



subject list

- 1-Company introduction
- 2- Company activities
- 3- summery list of projects

Introduction:

AJSI , Pharma , food & Chemical industries:

AJSI(Andishgaran Jame Sanat Iranian, National Registration No: 22612) was incorporated in 2007 with a vision to cater all the techno-commercial needs of the customers seeking industrial projects for pharmaceutical, food, biopharma and chemical applications with a meticulous sense of surety, reliability and guarantee in terms of rendering high value added services across Iran and abroad.

We have worked in all sectors of the industry dealing with Pharma, Biopharma, Bulk, sterile , API, food ,electronic and chemical facilities giving us a strong knowledge of all design requirements & standards within the industry.

All our engineers have a good knowledge background from the best universities. They are professionally well trained and experienced for execution of industrial projects in Food, Pharma and chemical industries.

We offer a full range of construction, qualification and validation services for start up and existing facilities, our engineers are also professionally well trained and experienced for clean room and validation.

AJSI Engineering Services is Dynamic Professional Engineers Engaged in The Various Services in Clean Room construction and Validation full range of validation activities(POICS Canada) Pre Insulated Ducting (ALP(Italy) and TD(Australia)), HVAC Projects Services as applied to manufacturing Establishments such as , Pharmaceuticals, biopharmaceutical , biochemical Processes, food industries, electronics , chemical industries .

Experience with a wide range of unit operations, knowledge of cGMP design, the manufacturing background of our professional staff, and our ability to provide hands-on support through start-up and commissioning, combine to meet the challenges of industries.

We bring to the marketplace everything from initial feasibility design studies, through to construction, project management and then testing, certification and validation of a facility.

List of company activities

1- pharmaceutical Validation

We are the first Iranian company which provide Validation and Services to the Pharmaceutical, Biotechnology and Medical Device Industries.

We have the team of talented and committed people to take care and provide excellent services for all type of regulatory requirements.

Our Pharmaceutical engineering and Quality assurance Department can provide services include, but are not limited to the activities below and will be tailored to meet the specific requirements of our clients

Quality Manual, Validation Master Plan (VMP), Design Qualification (DQ)

URS (User Requirement Specification), FDS (Functional Design Specification)

FAT (Factory Acceptance TEST), Installation Qualification (IQ), Pre commissioning and commissioning, SAT (Site Acceptance Test), Operational Qualification (OQ), Performance Qualification (PQ), Ongoing monitoring program, Process Validation (PV), Extensive Cleaning Validation Program (CLP), Method Validation, Equipments Qualification, Quality Assurance Validation of fermentation and cell culturing process

Process validation of oral solid/liquid, injectable (LVP/SVP) and topical dosage form process

Autoclave and oven qualification/validation

Labeling and packaging equipments for oral solid/liquid, injectable (LVP/SVP) and topical dosage form

Implementation of Quality systems including ISO 9000 series, ISO14000 & OHSAS18000.

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اما فرسندیم که بهترینیم، ما را بر کزیدماند



