oxigen
ANALİZ LABORATUVARI

TESTING LABORATORIES

For healthy GENERATIONS

Oxigen Laboratories in Brief

2014

Establishment

Oxigen Laboratories was founded in September 2014. Dioxins and GMO testing authorized.

2015

SCOPE EXPANSION

In June 2015, Chemical, Physical Addictive-Residue-Mineral-Toxin and Microbiology laboratories has activated.

2017

SCOPE EXPANSION

In the first quarter of 2017, Medical Testing Laboratory established..

2018

SCOPE EXPANSION

It is authorized in 375 different analyzes in food analysis by ministry.

2019

SCOPE EXPANSION

More than 400 testing parameters for food and 60 testing parameters for medical accredited by TURKAK under TS EN ISO 17025.

2020

SCOPE EXPANSION

Medical Device Testing as per Medical Device Directives of EU.

Oxigen Laboratories in Brief

50 +
Employee

20.000 +
sample / year

1500 m2
Labs

8 Countries
Active Sales

500 +
Accredited Test

Oxigen Laboratories in Brief

Leadership
We have a technological infrastructure in accordance with national and international norms. We are a strong family that follows scientific and technological developments related to our field.

Integrity and Trust
We establish relationships with all our stakeholders based on integrity and trust. We protect the confidential information and registered rights of all institutions, organizations and individuals with which we cooperate.

Objectivity
Our activities are carried out with complete objectivity. We avoid any behavior that would put nature and humanity at risk.

Respect and Loyalty
We establish respectful long-term partnerships with our employees and collaborators.

Oxigen Laboratories in Brief

Mission

To provide accurate and reliable service with our customer-oriented, entrepreneurial and innovative spirit; in accordance with the principles of confidentiality and objectivity, in line with scientific and technological developments by employing nationally and internationally accepted analysis methods.

Vision

To be a competitive and productive service organization with a young and dynamic staff that respects nature and humanity without sacrificing integrity and objectivity, and that characterizes with trust and quality.

Oxigen Laboratories in Brief

'For healthy GENERATIONS'

Accreditations

Ministry of Food, Agriculture and Livestock

Turkish Accreditation Agency

Turkish Standard Instutue

Ministry of Healty

Market

HQ Lab

Market

Food Testing Services

Oxigen Food Laboratories

Our Laboratory has ;

- **Dioxin Laboratory**
- **Toxin Laboratory**
- **Micro-biological Laboratory**
- **Molecular Biological Laboratory**
- **Chemical Laboratory**
- **Physical Laboratory**
- **Residue Laboratory**
- **Additives Laboratory**
- **Mineral Laboratory**

Oxigen Food Laboratories

Dioxin Laboratory

Dioxins and Dioxin-like PCBs (WHO PCDD/F/dl-PCBs-TEQ)

"Determination of Selected Polycyclic Aromatic Hydrocarbons (PAH) Benzo(a)anthracene; Chrysene;Benzo(b)fluroanthene; Benzo(a)pyrene"

Oxigen Food Laboratories

Toxin Laboratory

Total Aflatoxin (B1+B²+G1+G²)
Aflatoxin B1 Analysis
Ochratoxin A
Zearalenon Analysis
Fumonisin Analysis (B1+B2)
Multiple Mycotoxin Analysis
HT-2 Analysis
T-2 Analysis
Deoksinivalenol Analysis
Determination of Aflatoxin M1
Patulin Determination

