TRUKING TECHNOLOGY LIMITED

LIQUID FORMULATION

Introduction

Truking Technology Limited(hereafter referred to as TRUKING TECHNOLOGY) was founded in 2002, located in National Grade Ningxiang economic and technology development zone. It is mainly specialized in research, manufacturing, sale and service of pharmaceutical machinery, such as ampoule compact line, vial compact line, oral liquid bottle compact line, Infusion glass bottle compact line，Non-PVC IV infusion soft bag line, solution preparation system, Freeze Dry integration system, auto inspection machine, auto inspection & leak detection machine, leak detection machine, rubber(cap) washing machine etc. It is one of the biggest researcher and manufacturer of biological pharmaceutical machinery in China. TRUKING TECHNOLOGY was officially listing in GEM of Shenzhen Stock Exchange on Jan.21,2014, stock name: truking technology, stock code:300358.

TRUKING TECHNOLOGY established National Grade enterprise technology center, Post-Doctoral Research Center and the only Pharmaceutical Machinery Engineering Research Center in Hunan province, has a technology and research team with more than 200 persons, drafted 14 national standards for pharmaceutical equipment. Till to March 31,2014, TRUKING TECHNOLOGY applied for 1465 National patents (including 361 invention patents), attained 982 authorized patents(159 invention patents). And TRUKING TECHNOLOGY applied for 22 PCT international patents, attained 5 authorized patents in USA, Japan and Russia. TRUKING TECHNOLOGY is Hunan Province Hi-tech products and Hi-tech enterprise, Hunan Province IPR demonstration enterprise, Hunan Province Important strategic new industries, National IPR cultivation pilot enterprise.

Technology and quality of TRUKING TECHNOLOGY are in leading position in China, it won Hunan Province Governor Quality Prize and China Federation of Industry Scientific and Technological Progress Award. "TRUKING" brand has been identified as Chinese well-known trademark. Products of TRUKING TECHNOLOGY covered all over the country, it supplied equipment to more than 1000 biological and chemical pharmaceutical enterprises such as Sinopharm, Harbin Pharmaceutical, China National Biotec Group, North China Pharmaceutical Group etc. and is replacing imported products. TRUKING TECHNOLOGY had exported to more than 20 countries and areas such as Japan, India, Russia, Mexico and so on.

During these ten years, TRUKING TECHNOLOGY won dozens of National and Provincial honorary title such as "National May 1st Labor Certificate", "Hunan Province Excellent private –owned enterprise", etc. and numerous praise and prize from City and County government. Enterprise culture of TRUKING TECHNOLOGY is "To be respected person, to make respected products, to run respected enterprise.", operation principle is "to be unique, or to be the first", enterprise spirit is "Because of persistence,we are super excellent!" TRUKING TECHNOLOGY plans to be the first class global pharmaceutical machinery enterprise in 2020.

Applications

Formulation system is designed according to the client requirements, and implemented by the advanced concept, professional manufacturing, site installation and validation team. The system meets the requirement of Chinese GMP, EU-GMP, FDA cGMP, and could be applied in the following fields:

Bio-Technology

Upstream medium formulation and centrifuge homogeneity auxiliary process compact line

Downstream separation & purification auxiliary process integrated system

Human blood product process integrated system

Vaccine product manufacturing process integrated system

CIP/SIP

Chemical Pharmaceutical

Aseptic active pharmaceutical ingredients (API) manufacturing process system

Injection formulation system

Freeze dried formulation system

Large Volume Injection formulation system

Oral liquid formulation system

Eyedrop formulation system

Fat emulsion formulation system

CIP/SIP

Injection Formulation

Automatic Formulation And Transfer

- Automatic CIP system (automatic conductivity detection)
  Automatic SIP system(automatic temperature detection)
- Automatic on-line filter element integrity test system (automatic input from the integrity detector)
- Automatic on-line water supply & weight-transmitter system (automatic weight-transmitter)
- Automatic air tightness detection before SIP
  Automatic pressure maintenance after SIP
- Parameter invocation according to the type of product. The
- system is executed automatically, which can record the runtime & parameter, and to print & alarm automaticall

Process Solution

Manufacture process	Solution
Water supply / Metering	Flowmeter
	In-suit weighing
Feed	Adding the raw-material in aseptic situation manually
	Suction through feed inlet
	With aseptic sampling hole
Mix	Variable frequency agitator
	Annular rotation sealing & aseptic liquid sealing system
	Magnetic agitator at the bottom of tank
	Homogenizer
Temp-Control	Open or close circuit with proportional control
	Heating & cooling system
Sample	Sterilizable sample system
	Cleanable and sterilizable centrifugal pump, rotation pump, drain
Transfer	Aseptic compress air or nitrogen
Product Filtration	Pre-filtration & aseptic filtration
	On-line integrity detection
Storage	Magnetic agitator and temperature control system
	Nitrogen protection
	Aseptic sampling

Human Blood Product

Overall solution for human blood product including BD, DD and optimization, equipment selection, installation, commission and validation.

