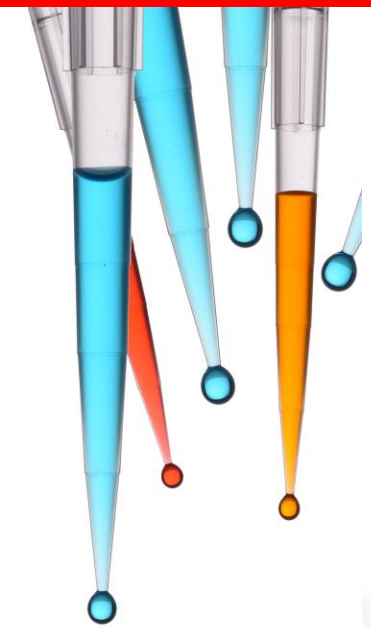
“QUALITY IS VITAL BUT CERTIFICATION ENSURES IT”






ABDOS

ABDOS 50

CELEBRATION FROM 50 TO INFINITY YEARS

Certificates Summary

1. **CE** certification
2. **ISO 9001:** QMS
3. **ISO 13485:** For Medical devices – Quality management systems
4. **ISO 14001:** Environment Management System
5. **ISO 11137:** Gamma sterilization (Sterile R)
6. **ISO 24988**: Petrdish standards
7. **ISO 8655**: Accuracy Standards
8. **ISO 6706:** Accuracy Standards
9. **DIN 12681**: Accuracy Standards
10. **NABL:** Graduation Measurement Certification
11. **IVD** certification
12. **Heavy Metal** Certification
13. **DNase RNase** Free
14. **ATP** free
15. **Endotoxin** Free
16. **Human DNA** free
17. **Cytotoxicity** Test
18. **GC/MS (Gas chromatography & Mass Spectrophotometry Test)**
19. **Migration Test**: Leachable compounds
20. **635 mm/Hg**: Leak Test
21. **95 kpa pressure test**: for Storage vial.

ABDOS

ABDOS

CELEBRATION FROM 50 TO INFINITY YEARS

Certification - How Valuable are these

ISO 9001

Quality Management System

CE Certificate

Certificate of Compliance

ISO 13485

Manufacturing of Plastic lab Ware for Clinical & Medical Use.

IVD Certificate

Certified In-vitro Products

EC-REP

European Union Representative

ISO 14001

Environment Management System

ABDOS

ABDOS 50
CELEBRATION FROM 50 TO INFINITY YEARS

ISO 9001 : Quality Management System

Certificate of Registration

This certificate has been awarded to

Abdos Labtech Pvt. Ltd.

Plot No.-1, Shiv Ganga Industrial Estate, Lakheshwari, Bhagwanpur, Roorkee, Uttarakhand, 247667, India

In recognition of the organization's Quality Management System which complies with

ISO 9001:2015

The scope of activities covered by this certificate is defined below

Development, Manufacture and Distribution of Life Science Plastic Consumables and its related Accessories for Pharmaceutical, Diagnostic, Research, Food, Water, Clinical and Medical Uses

Certificate Number: | Date of Issue: (Original) | Date of Issue:
15 October 2018 | 15 October 2018

Issue No: | Expiry Date:
1 | 14 October 2021

Issued by: | On behalf of the Scheme Manager

ABSTRACT

ISO 9001:2015 specifies requirements for a quality management system :

A) ABDOS demonstrate its ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements.

B) ABDOS aims to enhance customer satisfaction through the effective application of the system, including processes for improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements.

Celebrating 10 years of ISO 9001

ABDOS

ABDOS

CELEBRATION FROM 50 TO INFINITY YEARS

CE

Certification & Inspection

Certificate of Compliance

CE

Confirms that the products of class I according to EU Council Directive: 98/79/EC of 27 October 1998 on in vitro diagnostic medical devices Directive.