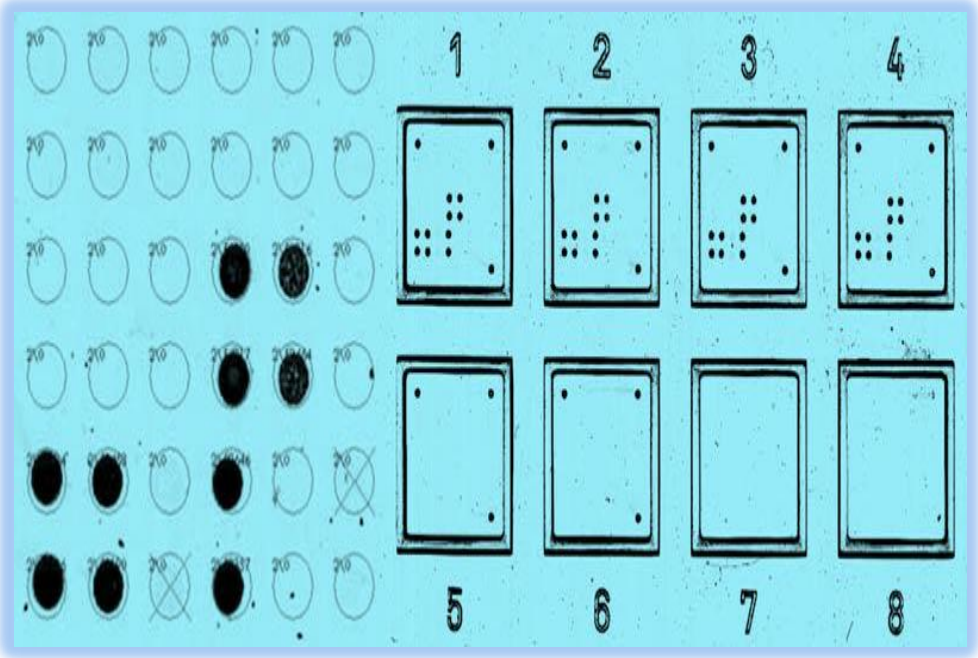
Oxigen Food Laboratories

Molecular Biology Laboratory

GMO «Genetically Modified Organism»
Qualitative and Quantitative
Screening Test.

<u>Halal Testing</u>
«Pork, Horse and Donkey» meat type detections

<u>Meat Type Detection</u>
Beef-Sheep-Goat DNA
Pork DNA
Chicken DNA
Horse DNA
Donkey DNA
Fish DNA
Sheep DNA
Beef DNA



Oxigen Food Laboratories

Micro Biology Laboratory

Salmonella spp Detection
Mold and Yeast
Escherichia coli
Bacillus cereus
Enterobacteriaceae and Detection
Coliform Bacteria
Coagulase Positive Staphylococci (Staphylococcus aureus and other species)
Listeria monocytogenes detection

And more 60 different analysis

Oxigen Food Laboratories

Residue Laboratory

Pesticides-GCMS
Pesticides-LCMSMS

"Dithiocarbomate group pesticide analysis (Sum of CS_2 related Ferbam, Maneb,Mancozeb, Metiram, Propineb, Thiram, Zineb, Ziram,etc.)«

Veterinery drugs,

More than 500 Pesticide analysis,

Oxigen Food Laboratories

Additive Laboratory

Nitrate
Antioxidant Determination (BHT)
Antioxidant Determination (BHA-BHT-TBHQ-Propil Gallat)
Antioxidant Determination (BHA)
Histamine, Melamine, Sulfur dioxide, Caffeine, Potassium Ioderate, Natamycin
Acetyl Methyl Carbinol, Nitrite
Azodicarbonamite,
Hydrogen Peroxide,
Carotene, Sucralose, Taurine
Carboxymethylcellulose, Sorbic Acid
Benzoic Acid, P-Hydroxybenzoic Acid Esters (PHB Analysis) , Acesulfame-K, Aspartame, Saccharin
Ascorbic Acid, Quinic Acid, Malik Acid, Lactic Acid
Propionic Acid, Acetic Acid, Suksinic Acid and more

Oxigen Food Laboratories

Mineral Laboratory

Lead, Cadmium, Mercury,
Arsenic, Sodium, Zinc
Calcium, Magnesium
Potassium, Tin
Chromium, Copper
Iron, Nickel
Selenium Manganese
Cobalt, Phosphorus Etc…

Oxigen Food Laboratories

Chemical & Physical Laboratories

More than 150 accredited parameters for foods including water, oil, fats etc…

Medical Device Testing Services

Chemical Caracterization of Medical Devices

Item	Analysis	Standard
Medical Devices	Bioburden	TS EN ISO 11737-1
Medical Devices	Sterility	European Pharmacopiea 9th Edition 2.6.1 USP 38 NF 33 (85)
Medical Devices sterilized By Gamma	Sterility	TS EN ISO 11737-2
Medical Devices Polymeric and Elastomeric Plastics	In vitro cytotoxicity	TS EN ISO 10993-5 TS EN ISO 10993-12
Medical Devices	Bacterial Endotoxin (LAL)	USP 38 NF 33 (85) European Pharmacopiea 9th Edition 2.6.14
Medical Devices	Stability Tests	ASTM F 1980
Medical Device Package	Physical tests	ASTMF 1929 / EN 868-5
Medical Devices	Ethylene oxide Ethylene chlorhydrine	ISO 10993-7
Hand tools using surgery and dentistry	Corrosion	TS 5172 EN ISO 13402
Intravenous catheters and other catheters	Corrosion	TS EN 1618
Disposable Sterilized Intravenous catheters	Corrosion	BS EN ISO 10555-1
Hemodialysis dilution water	Microbiological analysis Bacterial Endotoxin Chemical analysis	

