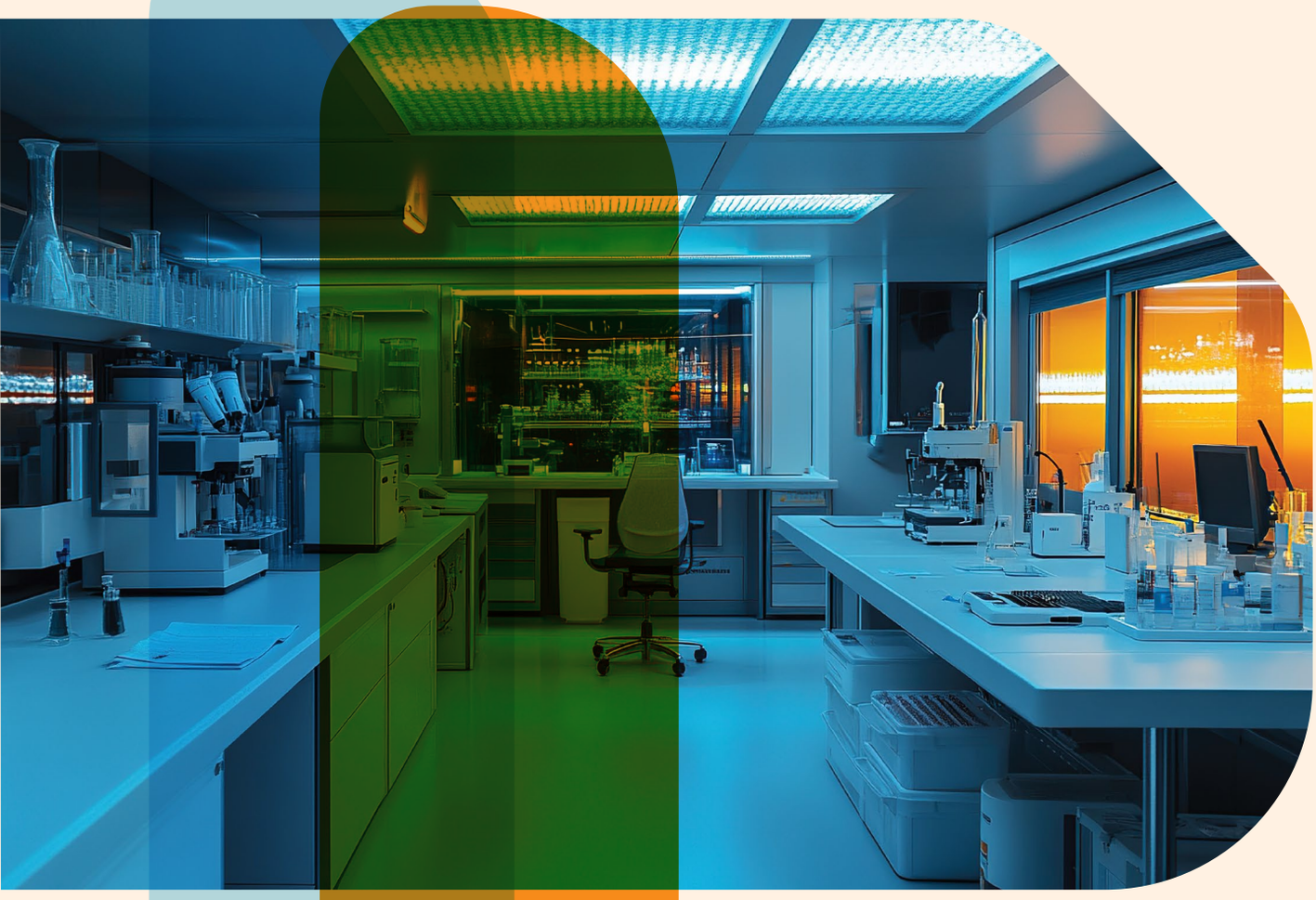
ARMAN SHIMISANJ
Good sense of quality

Provider of high-quality services in the healthcare industry



- Calibration of measuring instruments
- Qualification of laboratory equipment
- Drug analysis laboratory Row materials & pharmaceutical products
- Formulation of pharmaceutical and cosmetic products
- Production of certified reference standards

ABOUT COMPANY

Arman Shimi Sanj Company Established in 2011, Arman Shimi Sanj Company has leveraged the expertise of its founders to provide educational and research services in the field of analytical equipment, specializing in chromatography and spectroscopy. In its early years, the company conducted numerous in-house and external training courses and executed several industrial projects focused on online analytical methods for production lines. These initiatives formed the cornerstone of the company's educational and research activities during its formative period.