Certificate No.: CE-2695

Manufacturer

Name : Abdos Labtech Private Limited

Address : Plot No-1, Shivganga Industrial Area, Lakheswari Bhagwanpur, Roorkee, Uttarakhand-247667, India

Products : Micro Tips, Micro Centrifuge Tubes, Centrifuge Tube with Conical Bottom, Cryo Vials, Rin Vials, Sample Containers with Cap, Petry Dish & Storage vial

Product Description : ALPL/TCP/80 dated 20.10.2015

Complies with the requirements applicable to it.

The manufacturer's technical documentation as required for class I device has been reviewed and found to comply with the requirements as Annex VII, Section 4 and any significant changes to the design or construction of the product, not agreed upon by us, this declaration will lose its validity.

This certificate is issued under the following conditions:

1. It applies only to the quality system maintained in the manufacture of above referred models and it does not substitute the design or type examination procedures, if required.
2. The certificate remains valid until the manufacturing conditions or the quality systems are changed.
3. The certificate validity is maintained by positive results of surveillance audits on yearly basis.
4. After fulfilling the relevant EU legislation, the manufacturer shall affix to each device, of the referenced models:
5. The CE mark as shown above can be used, under the responsibility of the manufacturer, after completion of an EC Declaration of conformity and compliance with all relevant EC Directives. This statement is based on a single evaluation of each sample of above mentioned products. It does not imply an assessment of the whole production.

Validity of this certificate can be verified at www.ukcertification.co.uk/verify

Date of initial registration	18th November 2016
Date of this certificate	18th November 2016
Certificate expiry	17th November 2017
Recertification due subject to the company maintaining its system to the required standard	17th November 2019

Authorised Signatory

This certificate is the property of UK Certification & Inspection Limited and shall be returned immediately on request.
5 Jupiter House, Calleva Park, Aldermaston, Reading, Berkshire RG7 8NN, UK.
Website: www.ukcertification.co.uk

ABSTRACT

A) ABDOS is authorized CE on its products in trade movement in the European Economic Area.

B) ABDOS Conformity with Europe, demonstrate that the products have been **audited/assessed** in terms of minimum **safety, health and environmental** requirements.

C) ABDOS CE marking also indicates fair competition among manufacturers as it enforces accountability and conformity with the same requirements.

Celebrating 10 years of CE

ABDOS

ABDOS

CELEBRATION FROM 50 TO INFINITY YEARS

IVD Certificate

ABDOS **Cryo vials , Sample containers, & Storage vials** ranges are IVD certified

IVD Certificate

Certified In-vitro Products

ABSTRACT

A) **ABDOS** is strongly delivering IVDs certified products. IVDs certified & accessories used to perform tests on **samples**, such as **blood, urine, tissue**, taken away from the **human body** to help detect **infection, diagnose a medical condition, prevent disease or monitor drug therapies**.

B) The first step is to determine if the product is a medical device as defined by the Directive. The In Vitro Device Directive Article 1, point 2b defines an IVD as any medical device which is a

- **Cryo product, containers & Storage, Instrument, Apparatus**
- **Reagent, Reagent Product Calibrator, Control Material**
- **Kit**
- **Equipment, System**

IVD CERTIFIED

C) Whether used alone or in combination, intended to used in vitro for the **examination of specimen, including blood and tissue donations**, derived from the **human body, solely or principally for the purpose of providing information**:

- concerning a physiological of pathological state of health or disease, or
- concerning a congenital abnormality, or
- to determine the safety and compatibility with potential recipients, or
- to monitor therapeutic measures.

Celebrating 10 years of IVD

ABDOS

ABDOS 50 CELEBRATION FROM 50 TO INFINITY YEARS

ISO 14001 : 2015 Environment Management System

QRO
QUALITY RESEARCH ORGANIZATION

Certificate of Registration

This is to certify that

Abdos Labtech Private Limited

Plot No-1, Shivganga Industrial Area, Lakheswari Bhagawanpur,
Roorkee, Uttarakhand-247667, India

has been independently assessed by QRO
and is compliant with the requirements of:

ISO 14001:2015

Environment Management System

For the following scope of activities:

Development, Manufacture and Distribution of Life Science Plastic Consumables and Its Related Accessories for Pharmaceutical, Diagnostic, Research, Food, Water, Clinical and Medical Uses

