

Technical Data Sheet

Doc No – Ab/TDS/LH-71

Rev No : 04 Date 01/2021

TECHNICAL DATA SHEET

Abdos Labtech Pvt. Ltd.

Serological Pipettes Sterile (PS)

Valid for Catalog No. P10601, P10602, P10603, P10604, P10605, P10606

1. Description/Specification

1.1 Description:

Disposable Serological Pipettes Sterile (PS), DNase, RNase, & Pyrogen Free, CE certified.

1.2 Design:

Transparent Cylindrical Design

1.3 Performance Specifications:

Code	Capacity (ml)	Colour (Pouch)	OD(mm)	Orifice External(mm)	Height (mm)	No./Case
P10601	1	Yellow	4.70	2.6	262	500
P10602	2	Green	6.40	2.6	280	400
P10603	5	Blue	8.10	3.2	333	200
P10604	10	Orange	10.05	7.9	354	200
P10605	25	Red	15	5	312	200
P10606	50	Black	18	5.5	360	100

1.4 Material:

1.4.1 Polystyrene (PS), 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.

1.4.4 The product has passed the USP testing including class VI tests & has been assigned the FDA Drug master file DMF 12123



Shiv Ganga Industrial Estate,
Plot no.1 Lakeshwari, Bhagwanpur,
Roorkee – 247667 Uttarakhand, India
An ISO 9001 ,13485, 14001 & CE Certified
A Division of Abdos

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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)

1.6 Graduations:

1.6.1 Large Cylindrical with temperature, chemical and solvent resistant ink.

1.6.2 Accuracy within $\pm 2\%$ At Full volume

1.6.3 Bidirectional graduations provide choice of ascending and descending scales

1.7 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}

1.8 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:

1.9.1 ABDOS Advance PU filter offers complete protection against contamination

1.9.2 Negative graduations allow additional working volume.

1.9.3 Recommended for single use only

1.9.4 Individually wrapped graduated pipettes with paper/plastic peel-pack with printed Batch no. & shelf life.



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2. Basic Features

2.1 **Temperature range:** -80°C to +90°C

2.2 **Autoclavability:** NO

2.3 **Chemical resistance:** See website (www.abdoslifesciences.com)

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


Quality Assurance Incharge
Abdos Labtech Pvt. Ltd.




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