

Technical Data Sheet

Doc No–Ab/TDS/GLP-163

Rev No: 00 Date 01/2021

TECHNICAL DATA SHEET

Abdos Labtech Pvt. Ltd.

Dual Purpose Scoop, HDPE

Valid for Catalog No. P11907, P11908

1. Description/Specification

1.1 Description: Dual Purpose Scoop, HDPE

1.1.1 ABDOS Dual purpose Scoop is designed to combine the function of a scoop, weigh boat, and funnel to make this product economically beneficial.

1.1.2 These Scoops are made from high quality anti-static polystyrene that is waterproof and reduces the probability of materials sticking to the scoop.

1.1.3 These scoops have locking tabs that help to retain materials.

1.1.4 These scoops can withstand powders, gels, and semi-solids.

1.1.5 The broad tip design keeps the scoop stable while on the scale and enables materials to be easily scooped and dispensed.

1.1.6 The dosage requirements for electron beam sterilization that results in sterilized products is determined by procedures that are compliant with ISO 11137..

1.2 Design: Round bottom Scoop

1.3 Performance Specifications:

Code	Size	Dimension (mm)	Colour	No. Per Case
P11907	Large	127x90	White	100
P11908	Small	127x63	White	100

1.4 Material:

1.4.1 High Density poly Ethylene (HDPE), 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



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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:

Translucent (Natural)

1.6 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.

1.7 Other information

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

1.7.2 **Manufactured** in Aseptic Environment

CE mark	No
Autoclavability	No
Translucence	Yes
Resistant	To be effected by radiations
Sterilization	Yes
Temperature	From – 40°C to + 80°C

1.8 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*



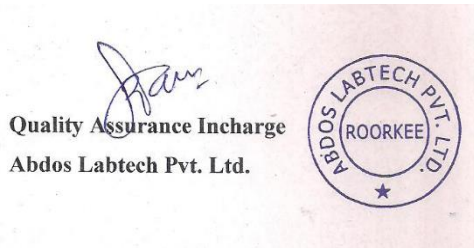
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and routine control- Radiation sterilization. The product has been sterilized with Co-60 Gamma Radiation.



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