Date of Initial Registration: 04th December 2019 — Certificate Expiry: 03rd December 2022
Date of this Certificate: 04th December 2019 — Recertification Due: 03rd December 2022

Certificate Number: 1031219053K

Head of Certification

Validity of this certificate is subject to annual surveillance audits to be done successfully on or before 365 days from date of the audit.
(In case if surveillance audit is not allowed to be conducted: this certificate shall be suspended / withdrawn).
The Validity of this certificate can be verified at www.qrocert.com
This certificate of registration remains the property of QRO Certification LLP, and shall be returned immediately upon request.
QRO Certification LLP is accredited by UK Akkreditering Forum Limited, UK (www.ukaf.org.uk)
5 Jupiter House, Calleva Park, Aldermaston, Reading Berkshire RG78NN UK

India Office : QRO Certification LLP
142, IInd Floor, Avtar Enclave, Near Paschim Vihar West Metro Station, Delhi-110063, (INDIA)
Website : www.qrocert.com, E-mail : info@qrocert.com

ABSTRACT

ABDOS Labtech Achieves **ISO 14001:2015** Environmental management systems Certification.

A) Based on ISO 14001:2015 specifies the requirements for an environmental management system, **ABDOS** is committed to enhance its environmental performance.

B) ABDOS is intended to manage its environmental responsibilities in a systematic manner that contributes to the environmental pillar of sustainability.

C) ISO 14001:2015 helps organization achieve the intended outcomes of its environmental management system, which provide value for the environment & Sustainability**. ABDOS** aims to deliver Consistent environmental policy, the intended outcomes of an environmental management system include:

- **Enhancement of environmental performance;**
- **Fulfilment of compliance obligations;**
- **Achievement of environmental objectives**.

NEW

ABDOS

ABDOS
CELEBRATION FROM 50 TO INFINITY YEARS

ISO 13485 : Quality Management System

Certificate of Registration

This certificate has been awarded to

Abdos Labtech Pvt. Ltd.

Plot No.-1, Shiv Ganga Industrial Estate, Lakkeshwari, Bhagwanpur, Roorkee, Uttarakhand, 247667, India

In recognition of the organization's Quality Management System which complies with

EN ISO 13485: 2016

The scope of activities covered by this certificate is defined below

Development, Manufacture and Distribution of Life Science Plastic Consumables and its related Accessories for Pharmaceutical, Diagnostic, Clinical Research and Medical Uses

Certificate Number: 10105418/0001/UKAS | Date of Issue: (Original) 15 October 2018 | Date of Issue: 15 October 2018

Issue No: 1 | Expiry Date: 14 October 2021

Issued by: | On behalf of the Scheme Manager

ABSTRACT

A) ABDOS accounted for in the organization's **quality management system** by **monitoring, maintaining, and controlling** the processes.

B) ABDOS is committed in one or more stages of the **life-cycle**, **including design and development, production, storage and distribution, installation, or servicing of a medical device** and **design and development** or provision of **associated activities (e.g. technical support).**

- **ISO 13485:2016** specifies requirements for a quality management system , **ABDOS** demonstrate its ability to provide medical devices and related services that consistently meet customer and applicable regulatory requirements.

C) ABDOS is committed to empower 5 clauses of **IS**O 13485 that are numbered 4, 5, 6, 7, 8

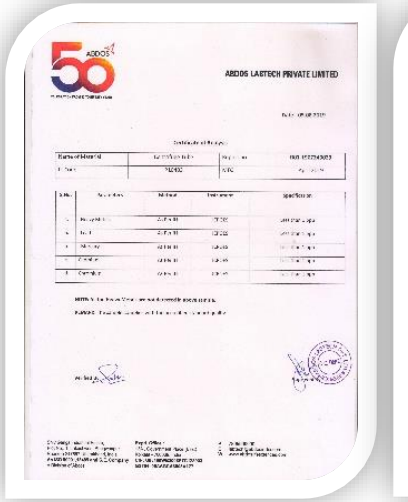
4 . **Quality management system**
5 . **Management responsibility**
6 . **Resource management**
7 . **Product /service realization**
8 . **Measurement, analysis and improvement**