- Plasma thawing & fractionation
- IgG, albumin ,special immune globulin, TB,PCC,FⅧ,FNG, etc.
- Unit design and integrity: protein centrifuge, plate frame filtration, UF, chromatography, pasteurization automatic temperature control system, hot water bath temperature control system.
- Compact line of cleaning, sterilizing, drying, filling and sealing & lyophilizer
- Automatically controlled CIP and SIP system.
- Utility: low temperature holding pasteurization accuracy temperature control system, low temperature media temperature control

Features

- Prospective design concept
- First class selection and manufacture
- Rich project experience
- High integrated automatic system with manual intervention ability

Fat Emulsion

Provide set of product system of fat emulsion, liposome, microcapsule, targeting preparation for liquid injection.

Common Emulsification Process

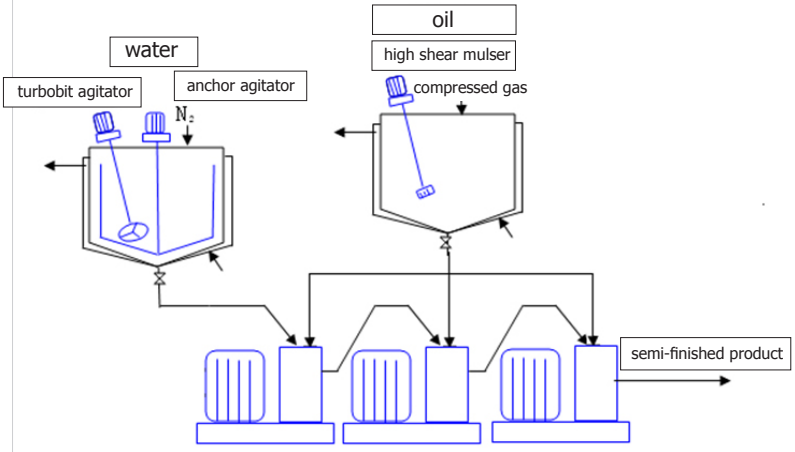
1.Vertical Super speed mulser and high pressure homogenizer. This combination improves the efficiency and reduces the width of particle size distribution, which made the system could work continuously, and avoid the operation mode of manifold cycles when using the super-speed mulser.

2.Continuous emulsification (the latest technology) , high speed mulsers combination ,a single emulsification without circle.

We integrate the advanced continuous emulsification technology, to reduce equipment investment, improve production efficiency. The system can be operated continuously in 24h with high stable product quality. Moreover, the system has the function of CIP and SIP. It is the best choice for a big batch production, due to the advantages, such as high equipment utilization rate, quick transfer, reducing the investment on mix tank and plant space.

Features

- Meeting Chinese GMP, EU GMP and FDA cGMP regulation
- Meeting process requirement aseptic process tank, tube and fluid components.
- Advanced and flexible modularization process unit
- All core process components and equipments are provided by well-known suppliers.



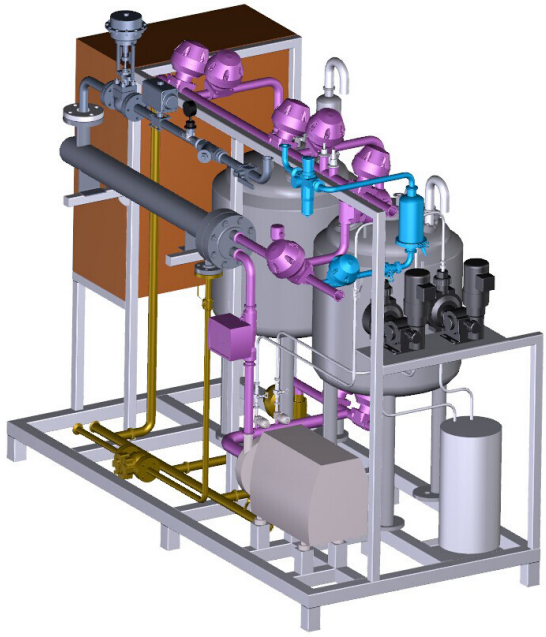
Continuous emulsification diagram

CIP Station

CIP station is a set of stable equipment, which can achieve the online cleaning, adopting the H&M interface and image display, the station could be able to automatically. switch the process parameters and regulate cleaning time, pH & temperature etc. The traceable operation records can facilitate your validation.

Various combinations: stationary type or movable type, single tank system or double tanks system, with or without heating.

The CIP station enables automatic different concentrated solution preparation and self detection. It conforms to the validation requirements of Chinese GMP, FDA cGMP and EMA.