In 2015, the company achieved accreditation under ISO/IEC 17025 from the National Accreditation Center for the calibration of chromatography equipment and obtained a license to operate from the Food and Drug Administration (FDA). These milestones enabled the launch of its calibration and qualification services. With the expertise of its specialists, Arman Shimi Sanj quickly gained the trust of pharmaceutical companies, establishing them as its primary clients for these services.

The company expanded its offerings by introducing calibration services for a broader range of laboratory equipment and establishing a dedicated "High-Level Qualification and Quality Services" department. This expansion allowed Arman Shimi Sanj to provide a comprehensive portfolio of calibration and qualification services for analytical instruments and general laboratory equipment to its valued customers.

In 2020, recognizing the pharmaceutical industry's need for reference drug standards, the company began producing these standards and successfully obtained FDA approval for their manufacture. Additionally, equipped with a state-of-the-art analytical laboratory, the company expanded into pharmaceutical, raw material, and cosmetic analysis services, earning ISO/IEC 17025 certification from both the National Accreditation Center and the FDA.

The company's growth, both in scope and quality, has been driven by the trust of its esteemed clients and the dedicated efforts of its employees, experts, and management. With continued client support, Arman Shimi Sanj aims to further advance its services and capabilities.

We are committed to delivering high-quality services, providing exceptional after-sales support, and upholding the dignity and satisfaction of our clients, which we consider their fundamental rights.

The operation of this company

PART 01 Calibration of measuring instruments

PART 02 Qualification of laboratory equipment

PART 03 Drug analysis laboratory Row materials and pharmaceutical products

PART 04 Formulation of pharmaceutical and cosmetic products

PART 05 Production of certified reference standards

Calibration
of measuring instruments

PART
01

CALIBRATION OF MEASURING INSTRUMENTS

The calibration services of this company have the following features.

- Provision of reliable and comprehensive data on the instrument's status, with traceability to international standards.
- Detailed technical explanations provided by expert technicians during the calibration process.
- Issuance of detailed and comprehensive calibration certificates, including calibration graphs.
- Complimentary intermediate control and recalibration for analytical instruments.
- Free recalibration following repairs for equipment that fails initial calibration.
- Specialized calibration services tailored for analytical instruments.

Calibration of General Laboratory Equipment

The overarching policy of this company in providing services focuses on the quality of services, adherence to scientific principles, and respect for customer rights. In line with this policy, the company offers a variety of calibration services for the quantities and equipment listed below. To meet the diverse needs of customers, the company provides its calibration services at two levels:

Level 01

In accordance with calibration standard requirements for each device, and the issuance of a standard certificate.

Level 02

Special calibration services for customers who require comprehensive calibration of parameters, graphs, and additional information related to the equipment being calibrated.

Scope of Calibration Services for General Laboratory Equipment Offered by This Company:

- Mass Quantities: Balances, scales, and reference weights.
- Volume Quantities: Various volumetric containers.
- Thermal Environments: Ovens, incubators, furnaces, refrigerators, freezers, autoclaves, and sterilization tunnels
- Temperature Measuring Devices: Thermometers, sensors, transmitters, and temperature switches.
- Pressure Measuring Devices: Pressure gauges, differential pressure gauges, and pressure transmitters.
- Humidity Quantities: Various humidity environments.
- Chemical Quantities: pH meters, conductivity meters, refractometers, polarimeters, viscometers, Karl Fischer titrators, and potentiometric titrators.
- Particle Counters: Liquid and gas particle counters.
- Fume Hoods: Laminar flow hoods and chemical fume hoods.
- Temperature Reference Sensors: Various types of temperature reference sensors.

Calibration of Analytical Instruments

The calibration of analytical instruments differs significantly from that of general equipment and physical quantities. This distinction stems from the complexity of the processes within these devices, their modular design, and their multi-parameter characteristics. Consequently, evaluating the performance of these instruments within their specified range is critical in the calibration process. A thorough understanding of the instrument's functionality and characteristics is essential for both the calibration approach and metrological considerations to ensure accurate results.