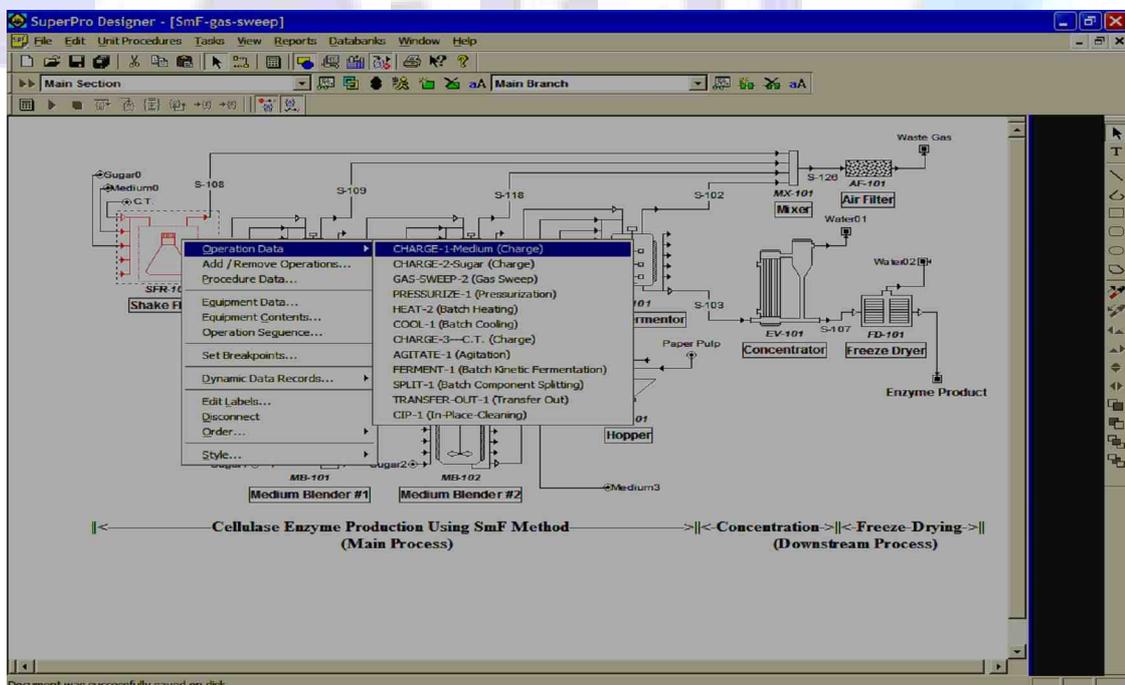
Documentations.



2-Biotechnology projects

Design and Implementation of Pharmaceutical Biotechnology, Chemical and food:

- Biotechnological production processes and downstream process, including industrial biotechnology, biopharmaceutical recombinant process and cell culture process.
- Process design with manual and software related to MIT University (super pro Designer intelligen Inc.)
- Fermentation process design and procurement of fermentation equipments
- Transfer of technology in the biopharmaceutical industry and industrial biotechnology.



Design, Engineering, Procurement and Construction (EPC)

Design, Engineering ,Procurement and Construction (EPC) of various sizes of projects

Design and manufacturer of EPC pharmaceutical, food, chemical plants and clean rooms according to cGMP standard.

Pharmaceutical and Biotechnological processing, chemical, food and related equipments



3-Maintenance and Industrial Automation

Equipments Maintenance

Our company with experienced staff and trained personnel in installation, commissioning ,automation and operation of production equipment offers the following services:

Maintenance Planning, including preventive and breakdown maintenance compliance with cGMP and quality systems.

Total Productive Maintenance System (TP M)

Preventive maintenance

Predictive maintenance

Industrial Automation:



Automation and control systems design and installation of manufacturing automated equipment and devices includes :

Consulting in designing control systems, industrial automation equipment procurement including industrial computers (IPC), PLC, type Remote I / O with different field bus, Sensor and pressure, temperature Trimester and humidity sensors and motorized control valves and Operator panel (OP-Panel)

Automation and complete monitoring system for clean rooms ranging from medicine, biology and microelectronics.

PLC of Laminar flow hood systems (Class A)

Building Automation System (BMS)

commissioning and operation of equipment control and automation equipment, machinery and production equipments in food, pharmaceutical and chemical industries

4-Manufacture and supply of equipment and machinery for chemical, pharmaceutical, food Biotechnology industries

we are only representative companies such as shree pharma , flexcontech cleanroom, POICs of Canada and UKELEFE in Iran . with regard to experience in importing machinery and accessories in chemical, pharmaceutical, food and biotechnology industries to importing the devices.