Celebrating 10 years of ISO 13485

ABDOS

ABDOS 50 CELEBRATION FROM 50 TO INFINITY YEARS

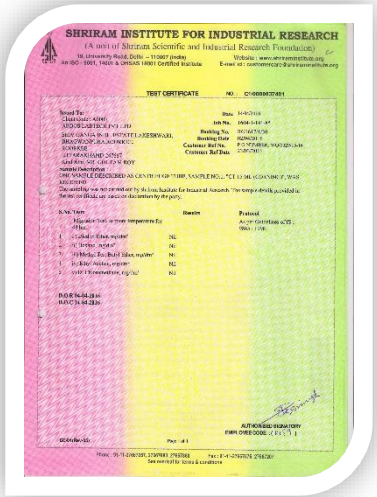
Certification - How Valuable are these



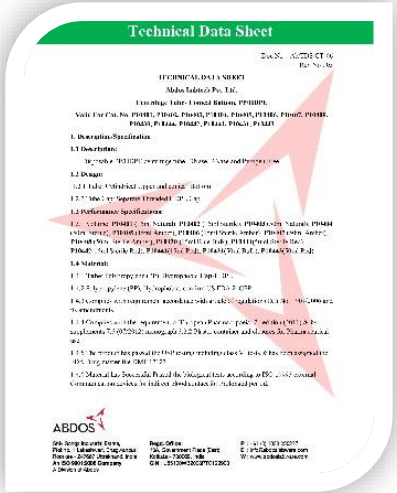
Heavy Metal Free

Sterility Test Report

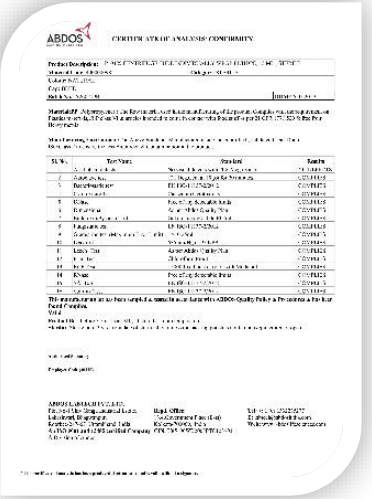
Endotoxin And ATP Free Test Report



Migration Test Report



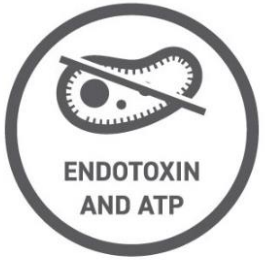
Technical Data Sheet



Certificate of Analysis (COA)

GCMS/ TOC test report

FREE



FREE

HUMAN DNA FREE

LEAK TEST

Petrdish Standards

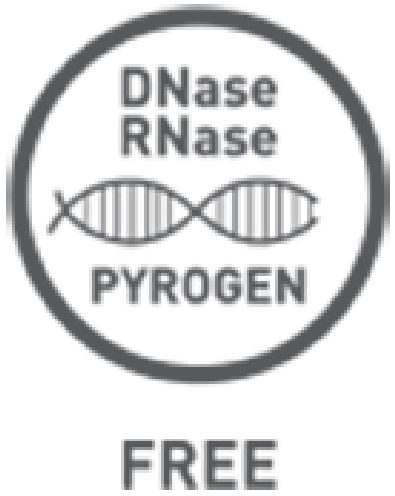
DNase RNase & Pyrogen Free

ABSTRACT

A) **ABDOS** Confirm that all essential range is **"DNase/RNase-free"**. It can be used for the sensitive applications such as PCR & qPCR.

B) DNase and RNase are ubiquitous in the environment, and in some biological materials. They are present in relatively **high concentrations**. RNase frequently contaminates common molecular biological reagents such as reaction buffers, enzymes such as reverse transcriptase, RNA polymerase, and buffers for RNA purification and storage. DNase degrades DNA and its presence is a threat to many molecular biology experiments.

