natural
P11093	0.1-10 Extended (Graduated)	10Racksx96pcs	Natural
P11094	1-20 ( Graduated)	10Racksx96pcs	Natural
P11095	1-100 (Graduated)	10Racksx96pcs	Natural
P11096	1-200 (Graduated)	10Racksx96pcs	Natural
P11097	1-300 (Graduated)	10Racksx96pcs	Natural
P11098	100 – 1000ul	10Racksx96pcs	Natural
P11099	100 – 1000ul XL	10Racksx96pcs	Natural
P11000	100 – 1250ul	10Racksx96pcs	Natural



Shiv Ganga Industrial Estate,

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

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1.3.2 Fitting to pipettes: Universal Fit (For detail refer the Abdos compatibility chart)

#### 1.4 Material:

- 1.4.1 Polypropylene (PP), 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, 7<sup>th</sup> 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
- 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:**

**Tip Colour** -Natural

Wafer Colour - 10ul Green, 20 to 100ul Yellow, 200 to 300ul Orange, 1000ul Blue, 1000XL & 1250ul Light Blue

#### 1.6 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<sup>-6</sup>

## 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



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Management System. Testing of various characteristics in accordance with the valid specification, inspection reviewed & signed for product release.

## 1.8 Other information:

Super filter provides aerosol & aqueous liquid by pass prevention in over pipetting thereby preventing cross contamination. Hydrophobic filter that is additive free & does not absorb samples.

Recommended for single used only.

1.9. Basic Features:

**1.9.1 Made up of :** High Purity Virgin Polypropylene (PP)

**1.9.2 Temperature range :**  $-80^{\circ}$ C to  $+ 121^{\circ}$ C for 20 minutes

**1.9.3 Autoclavability:** Can be autocalve but might loose the fitting of filters.

**1.9.4 Chemical resistance:** see website (www.abdoslifesciences.com)

**1.9.5 Retention:** Best in its class. (with Acidic & Basic dyes)

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

**1.9.7** ABDOS Super Filter Tips has a 100% pure, porous polyethylene (PE) filter that prevents aerosol contamination and carryover generated during sample aspiration. In addition, Filter Pipette Tip does not trap samples and allows for sample recovery in the event of overpipetting. 99.9% Bacterial Aerosol Filtration Efficiency (BFE), (ASTM F21012) Inert, hydrophobic PE filter does not trap or block the liquid. Free of leachables, extractables and heavy metals. Non Cytotoxic (ISO 10993-5 MRM, Minimal Essential Media Elution, GLP CompliantNon-hemolytic.





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