



NikoPharmed

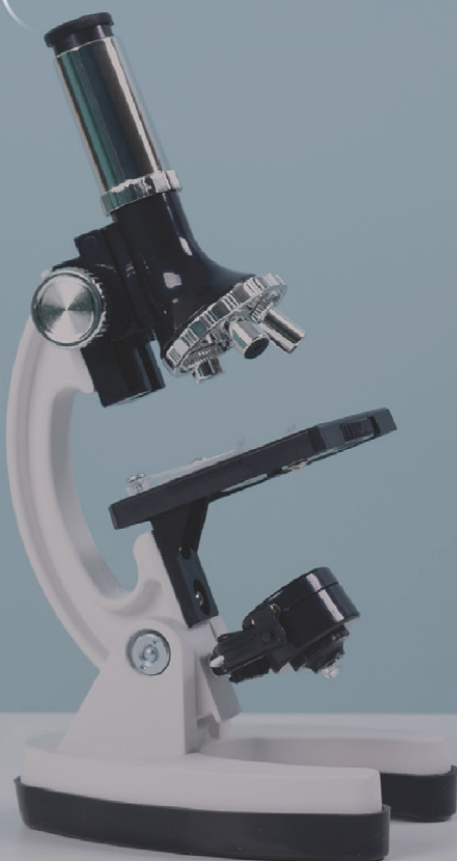
International & Accredited Lab Network



Nikopharmed International & Accredited Lab Network

Nikopharmed, as the largest and most advanced quality control laboratory in the country, is a trusted partner of the Iranian Food and Drug Administration (IFDA) and the General Directorate of Medical Equipment and Supplies. It is accredited by the National Accreditation Center of Iran (NACI) and certified under ISO 17025 standards. Additionally, it is a member of the Strategic Technology Laboratory Network.

Spanning over 3,000 square meters, Nikopharmed provides a comprehensive range of testing services, including biocompatibility, microbiology, cleanroom validation, molecular, cellular, animal studies, and physicochemical analyses. These services cover pharmaceuticals, food products, cosmetics, veterinary items, and specialized medical devices and equipment.



Medical Equipment and Supplies

Food Products

Cosmetics and Personal Care



Drugs and Supplements

Livestock and Poultry

Chemical

- Active ingredient concentration
- Heavy metals
- TOC, EC-TDS, pH
- Fat content analysis
- Protein content analysis
- Fiber measurement
- Peroxide value
- Acid value
- Calcium measurement
- Aflatoxin detection
- Ash content
- Manganese measurement
- Vitamin analysis (A, B, C, D, E) etc.

Physical

- Shelf Life Determination
- Packaging Material Testing
- Box and Carton Testing
- Tensile and Compression Tests
- Dimensional Control (vmm) etc.

Microbial - Sterility

- Sterility Validation
- Bioburden Determination
- Detection of Specific Microorganisms
- Antimicrobial Activity Testing
- Endotoxin Testing (LAL)
- Growth Promotion Test (GPT)
- Bacterial Ingress Challenge Test
- Mycoplasma Detection (PCR & Culture) etc.

Types of Cleanrooms and EO Chambers

- Manufacturing Consultation
- Microbial Monitoring
- Validation of Ethylene Oxide Chambers
- Cleanroom Qualification & Validation
- Design Qualification (DQ)
- Installation Qualification (IQ)
- Operational Qualification (OQ)
- Performance Qualification (PQ)

Biocompatibility

- Cell Toxicity
- Induction Potential
- Sensitization Potential
- Systemic Toxicity
- Cultivation
- Pyrogenicity
- Carcinogenicity
- Genotoxicity
- Ethylene Oxide Residue
- Blood Compatibility

Specialized Testing

- Bandage & Gauze
- Dental Amalgam
- Syringe
- Catheter
- Blood Collection Set
- Microset
- Surgical Suture etc.

Biocompatibility Testing Requirements Table for Medical Products

Classification of Medical Devices			Titles of Biocompatibility Evaluation Tests											
Classification	Contact With	(A) Limited (<24h) (B) Prolonged (>24h to 30d) (C) Permanent (>30d)	Cytotoxicity	Sensitization	Irritation or Intracutaneous Reactivity	Material-Mediated Pyrogenicity	Acute Systemic Toxicity	Subacute Systemic Toxicity	Subchronic Systemic Toxicity	Chronic Systemic Toxicity	Implantation Effects	Hemocompatibility	Genotoxicity	Carcinogenicity
Medical Devices with Surface Contact	Intact Skin	A	✓	✓	✓									
		B	✓	✓	✓									
		C	✓	✓	✓									
	Mucous Membrane	A	✓	✓	✓									
		B	✓	✓	✓		✓	✓			✓			
		C	✓	✓	✓		✓	✓	✓	✓	✓		✓	
	Compromised Surface	A	✓	✓	✓	✓	✓							
		B	✓	✓	✓	✓	✓	✓			✓			
		C	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓
Medical Devices with External Communication	Blood Pathway (Indirect)	A	✓	✓	✓	✓	✓					✓		
		B	✓	✓	✓	✓	✓	✓				✓		
		C	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	Tissue Bone Tooth	A	✓	✓	✓	✓	✓							
		B	✓	✓	✓	✓	✓	✓			✓		✓	
		C	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓
	Direct Circulating Blood Pathway	A	✓	✓	✓	✓	✓					✓	✓	
		B	✓	✓	✓	✓	✓	✓			✓	✓	✓	
		C	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Implantable Medical Devices	Tissue Bone	A	✓	✓	✓	✓	✓							
		B	✓	✓	✓	✓	✓	✓			✓		✓	
		C	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓
	Blood	A	✓	✓	✓	✓	✓				✓	✓	✓	
		B	✓	✓	✓	✓	✓	✓			✓	✓	✓	
		C	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓



