

Technical Data Sheet

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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)	No. per case
P10601	1	500
P10602	2	400
P10603	5	200
P10604	10	200
P10605	25	200
P10606	50	100

1.4 Material:

1.4.1 Comply with requirement of Directive EU No 10/2011 and requirement of FDA Regulation 21 CFR 177.1640

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,
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Roorkee – 247667 Uttrakhand, India
An ISO 9001 & 13485 Certified
A Division of Abdos

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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 according to ELV Direction 2000/53/EC, EU CONEG & it's following amendments. It is safe use in contact with food stuff, Pharmaceuticals & drinking water.

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

1.8 Quality control:

Testing of various characteristic in accordance with the valid Specification

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.

2. Basic Features

2.1 **Temperature range:** -80°C to $+90^{\circ}\text{C}$

2.2 **Autoclavability:** NO

2.3 **Chemical resistance:** See website.




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Quality Assurance Incharge
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