- A deoxy ribonuclease, or DNase, is an enzyme degrades DNA by catalysing the hydrolytic cleavage of phosphodiester linkages in the DNA backbone.
- DNase contamination can come from contact with human skin, and is often present in the lab environment.
- DNase contamination is of great concern in the medical device and pharmaceutical industries as well as the biotech and research fields, because DNase can cause degradation of valuable DNA samples, which may make it impossible to analyse the DNA via PCR, QPCR or next generation sequencing



Celebrating 10 years of DNase , Rnase free authentication

ABDOS

ABDOS 50
CELEBRATION FROM 50 TO INFINITY YEARS

Endotoxin And ATP Free Test Report

ABDOS achieved Endotoxin level ≤0.03 EU/ml & Aiming for 0.005 EU/ml

ABSTRACT

A). ABDOS achieved the endotoxin level **≤0.03 EU/ml** & met the criteria established in ANSI/AAMI ST 72, IP & USP, Bacterial Endotoxins – Test methodologies, routine monitoring & alternatives to batch testing. The acceptance level for product is ≤0.03 EU/ml by LAL test.

B) Endotoxins are bacterial structural components that are released when such a cell is lysed.

• These components are toxic if administered to humans and/or animals, causing a pyrogenic response (rise in body temperature). For this reason it is important it must be tested for their endotoxin content. ABDOS provides endotoxin free products in **Liquid , Centrifuge , Cryo & General laboratory category**.

ENDOTOXIN AND ATP FREE

ABDOS

ABDOS

CELEBRATION FROM 50 TO INFINITY YEARS

Gamma Sterilization : ISO 11137

CERTIFICATE OF ANALYSIS/CONFIRMITY

Sterility Assurance Certificate

SL.NO.	PRODUCT DESCRIPTION	LOT NO.	PRODUCT CODE
1.	Filter Tip Racked 100-1000ul	A010119A	P11037

The above mention Product has been irradiated on 11/03/2019 with Co-60 gamma radiation at **SHRIRAM APPLIED RADIATION CENTRE (S.A.R.C.), New Delhi**. This certificate is provided on the ground of **CERTIFICATE OF THE GAMMA IRRADIATION, No-C1/0000120660, Date -11/01/2019** by the SHRIRAM INSTITUTE FOR INDUSTRIAL RESEARCH, NEW DELHI.

Dose validation: The dose is validated according to IS. EN. ISO 11137-2 Method 1 to confirm the SAL 10^{-6}.For that routine testing of Bioburden & Sterility test carried out.

Validity of Sterility:

We assure the above Mention product has been Sterile through Co-60 gamma radiation of valid Dose & it has been **PASSED** for the sterility test. We confirm that the Sterile product would be Sterile until unless the packing pouch is not tampered/punctured/Open OR 3 yrs. From date of Radiation."

Quality Assurance Incharge
Abdos Labtech Pvt. Ltd.

ABDOS

Shiv Ganga Industrial Estate, Plot no. 1 Lakeshwari, Bhagwanpur, Roorkee - 247667 Uttrakhand, India
An ISO 9001:2008 Company
A Division of Abdos

Regd. Office : 13A, Government Place (East) Kolkata – 700069, India
CIN : U85100WB2008PTC123903

P : +91 (0) 1332 235277
E : info@abdoslabware.com
W : www.abdoslabware.com

ABDOS

ABSTRACT

A) Gamma radiation sterilization is the most popular form of radiation sterilization. Gamma based radiation sterilization has been deemed safe and effective by a number of government and public health agencies including the US Centre for Disease Control and Prevention, the Food and Agriculture Organization, the United Nations and the World Health Organization.

- Gamma rays pass readily through plastics and kill bacteria by breaking the covalent bonds of bacterial DNA.
- They are measured in units called kiloGrays (kGy). (ABDOS kGy is most ideal)
- Gamma irradiation provides a number of benefits in cost and sterility assurance. It can be applied under safe, well defined, and controlled operating parameters, **and** is not a heat- or moisture generating process.
- Environmental friendly: There is no residual radioactivity after irradiation.