Backed by extensive technical expertise and operating as the most comprehensive laboratory in the country for calibration services, our company provides the following calibration services for analytical instruments:

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- High-Performance Liquid Chromatography (HPLC)
- High-Performance Liquid Chromatography – Mass Spectrometry (LC-MS)
- Gas Chromatography (GC)
- Gas Chromatography – Mass Spectrometry (GC-MS)
- Ion Chromatography (IC)
- Atomic Absorption Spectroscopy (AAS)
- Inductively Coupled Plasma Optical Emission Spectroscopy (ICP-OES)
- Flame Photometry
- Fourier Transform Infrared Spectroscopy (FT-IR)
- UV-Vis Spectrophotometry
- Total Organic Carbon (TOC) Analysis
- Fluorescence Spectrophotometry

Calibration Of Analytical Instruments

Qualification
of laboratory equipment

PART
02

QUALIFICATION SOLUTIONS

In other words, qualification is defined as a documented program that provides a high level of assurance that a specific device, instrument, or system produces a result in compliance with predefined acceptance criteria and requirements.

Qualification, alongside validation, is classified as a high-level quality method and is considered a fundamental concept of Good Manufacturing Practices (GMP). Today, it is widely recognized as a standard for high-quality production in the pharmaceutical and cosmetic industries.

Considering this, and to meet the demand for these high-quality services, the company has taken steps to establish the necessary scientific and research infrastructure within its R&D department. By preparing the required facilities and acquiring the appropriate equipment, the company began offering services in this field. Within a short period, it successfully executed multiple projects in this area for major pharmaceutical companies in the country.

This company provides qualification, validation, and accreditation services for the following devices and processes:

1. High-Performance Liquid Chromatography (HPLC)
2. Liquid Chromatography-Mass Spectrometry (LC-MS)
3. Gas Chromatography (GC)
4. Gas Chromatography-Mass Spectrometry (GC-MS)
5. Ion Chromatography (IC)
6. Atomic Absorption Spectroscopy (AAS)
7. Inductively Coupled Plasma Optical Emission Spectroscopy (ICP-OES)
8. Flame Photometry
9. Fourier Transform Infrared Spectroscopy (FT-IR)
10. Ultraviolet-Visible Spectrophotometry (UV-Vis)
11. Total Organic Carbon (TOC Analyzer)
12. Fluorescence Spectrophotometer

Analytical Instrument

Reference Materials for Calibration

Reference materials are essential for ensuring traceability in chemical measurements. Recognizing the challenges of limited access to high-quality reference materials in Iran and their high costs, our company has taken the initiative to produce these materials locally. Our reference materials are manufactured with exceptional precision and accuracy and are accompanied by comprehensive certificates that include detailed analyses and reported uncertainties.

We offer calibration kits and reference materials for performance evaluation and qualification of various instruments, including GC, HPLC, standard calibration water, Karl Fischer titrators, and more, ensuring reliable and accurate calibration solutions for your analytical needs.

Qualification Procedures

General Laboratory Equipment

- Oven
- Autoclave
- Balance
- Dissolution Tester
- Disintegration Tester
- Hardness Tester
- Titrator (Potentiometric and Karl Fischer)
- Polarimeter
- Incubator
- Refractometer
- Refrigerator, Freezer
- Conductivity Meter and pH Meter
- Temperature and Humidity Chamber

Temperature Mapping

- Temperature Mapping for Pharmaceutical Storage Areas
- Cold Room Temperature Mapping (Cold Room)

Validation of Processes

- Sterilization Processes
- Cleanroom Validation

Clean Equipment

- HVAC Systems
- Vertical Gas & Liquid Counters
- Laminar Flow Hood
- Microbial LaminarFlow Hoods (BSC)

DRUG ANALYSIS LABORATORY
ROW MATERIALs, AND PHARMACEUTICAL PRODUCTS

PART
03

TESTING SERVICES FOR RAW MATERIALS PHARMACEUTICAL PRODUCTS, SUPPLIES, AND COSMETICS

Our pharmaceutical analysis laboratory operates in full compliance with ISO/IEC 17025 and Good Laboratory Practice (GLP) standards, providing a comprehensive range of analytical services for the pharmaceutical and cosmetics industries. The laboratory is accredited as a partner by the Food and Drug Administration (FDA) and holds certification from the National Accreditation Center in relevant fields.

We offer a wide variety of testing services, including:

- Physical and chemical analysis of pharmaceuticals and raw materials
- Heavy metals testing
- Analysis of cosmetics and hygiene products
- Disinfectant material testing
- Short-term and accelerated stability testing for pharmaceutical and cosmetic products

These are just a few examples of our laboratory's extensive analytical capabilities.

• All general equipment, analytical instruments, and chromatographic columns are qualified in accordance with Good Manufacturing Practice (GMP) and Good Laboratory Practice (GLP) requirements.

• The final test certificate is comprehensive, providing detailed information accompanied by in-depth equipment reports, including chromatograms, spectra, balance calibration printouts, and more.