Chemical Caracterization Of Medical Devices

Chemical Caracterization of Medical Devices

ISO 10993	BIOLOGICAL EVALUATION OF MEDICAL DEVICES
Part 1	EVALUATION AND TESTING WITHIN A RISK MANAGEMENT PROCESS
Part 2	ANIMAL WELFARE REQUIREMENTS
Part 3	TESTS FOR GENOTOXICITY, CARCINOGENICITY AND REPRODUCTIVE TOXICITY
Part 4	SELECTION OF TESTS FOR INTERACTIONS WITH BLOOD
Part 5	TESTS FOR IN VITRO CYTOTOXICITY
Part 6	TESTS FOR LOCAL EFFECTS AFTER IMPLANTATION
Part 7	ETHYLENE OXIDE STERILIZATION RESIDUALS
Part 8	SELECTION AND QUALIFICATION OF REFERENCE MATERIALS FOR BIOLOGICAL TESTS - withdrawn
Part 9	FRAMEWORK FOR IDENTIFICATION AND QUANTIFICATION OF POTENTIAL DEGRADATION PRODUCTS
Part 10	TESTS FOR IRRITATION AND SKIN SENSITIZATION
Part 11	TESTS FOR SYSTEMIC TOXICITY
Part 12	SAMPLE PREPARATION AND REFERENCE MATERIALS
Part 13	IDENTIFICATION AND QUANTIFICATION OF DEGRADATION PRODUCTS FROM POLYMERIC MEDICAL DEVICES
Part 14	IDENTIFICATION AND QUANTIFICATION OF DEGRADATION PRODUCTS FROM CERAMICS
Part 15	IDENTIFICATION AND QUANTIFICATION OF DEGRADATION PRODUCTS FROM METALS AND ALLOYS
Part 16	TOXICOKINETIC STUDY DESIGN FOR DEGRADATION PRODUCTS AND LEACHABLES
Part 17	ESTABLISHMENT OF ALLOWABLE LIMITS FOR LEACHABLE SUBSTANCES
Part 18	CHEMICAL CHARACTERIZATION OF MEDICAL DEVICE MATERIALS WITHIN A RISK MANAGEMENT PROCESS

Chemical Caracterization of Medical Devices

10993-18 Chemical characterization of medical device materials within a risk management process

specifies a framework for the identification, and if necessary, quantification of constituents of a medical device, allowing the identification of biological hazards and the estimation and control of biological risks from material constituents, using a generally stepwise approach to the chemical characterization which can include one or more of the following:

— the identification of its materials of construction (medical device configuration);
— the characterization of the materials of construction via the identification and quantification of their chemical constituents (material composition);
— the characterization of the medical device for chemical substances that were introduced during manufacturing (e.g. mould release agents, process contaminants, sterilization residues);
— the estimation (using laboratory extraction conditions) of the potential of the medical device, or its materials of construction, to release chemical substances under clinical use conditions (extractables);
— the measurement of chemical substances released from a medical device under its clinical conditions of use (leachables).

Chemical Caracterization of Medical Devices

10993-18 Chemical characterization of medical device materials within a risk management process

can also be used for chemical characterization (e.g. the identification and/or quantification) of degradation products. Information on other aspects of degradation assessment are covered in ISO 10993-9, ISO 10993-13, ISO 10993-14 and ISO 10993-15.
The ISO 10993 series is applicable when the material or medical device has direct or indirect body contact (see ISO 10993-1 for categorization by nature of body contact).
This document is intended for suppliers of materials and manufacturers of medical devices, to support a biological evaluation.

Chemical Caracterization of Medical Devices

ISO 10993-17 Establishment of allowable limits for leachable substances

ISO 10993-17:2002 specifies the determination of allowable limits for substances leachable from medical devices. It is intended for use in deriving standards and estimating appropriate limits where standards do not exist. It describes a systematic process through which identified risks arising from toxicologically hazardous substances present in medical devices can be quantified.