STERILE R

DOSE VALIDATION

Gamma Radiation dose is validated according to IS**. EN. ISO 11137-2** Method 1 to confirm the **SAL 10-6**. For that routine testing of bioburden & Sterility test carried out at our manufacturing facility.

VALIDITY OF STERILITY

We assure all sterile products have been sterile through Co-60 gamma radiation with valid certified dose and has been PASSED for all sterility tests. We confirm that the Sterile product would be Sterile until unless the packing pouch is not tampered/punctured/open or 5 yrs from date of Radiation.

ABDOS 50
CELEBRATION FROM 50 TO INFINITY YEARS

Heavy Metal Test Report

ABDOS LABTECH PRIVATE LIMITED

Date - 05.08.2019

Certificate of Analysis

Name of Material	Centrifuge Tube	Report no.	R01-1907240029
P. Code	P10403	MFG	April 2019

S.No.	Parameters	Method	Instrument	Specification
1.	Heavy Metals	As Per IH	ICPOES	Less than 1 ppb
a.	Lead	As Per IH	ICPOES	Less than 1 ppb
b.	Mercury	As Per IH	ICPOES	Less than 1 ppb
c.	Cadmium	As Per IH	ICPOES	Less than 1 ppb
d.	Chromium	As Per IH	ICPOES	Less than 1 ppb

NOTE: All the Heavy Metals are not detected in above sample.

REMARK: The sample complies with the prescribed standard quality.

Verified By

Approved By

Q.C. DEPT.

Shiv Ganga Industrial Estate, Plot No., 1, Lakeshwari, Bhagwanpur, Roorkee-247667 Uttarakhand, India
An ISO 90001,13485 and C.E. Company
A Division of Abdos

Regd. Office :
13A , Government Place (East)
Kolkata - 700069, India
CIN: U85100WB2008PTC123903
GSTIN- 05AAGCA8605A1Z7

P : 7895999090
E : labtech@abdosindia.com
W : www.abdoslifesciences.com

ABSTRACT

A). ABDOS recommends Heavy metal free products**.** Presence of **HM** is less than 1PPM(not detectable). The sum of the incidental concentration levels of **lead, mercury, cadmium and hexavalent chromium** present does not exceed define limit of Coalition of Northeastern Governors (EU CONEG) model Toxics in Packaging Legislation.

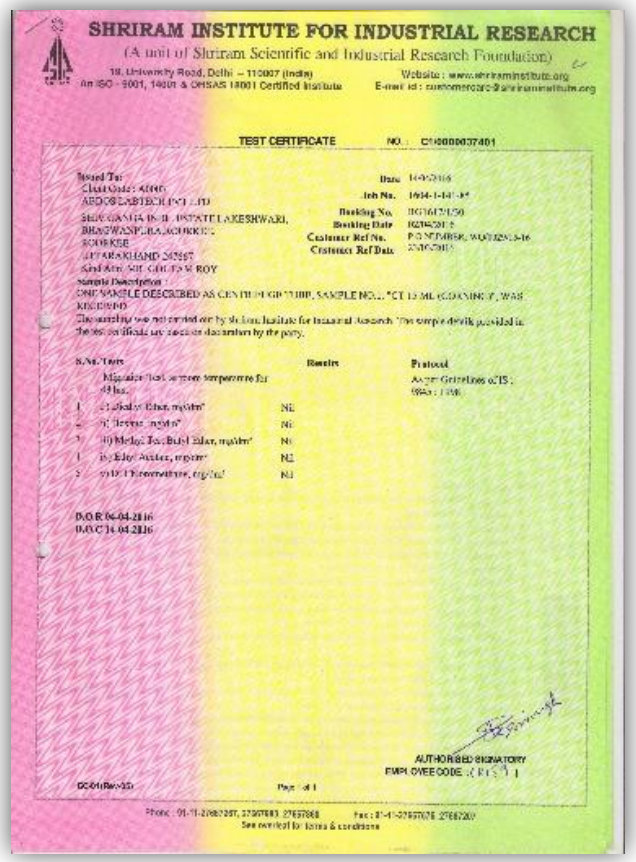
B) ABDOS products can be used for **storage and analysis** tasks that require extremely low levels of **most common metals.**