Biocompatibility Tests



Irritation

ISIRI 5568
ISO 10993-12
ISO 10993-10
ISO 10993-23



Sensitization

ISIRI 4688
ISO 10993-12
ISO 10993-10



Cytotoxicity

INSO 7216-5
ISO 10993-5



Implantation

ISIRI 6412
ISO 10993-6



Ethylene Oxide Residue

INSO 7216-7
ISO 10993-7



Systemic Toxicity

(Acute, Subacute, Chronic, Subchronic)

OECD 423
OECD 402
ISO 10993-11
ISO 10993-12



Hemocompatibility - Hemolysis

INSO 21665
ISO 10993-4
INSO 7216-4



Genotoxicity

INSO 7216-11
ISO 10993-3

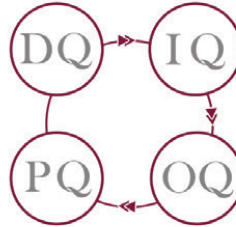


In Vivo Pyrogenicity

ISO 10993-12
U S P < 1 5 1 >
BP



- Microbial test-Settle plate
- Microbial test-Contact plate
- Microbial test-Finger plate
- Airborne Particle counting
- Supply/ Return Air flow volume
- Supply/ Return Air changes
- Air Flow Velocity
- Room Differential Pressure
- Temperature
- Relative humidity
- Luminous measuring and uniformity



Hood Monitoring



Chemical Biological

- Microbial test-Settle plate
- Microbial test-Contact plate
- Airborne Particle counting
- Air Flow Velocity
- Temperature
- Relative humidity
- Luminous measuring
- Differential Pressure
- UV intensity test (Inside)
- UV leak test (Outside)

Validation of Ethylene Oxide Chamber



Microbiological Tests



Microbial count

ISO 11737-1
INSO 7631-1
USP <61><62>



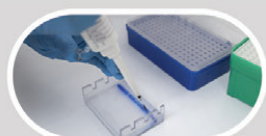
Accelerated aging test (Date of expiration)

ASTM F1980
ISO 11607
INSO 13705-1



Sterility Test

ISO 11737-2
ISIRI 7631-2
INSO 3001-1,2
USP <71>



Mycoplasma Detection Culture & PCR Method

USP <63>
USP <1223>



Antimicrobial Activity Assessment

ISO 20743	INSO 6986
ISO 22196	INSO 8512
INSO 2842	BS EN 1500
DINE EN BS 1276	INSO 10900
DIN EN 1650	INSO 11070
INSO 19851	INSO 10509



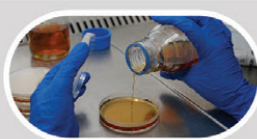
Endotoxin Testing (LAL)

INSO 10572
USP <85>
USP <161>



Retention Test

ISO 11930
INSO 17217
ISO 11970
USP <51>



Growth Promotion Test (GPT)

ISO 11133
INSO 8663
USP <61><62><71>



Challenge Test

USP <1207>
ISO 11607





Medical gauze

INSO	3061
AS	2835-1



Hydrophilic cotton

INSO	258
SANS	228



Petrolatum gauze

INSO	11032
USP 30-NF	25



Wound bandage

INSO	583
EN	14079



Non-Adhesive Elastic Bandages

ISIRI	5557
BS	7505



Plaster bandage

ISIRI	11806
IS	4738



Fiberglass orthopedic casting tape

INSO	18149
ASTM	F1536



Primary wound dressings

INSO	21495
BS	13726



Adhesive bandage (wound plaster)