In short term our way to choosing of equipment and machines to be installed at the customer site are the following manner :

- 1 - Obtaining the necessary technical and process requirements of customers(URS).
- 2 - Request Performa from the manufacturer in accordance with user requirements(URS)
- 4 - Initial inspections done before the delivery and transport of equipments (Predelivery Inspection)
- 5 - Transportation of goods to the customer site
- 6 - Final testing and commissioning at the customer's plant (Commissioning & Site acceptance Tests).

In the case of pharmaceutical industries and critical systems before the launch and testing in the factory (customer)The equipments in accordance with approved protocols and internationally accepted standards will be tested (Performance Qualification). All documentation will be delivered to the customers at all stages.

Manufacturing activities, installation, commissioning and importing including but not limited to the following items:

- 1 - Pharmaceutical production line equipments includes tablets, capsules, ampoules, prefilled, syrup and product lines of Pharmaceutical Biotechnology, Fermentation, purification and filling and packaging equipments.
- 2 - All equipments and units related to food industries lines
- 3 - All equipment and installations related UTILITY include:
 - Hygenic and conventional air Handling systems for sterile and clean spaces.
 - Production systems, including pure steam and steam used in the pharmaceutical industry

- Production lines of water treatment systems including the production of deionized water, purified water and water for injection.
- Compressed air systems and automated industrial equipment including compressed air and compressed air used in process and instruments.



KLX Series Vials Compact Line for Cleaning, Sterilizing, Drying, Filling and Sealing



5-Design and construction of water and wastewater systems

Our services in design and construction of water and wastewater systems include:

conceptual design, basic design (Basic Engineering) and complete or detailed design (Detail Engineering) and projects for the following units:

- Critical Systems (Critical systems), including drug production unit Deionized water, pure water production unit (Purified water), water injection (water for injection), and clean steam (pure steam) in accordance with the latest USP.
- Design and construction unit of injectable solution (Injectable solutions)
- Design, install and operation of filtration system (RO (Reverse Osmosis), UF (Ultra Filtration) and Micro Filtration
- Design and construction of water and wastewater treatment systems for the food, pharmaceutical and chemical industries including advanced biological removal (biological treatment) and chemical inactivation system.
- Design and production of drinking mineral bottled water

آب شیرین کن های صنعتی لونا واتر



مشخصات فنی آب شیرین کن های صنعتی لونا واتر:

| نوع پمپ | برق مصرفی | نوع و تعداد ممبران | مدل |
|-----------------|--------------|--------------------------|---------|
| Procon (1507) | 220 V تک فاز | تک ممبران CSM 4021 | RO1000G |
| Procon (2507) | 220 V تک فاز | تک ممبران Filmtec 4040 | RO2000G |
| Grundfos | 220 V سه فاز | دو ممبران Filmtec 4040 | RO4000G |
| Grundfos | 220 V سه فاز | چهار ممبران Filmtec 4040 | RO8000G |

- دارای سه مرحله پیش تصفیه PP (پلی پروپیلن)، GAC (کربن فعال پودری)، CTO (کربن فعال بلاک)
- شاسی از نوع Stainless Steel با قابلیت جابجایی دستگاه
- مجهز به R.O Controller از نوع EC Analyzer Hotec و تابلو کنترل
- مجهز به شیرهای برقی، سوشیج فشار، شیرآلات و لوله کشی کامل، دستی سنج (فلومتر) و فشارسنجهای مراحل مختلف کار دستگاه
- قابلیت تجهیز به تزریق مواد شیمیایی پیش تصفیه (Anti Scalant) و سیستم شستشوی ممبران (CIP)



6-Clean Rooms Design , Construction , Qualification and Validation

AJSI is a representative of big manufacturer of clean room companies in pharmaceutical and micro electronics field in Europe such as Flexcontech clean room system, sinoarch technical and Pdana cleanroom (Italy). The constructed Clean rooms under the vision of these large reputable companies will be Validated and Qualified.