ABDOS

ABDOS

CELEBRATION FROM 50 TO INFINITY YEARS

Migration Test Report



SHRIRAM INSTITUTE FOR INDUSTRIAL RESEARCH

(A unit of Shriram Scientific and Industrial Research Foundation)

TEST CERTIFICATE

ABSTRACT

- **ABDOS** ensures **migration free product.** The Overall Migration limit (OML) applies to the sum of all substances that can migrate from the plastic contact material to the **chemical** (or chemical simulant). The overall migration limit is a measure for the **inertness of the material**.
- Within the area of contact materials, migration limits have been set for many substances based on the toxicological risk assessment of these substances. These limits are included in Contact regulations with the aim to control the exposure to these substances to **protect the samples**.

ABDOS

ABDOS

CELEBRATION FROM 50 TO INFINITY YEARS

GCMS/TOC test report

ABDOS CT, **MCT , CRYO VIAL & RIA VIAL** RANGE IS **GC/MS** CERTIFIED.

ABDOS LABTECH PRIVATE LIMITED

Date - 06.01.2020

Certificate of Analysis

Name of Material	Cryo Vials	Report no.	27121IN-NL-004
P. Code	P60116	B.No/MFG	A101219A (mfg. Dec19)

S.No.	Leachable Solvents	Method	Instrument	Specification	Results
1.	Dimethyl sulfoxide (DMSO)	BPOG Guidelines	GCMS	Less than 1 ppm or mg/kg	No organic solvent peak observed on GCMS during Extractable & Leachable Study
2.	Cadmium Sulphate ($CdSO_4$)	BPOG Guidelines	GCMS	Less than 1 ppm or mg/kg	No organic solvent peak observed on GCMS during Extractable & Leachable Study
3.	Ethanol	BPOG Guidelines	GCMS	Less than 1 ppm or mg/kg	No organic solvent peak observed on GCMS during Extractable & Leachable Study
4.	Sodium Hydroxide	BPOG Guidelines	GCMS	Less than 1 ppm or mg/kg	No organic solvent peak observed on GCMS during Extractable & Leachable Study
5.	Phosphoric Acid	BPOG Guidelines	GCMS	Less than 1 ppm or mg/kg	No organic solvent peak observed on GCMS during Extractable & Leachable Study
6.	Hexane	BPOG Guidelines	GCMS	Less than 1 ppm or mg/kg	No organic solvent peak observed on GCMS during Extractable & Leachable Study
7.	Total Organic Carbon(TOC)	In House	GCMS	-	6.23ppm

REMARK: The sample complies with the prescribed standard quality.

Verified By

Approved By

Unit No. 319, 3rd Floor, DLF Tower – A , DDA Dist. Centre, Jasola, New Delhi – 110025, India

Regd. Office : 13A, Government Place (East) Kolkata – 700069, India

P : +91 (0) 44800980-86
F : +91 (0) 11 44800987
E : info@abdoslabware.com

ABSTRACT

A). Gas chromatography/mass spectrometer (GC/MS) is a technique useful for detecting and measuring trace organic constituents in a bulk sample. In GC/MS , the components of a mixture are separated in the gas chromatograph (GC) and identified in the mass spectrometer..

B). GC/MS is the analysis method of choice for smaller and volatile molecules such as benzenes, alcohols and aromatics, and simple molecules such as steroids, fatty acids, and hormones. It can also be applied towards the study of liquid, gaseous and solid samples.

C) For next generation analysis GC/MS for compound analysis is imperative, including its ability to separate complex mixtures, to quantify analytes, and to determine trace levels of organic contamination.

D) **ABDOS** have validated GC/MS report with the guideline of **BPOG**.

ABDOS

ABDOS

CELEBRATION FROM 50 TO INFINITY YEARS

“ CERTIFIED PRODUCTS ALWAYS LEAD TO BETTER RESULTS ”

ABDOS

Creating For Life Science

ABDOS

ABDOS

CELEBRATION FROM 50 TO INFINITY YEARS