TS	3957
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Dental sealer

INSO	18029
ISO	6876



Dentures

INSO	11791
ISO	22112



Dental amalgam

INSO	21005
ISO	24234





Medical face mask

INSO 6138
EN 14683



Manual Toothbrush

ISO 20126
INSO 2063



Floss Pick

INSO 14019
ISO 28158



Paper and cardboard

ISO 3781
ISO 1924-2,3



Eau de Cologne

ISIRI 1022
IS 8482



Lipstick

INSO 14622
BIS 9875



Ureteral stent

ASTM F1828



Blood lancet

ISIRI 8501
DIN 58916



Scalpel

ISIRI 5187
ISO 7740



Aluminum tubes

INSO 2149
BS 15421



Medical fluid transfer tubing

INSO 8357-9
ISO 8536-9



Surgical suture thread

SANS 494
INSO 7327





Household gloves

INSO 3671
ISO 20057



Surgical gloves

INSO 1644
ISO 10282



Medical examination gloves

INSO 9552-1,2
ISO 11193-1,2



Male latex condom

ISO 4047
INSO 14768



Female condom

INSO 18439
ISO 25841



Lab-use Condoms

ISIRI 9551
ISO 16037



Hot water bag

INSO 20490
BS 1970



Blood bag

INSO 12139-1
ISO 3826-1



Urine collection bag

ISIRI 4928
ISO 8669



Disposable Medical Containers

ISIRI 8502
AS 4031



Surgical Drapes & Gowns

INSO 14350
EN 13795



PET medical bottles

ISO 12418
INSO 11610





Hypodermic Needle

INSO 3979
ISO 7864



Stainless Steel Needle Tube

INSO 3981
ISO 9626



Surgical needles

INSO 14351
JIS T 3102



Insulin syringe

INSO 3591
ISO 8537



Subcutaneous syringe

INSO 770-1
ISO 7886-1



Dental needle

INSO 5554
ISO 7885



Peripheral Catheters

INSO 7325-5,1
ISO 10555-5,1



Suction catheter

ISO 8836



Self-Destruct Syringe

INSO 770-3
ISO 7886-3



Balloon Catheters

INSO 7325-4,1
ISO 10555-4,1



Angiography Catheters

INSO 7325-2,1
ISO 10555-2,1



Central Venous Catheters

INSO 7325-3,1
ISO 10555-3,1





Microset

ISO 8357-5
ISO 8536-5



Blood Collection Set

ISO 1135-4
ISO 4638-4



IV infusion set

ISO 8536-4
ISO 8357-4



Angiocatheter

ISO 10555-1
ISO 7325-1



Medical catheter

ISIRI 4641
EN 1695-1



Extension Tube

ISIRI 7326-4
ISO 8536-4



Gamma Sterilization Validation

ISO 11137-1



Biological Indicator Validation

ISO 5610
ISO 11138



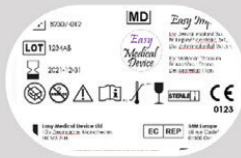
Chemical Indicator Validation

ISO 8436-1
ISO 11140-1
ISO 15882



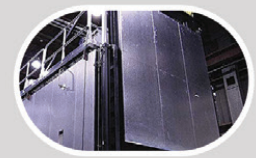
Water Analysis

ISO 1728
ISO 3696
ASTM D1193



Medical Symbols Markings &

ISO 8629
ISO 15223



EO Sterilization Validation

ISO 7216-7
ISO 10993-7



Professional Training Courses

- ISO 13485 & GMP Compliance Essentials
- General Course for Medical Device Q.A. Officers
- Fundamentals of Quality Assurance
- Laboratory Animal Handling & Ethics
- Microbiology Laboratory Practices
- In Vitro Cell Culture Techniques
- Physicochemical Laboratory Training
- Molecular Biology Laboratory Training
- Practical Cleanroom Operation



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Licenses



ILAC MRA SIGNATORY CONTACT DETAILS



Name : National Accreditation Centre of Iran

Acronym : NACI

Membership Category : Full Member (ILAC MRA signatory)

Economy : IRAN

ILAC MRA Scope : Calibration: ISO/IEC 17025 29 Apr 2024
Testing: ISO/IEC 17025 29 Apr 2024
Medical Testing: ISO 15189 29 Apr 2024
Inspection: ISO/IEC 17020 29 Apr 2024
Proficiency Testing Providers: ISO/IEC 17043 29 Apr 2024

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ilac



IRI.FDO



National Accreditation Center of Iran

مرکز ملی تایید صلاحیت ایران



جمهوری اسلامی ایران

Islamic Republic of Iran

مرکز ملی تایید صلاحیت ایران

گواهینامه تایید صلاحیت آزمایشگاه Laboratory Accreditation Certificate

The National Accreditation Center of Iran (NACI)

Iranian standards (IRI) body

Niko Pharmed Aria

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Fax: +98(21) 44184700

Web Site: www.nikopharmed.com

Has fulfilled the ISO-ISO/IEC 17025:2017

And is competent to carry out Calibration

services according to accreditation scope as listed in

page(s) of Annex

Validity of Accreditation Depends on Continuity of

Compliance with the Relevant Requirements and

Obtaining the Approval Based on the Annual

Surveillance Assessment

The Unique Identification Number of This

Accreditation Certificate and All Attachments Are the

Same

To Control the Originality of This Certificate, Visit the

Website of NACI (naciportal.nso.gov.ir)

Dr.A.Rahmani
NACI PRESIDENT

تایید صلاحیت مرکز
دکتر نوشه رحمانی
رئیس مرکز ملی تایید صلاحیت ایران

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