AJSI CLEANROOM designs, manufactures and installs movable partition walls and modular false ceilings for the creation of sterile and controlled contamination environments for the Pharmaceutical, Cosmetic, Electronic And Food Industries as well as Research Laboratories.



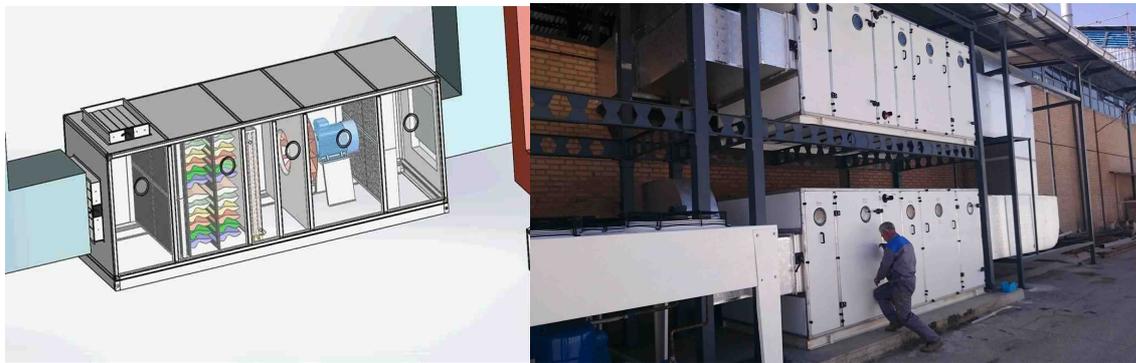
Our main services include, but are not limited to:

- Design (conceptual design, basic and detailed) and construction of clean rooms includes critical, controlled and conventional area

- Clean rooms 3D design and simulation with CFD
- Commissioning (commissioning and pre commissioning) and Balancing
- Testing, Validation and Qualification of cleanrooms
- Design and manufacture of HVAC Systems such as hygienic AHUs for sterile area
Validation and Qualification of HVAC systems
- Design , manufacture and qualification of cleanroom related Utilities.

6.1-Design and manufacture of HVAC SYSTEMS

Design and Manufacture of conventional AHU(Air Handling Unit), packaged unit and Hygienic AHUs for pharmaceutical , biopharmaceutical industries and Hospitals.



6.2-Our Hygienic AHU has following characteristics:

1. Air velocity on the cooling coil of 500 feet per minute and 400 feet/min in the wet areas.
2. Easy cleaning and sanitation of internal AHU in accordance with Eurovent Standard.
3. Only plug fan or direct coupled fan with electric motor manufacturing from Siemens and Coverco or Nicotra companies(Italy) with Thermal Class F and IP54 Protection Class .
4. In coils ,the number of Finn in inches not exceed more than 8.
5. Stainless steel 316 L sheet for Internal surface is used.
6. AJSI AHUs have one year warranty and after sales service is five to ten years.

6.3-AirDucts and facilities

Design and installation a variety of pre-insulated ducts, spiral and round galvanized or stainless steel Ducts.

TD Pre-insulated ducts form Australia



PAL and ALP pre-insulated ducts from Italy.

Ducts Specific test in accordance with American standard (SMACNA)

Supply of filters, diffusers and louvers in different types and sizes.

Design, manufacture and installation of industrial facilities including:

Compressors, chiller, boilers, fans and AHUs systems.

Installation and execution of pure steam and water purification system piping with ARC and orbital welding and provide associated documentation.

All Systems related to HVAC, Package Unit, and Utility plant

6.4-Clean room equipments and supplies

Supply of clean room equipment and supplies

AJSI Sales Department in order to provide clean rooms equipments, devices and supplies for industries offer the following services:

Clean rooms equipments and devices such as :

- Manufacture and supply of Class 2 and 3 biological safety cabinet laminar flow (Laminar flow) and chemical hoods which are equipped with the necessary controls .
- Clean-room window: double glass window with thickness, 45, 50, 60 and 80 mm which was filled with inert gas
- clean room HEPA fan filter unit
- Pass Box & Pass thru: AJSI Pass box and pass thru system consists of two general types: Static pass box (no flow inside box) and the dynamics pass box (including filtered air) with stainless steel body structure or panels.
 - Cleanroom testing equipments such as particle counter, accua balance ,temperature and humidity sensors,..etc
 - **interlocking system provide with optical indicator of doors status**

Supplies:

- Steel desk, shelves, table, chair in perforated and non perforated type, step over bench and mirror.

