## **Technical Data Sheet**

Doc No-Ab/TDS/LH-81

Rev No: 07 Date 10/2021-22

## **TECHNICAL DATA SHEET**

## Abdos Labtech Pvt. Ltd.

### Pasteur Pipettes, LDPE

### Valid for Cat. No. P31201, P31202, P31205, P31206, P31207, P31208, P31209, P31210,

### 1. Description/Specification

### **1.1 Description:**

Disposable Pasteur Pipette 0.4, 1.0, 2.0 & 3.0 ml, DNase, RNase and Pyrogen Free, CE certified

#### 1.2 Design:

1.2.1 Cylindrical Upper and conical Apex with orifice for liquid dispensing

### **1.3 Performance Specifications:**

Code	Capacity (ml)	Length (mm)	No. per case	Colour
P31207 Bulk	0.5	131	500	Natural
P31208 Sterile	0.5	131	500	Natural
P31201 Bulk	1	153	500	Natural
P31202 Sterile	1	153	450	Natural
P31209 Bulk	2	152	500	Natural
P31210 Sterile	2	152	450	Natural
P31205 Bulk	3	154	500	Natural
P31206 Sterile	3	154	450	Natural

### 1.4 Material:

1.4.1 Low Density Polyethylene (LDPE), 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.



Distribué par Humeau

Z.A. Hauts de Couëron - 11 rue des Imprimeurs CS 24220 - 44220 Couëron - France t. : +33 (0)2 40 93 53 53 info@humeau.com - www.humeau.com

# **Technical Data Sheet**

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:

Translucent (Natural)

## **1.6 Graduations:**

**Engraved Graduation** 

## **1.7 Sterilization: For sterile Product Only**

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>

## **1.8 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.

## **1.9 Other information:**

Recommended for Single use only

Pack Size: 500 & 450Pieces/case

## 2. Basic Features

**2.1 Autoclavability: NO,** LDPE material can't be Autoclavabled. Doing such may cause deformation of shape.

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



Distribué par **Humeau** Z.A. Hauts de Couëron - 11 rue des Imprimeurs CS 24220 - 44220 Couëron - France t. : +33 (0)2 40 93 53 53 info@humeau.com - www.humeau.com

# **Technical Data Sheet**

**2.3 High Retention:** Low affinity surface reduces the loss of cell & valuable proteins due to binding.

**2.4 Inertness:** LDPE Pipettes are inert & non Toxic to biological fluids and most acid and can be sealed and refrigerated

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

**2.6 Temperature range :**  $-50^{\circ}$ C to  $+70^{\circ}$ C

### 2.7 Dimension:

Description	Capacity	Overall length	Max Graduation Volume	Graduations Mark
P. Pipettes	0.4 ml	131 mm	0.4 ml	0.1 ml
P. Pipettes	1 ml	154 mm	1 ml	0.25 ml
P. Pipettes	2 ml	152 mm	2 ml	0.50 ml
P. Pipettes	3 ml	154 mm	3 ml	0.50 ml

Note : Available in Bulk & Individual Blister Pack.

Quality Assurance Incharge Abdos Labtech Pvt. Ltd.





Distribué par **Humeau** 

Z.A. Hauts de Couëron - 11 rue des Imprimeurs CS 24220 - 44220 Couëron - France t. : +33 (0)2 40 93 53 53 info@humeau.com - www.humeau.com