ISO 10993-17:2002 is not applicable to devices that have no patient contact (e.g. *in vitro* diagnostic devices).

Exposure to a particular chemical substance may arise from sources other than the device, such as food, water or air. ISO 10993-17:2002 does not address the potential for exposure from such sources.

Chemical Caracterization of Medical Devices

ISO 10993-12 Sample preparation and reference materials

ISO 10993-12:2012 specifies requirements and gives guidance on the procedures to be followed in the preparation of samples and the selection of reference materials for medical device testing in biological systems in accordance with one or more parts of ISO 10993. Specifically, ISO 10993-12:2012 addresses the following:
test sample selection;
selection of representative portions from a device;
test sample preparation;
experimental controls;
selection of, and requirements for, reference materials;
preparation of extracts.
ISO 10993-12:2012 is not applicable to live cells, but can be relevant to the material or device components of combination products containing live cells.

Chemical Caracterization of Medical Devices

Our approach for sample preperation
ISO 10993-12 Sample preparation and reference materials

A study protocol will be issued for client approval before starting the experimental studies. The protocol will include a description of the component tested, types and amounts of solvent, temperatures, duration, extraction method, and methods of analysis.

3 extraction solvents will be used for extraction (details will be defined in the protocol based on product information). Simulative solvents will also be used depending on the use of the medical device.

1) Polar solvent
2) Apolar solvent
3) Semi-polar solvent

Chemical Caracterization of Medical Devices

Our approach for sample preperation
ISO 10993-12 Sample preparation and reference materials

Extraction conditions:

Considering the place of use of the medical device;
a) (37 ± 1) °C for (72 ± 2) h;
b) (50 ± 2) °C for (72 ± 2) h;
c) (70 ± 2) °C for (24 ± 2) h;
d) (121 ± 2) °C for (1 ± 0,1) h.
extraction experiments will be performed on the final product using the solvents specified for the duration (ISO 10993-12).

* Other conditions may be used but shall be justified.

Chemical Caracterization of Medical Devices

Our approach for Chemical Caracterization
10993-18 Chemical characterization of medical device materials within a risk management process

1) LC-MS/MS - Non-volatiles
2) GC-MS - Semi-volatiles
3) GC-MS Headspaces - Volatiles
4) GF-AAS - Inorganic compounds (metals)
5) CHNO-S Elementel analysis
6) FT-IR, Surface functional structure
7) NMR, Molecular characterization

Chemical Caracterization of Medical Devices

ISO 10993-17 Establishment of allowable limits for leachable substances

Toxicological Evaluation of Extractables Compounds

The following references will be taken in account to perform the evaluation:

ICH HARMONISED TRIPARTITE GUIDELINE ASSESSMENT AND CONTROL OF DNA REACTIVE(MUTAGENIC) IMPURITIES IN PHARMACEUTICALS TO LIMIT POTENTIAL CARCINOGENIC RISK M7 Current Step 4 version dated 23 June 2014

ISO 10993-17:2002 - Biological evaluation of medical devices -- Part 17: Establishment of allowable limits for leachable substances

The purpose of the toxicological assessment is to explicitly address possible toxicological concerns arising from the extracted compounds.

Chemical Caracterization of Medical Devices

ISO 10993-17 Establishment of allowable limits for leachable substances

Toxicological Evaluation of Extractables Compounds

A TTC (Threshold of Toxicological Concern) will be determined based on the exposure scenario. All known compounds above TTC level will be evaluated.

If toxicological data are available through literature review, a single TI will be calculated for a single route of exposure without considering cumulative and/or synergic effects.

Derivation of a non-cancer-based TI value involves:

1. selection of appropriate NOAEL and LOAEL values from the literature
2. selection of uncertainty factors to account for inter-individual variability in the human population

Chemical Caracterization of Medical Devices

ISO 10993-17 Establishment of allowable limits for leachable substances

Toxicological Evaluation of Extractables Compounds

If no relevant toxicological data are available, a tolerable exposure will be estimated for each known compound by applying the Cramer class rules and the Beningi-Bosse rule base.
Unknown compounds above TTC will be considered as genotoxic impurities for conservative reasons.
Output: Comprehensive report including determination of Tolerable Intakes, Cramer class and Tolerable Exposures with proposed selection of compounds to be followed up.

Contact us

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