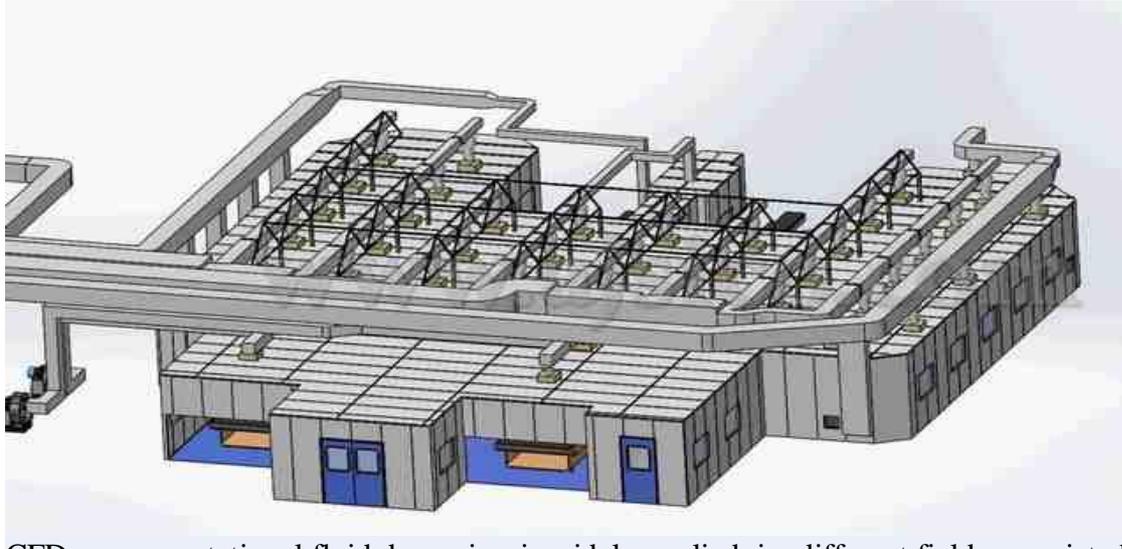


- Lighting fixtures for sterile and controlled contamination environments
- Clean room gown and clothes:

Cloth material :Made from the imported carbon fiber filament and PFY(polyester filament yarn) and 0.5 cm Conductive silk which Does not produce dust, not dust ani static . does not cause pollution and workplace, effective control of the air particles inside the clean room. Products can be sterilized in the 120□-140□ temperature for 40minutes.

Available in different sizes for class A-D.

6.5-CFD simulations of clean room



CFD or computational fluid dynamics is widely applied in different fields associated with industrial fluids, heat transfer and fluid for transportation of materials. These calculations are combined with computer simulations. CFD codes continuity equations for mass, momentum and energy over a range defined by the user. This technique is very powerful and a great range of industrial applications. It is applied in automotive ,space ,turbo machine, nuclear, military ,petrochemical , cleanroom and energy industries for solving and simulation of complex fluid system. By using this technique the experimental cost for testing the complicated cases which is impossible to measure or determine for special parameters will be reduced or even be eliminated.. Since construction cost for physical prototype model of cleanroom is expensive as well as problems may arise after the construction and operation of these controlled area. CFD software can help to simulate real cleanroom conditions and parameters in order to meet the acceptable range.

