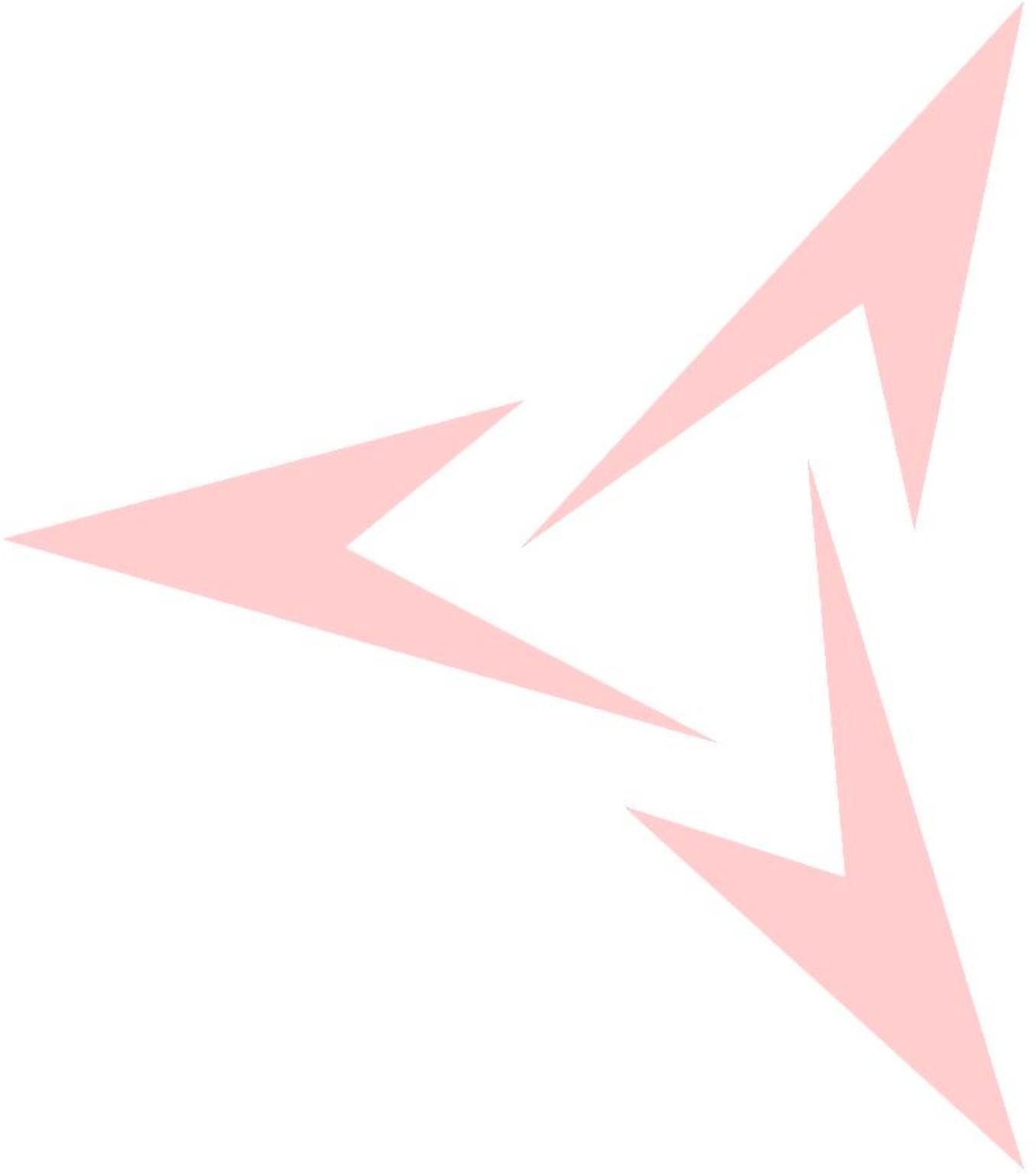


Technical Data Sheet



Shiv Ganga Industrial Estate,

Regd. Office:

P :
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Technical Data Sheet

1.4 Material:

1.4.1 **Tube:** Polypropylene (PP)

1.4.2 Confirm US FDA 21CFR

1.4.3 Complies with requirement accordance with article of regulation (EC) No. 1907/2006 and its amendments.

1.4.4 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.

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

1.4.6 Materials has successful passed the biological tests according to ISO 10993 external communication devices for indirect blood contact for Prolonged period.

1.4.7 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

1.4.8 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 color- Natural, Yellow and Blue

1.6 Sterilization:

NA

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

1.8 Other information:

Recommended for single use only

1.9 Basic Features:

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



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1.9.2. Temperature range : -80⁰C to + 121⁰C for 20 minutes

1.9.3. Autoclavability: Yes, Autoclavable at 15 psi and 121 ⁰C for 20 minutes

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

1.9.5 Chemical resistance: see website (www.abdoslifesciences.com)

1.9.6 Retention: Best in its class (with Acidic & Basic dyes)

Autoclaving Guideline for Plastics

All plastic consumables are autoclavable at 121⁰C 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 50⁰C before removing product.


Quality Assurance Incharge
Abdos Labtech Pvt. Ltd.



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