• The laboratory is equipped with a high-precision balance (accurate to seven decimal places), enabling analytical standards to be measured at quantities as low as 0.5 mg, in accordance with USP 42 requirements.

• All analyses are performed in compliance with the latest updates to standard methods or validated internal methods

THE COMPANY ALSO OFFERS ADDITIONAL ANALYTICAL SERVICES FOR THE FOLLOWING INSTRUMENTS

1. High-Performance Liquid Chromatography (HPLC) with various detectors
2. Gas Chromatography (GC) with Headspace
3. Atomic Absorption Spectrophotometry (Flame, Graphite Furnace, and Hydride Vapor Generator)
4. UV-Vis Spectrophotometry with Photodiode Array (PDA)
5. Fourier Transform Infrared Spectrophotometry (FT-IR)
6. Karl Fischer Titration

Formulation
of pharmaceutical and cosmetic products

PART
04

PHARMACEUTICAL FORMULATIONS

Pharmaceutical formulation is a process in which various chemical substances, including active pharmaceutical ingredients (APIs), excipients, sweeteners, and others, are combined to produce a final pharmaceutical product with specific clinical efficacy.

In the ICH Q8 guidelines, it is emphasized that quality should be designed into the product rather than measured in the product. The Quality by Design (QBD) approach is considered in all services provided in this section.

Risk assessments and experimental design use statistical design methods and mathematical modeling to understand the parameters and quality characteristics. These parameters and quality features impact the clinical effectiveness and safety of the formulations, as well as the manufacturability and long-term stability of dosage forms.

Pre-formulation

Each pharmaceutical molecule has inherent physical and chemical properties that must be thoroughly considered before drug development. The formulation development process combines the characteristics of the active pharmaceutical ingredients (APIs), such as crystal form, solid-state phase transitions, etc., with the product design features like solubility, stability, and more. Therefore, pre-formulation studies, which help assess and consider the factors affecting product quality, play a critical role in the drug product development process.

Pre-formulation studies conducted at this company include the following:

- Determination of purity, physicochemical properties, and hygroscopicity studies
- Solubility testing and analysis of behavior at different pH levels
- Studies on the effect of particle size, polymorph behavior, and selection of suitable salt forms
- Compatibility testing of excipients with each other
- Evaluation of factors affecting stability

Formulation of pharmaceutical Dosage forms in this section

1. Solids (various tablets, orally disintegrating tablets ODTs, capsules, powders and granules)
2. Tablets (immediate release, modified release, extended release)
3. Capsules (immediate release, modified release)
4. Semisolids (cream, gels, ointments, lotions)
5. sterile liquids (injectable, oral, nasal and ophthalmic)

Scale-up (industrial Batch production)

in this section, the proposal formulation is produced in an industrial batch and production parameters are optimized according to the available manufacturing equipment.

preparation and submission of CTD

Is prepared and provided open request , as needed.

During all staged of formulation, implementation and after submission of the CTD to the regulatory authority, the company is responsible for addressing any issues or ambiguities related to the project.

STANDARDS

Acetaminophen

Acetaminophen related compound C

Acetaminophen related compound D

Metformin

Metformin related compound A

Metronidazole

Ibuprofen related compound C

Production
of certified reference standards

PART
05

PRODUCTION OF CERTIFIED REFERANCE STANDARDS

Certified High-Quality Secondary Reference Standards for Karl Fischer Titration
The AccuWater™ series of certified reference standards offers a reliable and user-friendly solution for accurate water content measurement.
Karl Fischer (KF) titration is widely regarded as the gold standard for determining water content in both liquid and solid samples. This method is used daily across industries such as pharmaceuticals, food, oil and gas, lubricants, and more due to its speed and precision.

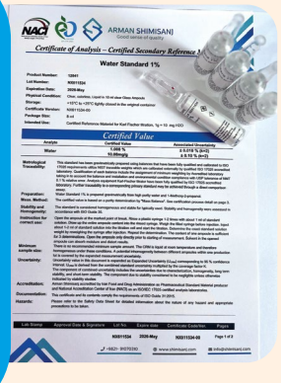
Our water standards are manufactured under strict quality controls in compliance with ISO 17034 and are characterized according to ISO/IEC 17025 standards, ensuring the highest level of reliability.
For precise and dependable KF titration, high-quality certified reference materials (CRMs) are essential.

Karl Fischer water standards are used for the following purposes

Monitoring Equipment Ensuring the accuracy of Karl Fischer equipment as part of quality control processes and identifying any equipment-related issues.

Measuring the titer of Karl Fischer reagents for volumetric titration.

Assessing the accuracy, precision, and performance of the titration process.