Problems which is resulted of wrong HVAC systems design for clean rooms and controlled environments

- 1 - inadequate air flow distribution
- 2 - No Laminarity or having a quiet stream in some places
- 3 - in proper pressure levels in clean environments
- 4 - Create static stream around the clean room equipment and services
- 5 - The creation of large areas without air conditioning
- 6 - Improper removal of chemical vapors and ... from rooms
- 7 - High noise
- 8 - Changes in temperature and humidity in controlled areas outside of specified range.

CFD can be as powerful tool for removal and reduction of above problems in the design of clean spaces and applied for verification of designed clean room(design Qualification).

Using these methods require experience, understanding of different numerical methods

and using appropriate hardware.

A team of experienced professionals in AJSI company who has excellent knowledge on CFD and numerical simulation methods can certainly design clean rooms to meet international standards for various industries. In our company clean rooms design with CFD technique simulated and critical points will be evaluated before construction in order to reach the standard conditions in operational phase.

example of our simulation film of clean rooms design with CFD is available in our site(www.ajsico.com).

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اما سرسندیم که بهترین ما، ما را برگزیده‌اند



Summery of projects list

- 1- Design and construction of biopharmaceutical pilot plant(bacterial and cell culture) including Class A,B,C and D cleanrooms 300 m2 in Pharbiosun biotech company.
- 2-design of biopharmaceutical plant near 5000 m2 facilities Pharbiosun biotech company.
- 3-renovation and costruction of Refrence LAB of Iran National Standard(INST) including Mass ,Length and dimention reference Laboratories 500m2.
- 3- design of veterinary pharmaceutical plant including of powder ,syrup ,syspunsion and desification line for Caspian safe pharmaceutical company 4000m2.
- 4- preparation of validation and project master plan for razi vaccine institute
- 5- Procurment of devices and cleanroom equipments for bayer aflak company
- 6-project study and bussines plan preparation for recombinant anti cancer drugs of pharbiosun company.
- 7- technical and feasibility study plan (Camfare based projects)for production of 4000 ton/year of veterinary pharmaceutical products.
- 8-Design and renovation of Ampule facility in Aburihan pharmaceutical company 280 m2.
- 9- GMP project implementation ,documentation and training in Aburihan pharmaceutical company.
- 10-consultant and commissioning of national recombinant plant Pasteur institute of Iran. 7000m2.
- 11- cleaning validation projects for ampule and vial equipments in Aburihan pharmaceutical company.
- 12-process validation projects for tablet and ampule departments in Aburihan pharmaceutical company.
- 13-automation and maintanace of Pand Sanat company equipmants.
- 14-design and construction and commissioning of pharmaceutical purified water system with 20m3/day in Sibeh Kish company.
- 15-dseign,construction and commissioning of pure steam generator and hygenic Air handling units of pharbiosun company.
- 16-design and construction and commissioning of pharmaceutical purified water system with 10m3/day in Pharbiosun company.
- 17- design ,fabrication and commissioning of Hygenic Air handling units of ICU,CCU for Mashhad Hefdah shahr river hospital.
- 18- fabrication of cleanroom equipments for hospital projects of Safrah bina Company.
- 19- design ,fabrication and commissioning of Hygenic Air handling units of cheese production plant for PEGAH dairy industrial company.

