## **Technical Data Sheet**

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## TECHNICAL DATA SHEET

Abdos Labtech Pvt. Ltd.

Volumetric Flask - TPX Class A

Valid for Catalog No. P50201,P50202,P50203,P50204,P50205,P50206

### 1. Description/Specification

## 1.1 Description:

TPX Volumetric Flask

- 1.1.1 These Flasks are made from Glass like TPX offering excellent clarity.
- 1.1.2 These Volumetric Flask Come with polypropylene stopper.
- 1.1.3 Meet accuracy requirements of class A under "ISO 1042".
- 1.1.4 Supplied with conformity test certificate that indicates batch number & year of production.
- 1.1.4 These flasks are recommended to be washed at max 60oC.

### 1.2 Design:

Volumetric Flask

## 1.3.Performance Specifications:

Code	Capacity (ml)	Error limit (+ ml)	Bulb Dia (mm)	Height with Stopper (mm)	Neck Size	No./Case
P50201	25	0.04	40	115	10/19	1
P50202	50	0.06	50	150	12/21	1
P50203	100	0.10	60	180	14/23	1
P50204	250	0.15	80	235	19/26	1
P50205	500	0.25	100	270	19/26	1
P50206	1000	0.40	125	310	24/29	1

#### 1.4 Material:

- 1.4.1 TPX- Polymethylpentene (PMP), confirm US FDA 21CFR
- 1.4.2 Complies with requirement accordance with article of regulation (EC) No. 1907/2006 and its amendments.



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- 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 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:

Meet accuracy requirements of class A under "ISO 1042"

#### 1.7 Sterilization:

NA

#### 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 amendments.

#### 1.9 Other Information:

Reusable, can be autoclaved up to 10 autoclave cycle.

- 2. Basic Features
- **2.1 Made up of** Polymethylpentene (TPX)
- **2.1 Temperature range:**  $-80^{\circ}$ C to  $+175^{\circ}$ C
- **2.3 Autoclavability:** Yes, Autoclavable at 15 psi and 121°C for 20 minutes

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- **2.4 Chemical resistance:** See website (<u>www.abdoslifesciences.com</u>)
- **2.5** 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  $50^{\circ}\mathrm{C}$  before removing product.

Quality Assurance Incharge Abdos Labtech Pvt. Ltd.

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