Product Specifications

1

1percent Water Standard in Glass Ampoules.

2

This product is an organic solvent with a certified water content of 1percent.

3

It is designed for evaluating Karl Fischer equipment & determining the titer of volumetric titrators.

01

Tested and traceable to international reference standards (NIST).

02

Includes a detailed certificate with analysis and measurement uncertainty for each batch.

03

Packaged in glass ampoules and stored at ambient temperature (51–52°C) to minimize the impact of environmental factors, such as humidity, on certified values.

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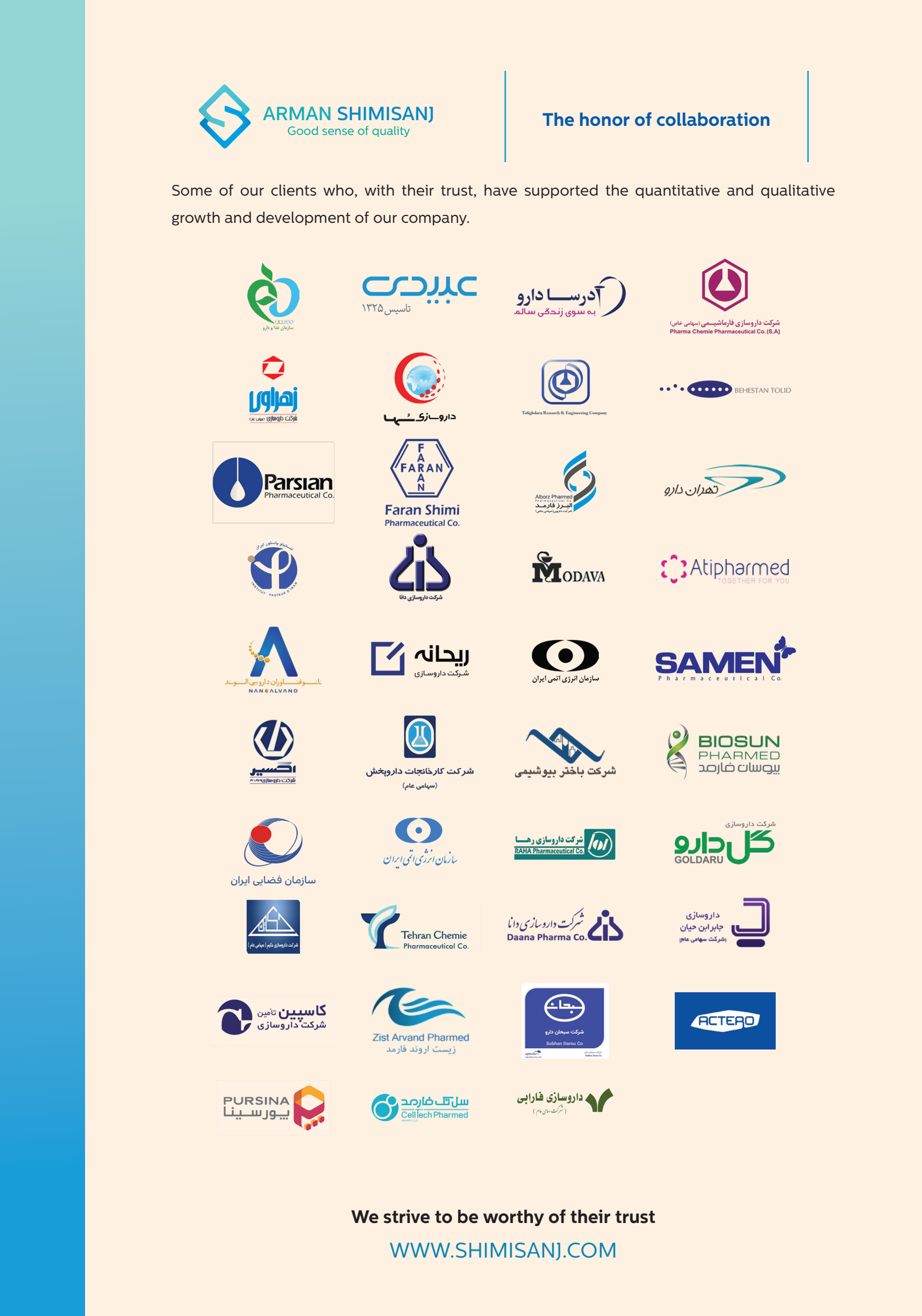
The honor of collaboration

Some of our clients who, with their trust, have supported the quantitative and qualitative growth and development of our company.



We strive to be worthy of their trust

WWW.SHIMISANJ.COM

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