- 20- turnkey projects of clean rooms , mechanical and power plant facilities for Rojin cosmetic company 1000m2.
- 22-design,fabrication and commissioning of Air Handling units of Pursina pharmaceutical company.
- 23- cleanroom design ,construction of Sience pharma company 600m2.
- 24-clean room project for new drug delivery system of Iran polymer and petrochemical research center 150m2.
- 25- turnkey projects of cleanroom for Razi pharmaceutical glass production company 1000m2.
- 26- design ,fabrication and commissioning of Air handling units and chillers of Razi pharmaceutical glass company 150 ton cooling plant.
- 27-- design ,fabrication and commissioning of pharmaceutical weighting and sample booth equipments for Simorgh attar company.
- 28- full design of hebal pharmaceutical for syrup,tablets and capsule line of Dramangar sabze company 1500m2.
- 29- design ,construction and commissioning of high tech electronic cleanrooms of SaIran Company.
- 30-- design ,construction and commissioning of 4000m2 high tech electronic cleanrooms of automative car production Sazepouyesh company.
- 32-design and construction of veterinary pharmaceutical cleanrooms of Biorun company 200m2.
- 33- fabrication and installation of cleanrooms equipments for HTL company.
- 34- design ,construction and commissioning of 200m2 high tech electronic cleanrooms of Rahandishan Dena Company.
- 36- full turnkey projects of 2000m2 pharmaceutical plant including cleanrooms, mechanical and power plant as well as laboratories of OJE Boland simorgh Company.
- 37- turnkey project of pharmaceutical cleanrooms , laboratories as well as mechanical and power plant facilities of Vala andishan Daroy Nab companies.
- 38- full design of soft gel cytotoxic production unit with EB5 grade hazard including mechanical ,electrical as well as power plant for Dana pharmaceutical Company.
- 39-Turnkey project for design,construction and commissioning of first GMP synthetic bone production plant in Iran ,Ide bartr kivan medical device Company.

- 40-Full turnkey project for design ,construction and operation of first synthetic bone production plant in Iran as per EU GMP aspect approved by national health and medical device Hamedan-Iran.
- 41- full GMP design of cyclosporine soft gel production plant(HAZARD =EB5) for Dana pharmaceutical company,Tabriz-Iran.
- 42- design and solid 3D simulation of Stem cell plant for Farabi hospital Tehran-Iran.
- 43- design and manufacture of Sample and weighting booth for Simorgh Attar Pharmaceutical company.
- 44- design and manufacture of weighting booth for modava Pharmaceutical Company .
- 45-basic and detailed design of factory for production of tablet,capsules and powder as well as syrup ,suspension and semisolid products ,Paria pharmaceutical company.
- 46-full turnkey project for design ,manufacturing and installation of pharmaceutical water systems with 55000 liters daily capacity for Buali research center of Mashhad medical science university.
- 47- full GMP design of pharmaceutical plant for tablets, syrup ,capsules ,suppository and semisolids production of Paria Daru near 9000m2.

List will be update in future

تاریخ:

شماره: -AJSI
CV/91/002

طراح و سازنده کارخانجات دارویی، غذایی، شیمیایی، اتاقهای تمیز (clean rooms)
صنایع دارویی مطابق با استاندارد cGMP و توسعه فرآیندهای بیوتکنولوژیک، شیمیایی
صنایع غذایی و تجهیزات وابسته

انژیستیک
جامع صنعت ایرانیان
شماره ثبت: ۳۴۱۰۰۹



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Central office: unit 6 ,2nd floor ,Ashkan tower,derakhti bulvared, Mehrvilla Sq. Karaj-Iran.
Factory : number 18,zafar st. Kamalshahr ,Karaj-Iran. Tel:+98-2633552800 ,34711103.
web:www.ajsico.com, email: info@ajsico.com



کاتالوگ تجهیزات اتاق تمیز (۳)

شرکت انژیستریک جامع صنعت ایرانیان

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آدرس: کرج میدان هنرمند تیر طلقاتی جنوبی ۱۲متری انقلاب بعد از قصر تارا ساختمان تخت جمشید طبقه سوم واحد ۴
تلفن: ۰۲۶۳۳۵۲۷۴۸
www.ajsico.com
info@ajsico.com

کاتالوگ تجهیزات اتاق تمیز (۱)

شرکت انژیستریک جامع صنعت ایرانیان

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تلفن: ۰۲۶۳۳۵۲۷۴۸
www.ajsico.com
info@ajsico.com

کاتالوگ تجهیزات اتاق تمیز (۲)

شرکت انژیستریک جامع صنعت ایرانیان

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