Automation

- Automatically controllable, Parameter detection
- Circulation , improving reliability
- Human errors elimination

Operation cost reduction

- Reducing Labor cost
- Reducing Cleaning time ,improving efficiency
- Reducing the consumption of water/ solvent/ detergent

Safety Improvement

- Reducing the dirct exposure risk of the product
- Equipment cleaning without splitting equipment or entering equipment.
- Avoiding the risky operation, such as high pressure water torch operation

Bio-Products

Upstream integrated system / downstream separation and purification integrated system

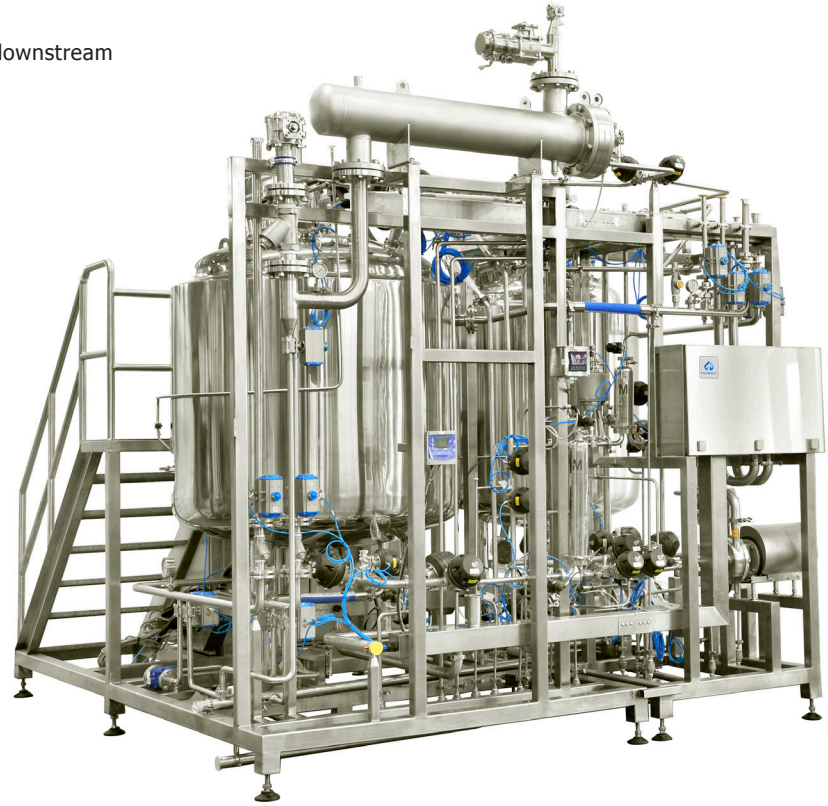
Features

Upstream integrated system

- Culture medium preparation unit.
- Culture medium filtration unit
- Culture medium storage
- Harvest unit
- CIP system unit
- Centrifugation and homogenization unit

Downstream Separation & Purity Process Integrated System

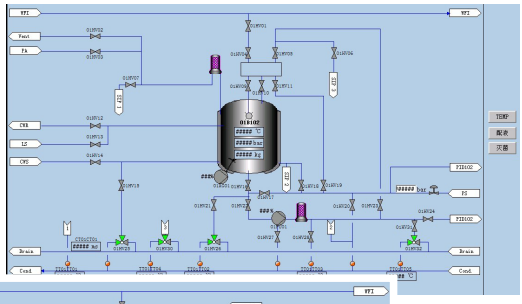
- Buffer preparation unit
- Buffer filtration unit
- Buffer storage unit
- Product storage unit
- Bio-waste inactivation unit
- UF&Chromatography unit
- CIP circulation piping system in downstream process module

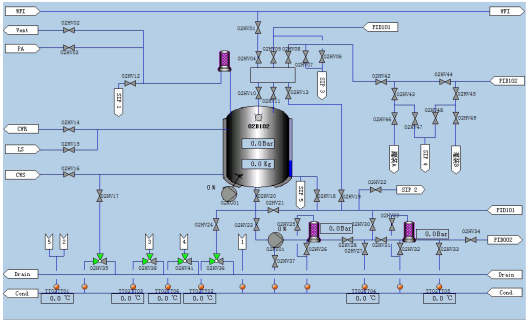


Automation

The advanced control system can optimize the effectiveness of the production process, ensure the stability of product quality, reduce the manufacture cost and improve the flexibility of production.

Our experienced local electrical automatic department can provide high cost performance automatic control system to fit your needs.





- Electric design
- Control cabinet manufacture
- FDS development
- Software programming
- System testing
- User training
- System commissioning

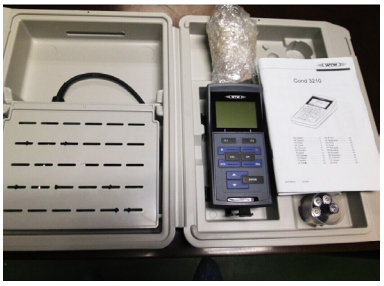
Manufacture Ability

- Excellent machining
- Clean manufacturing environment
- Advanced inspection tools

Warehouse management

Polisher

Digital miller



Portable conductivity meter

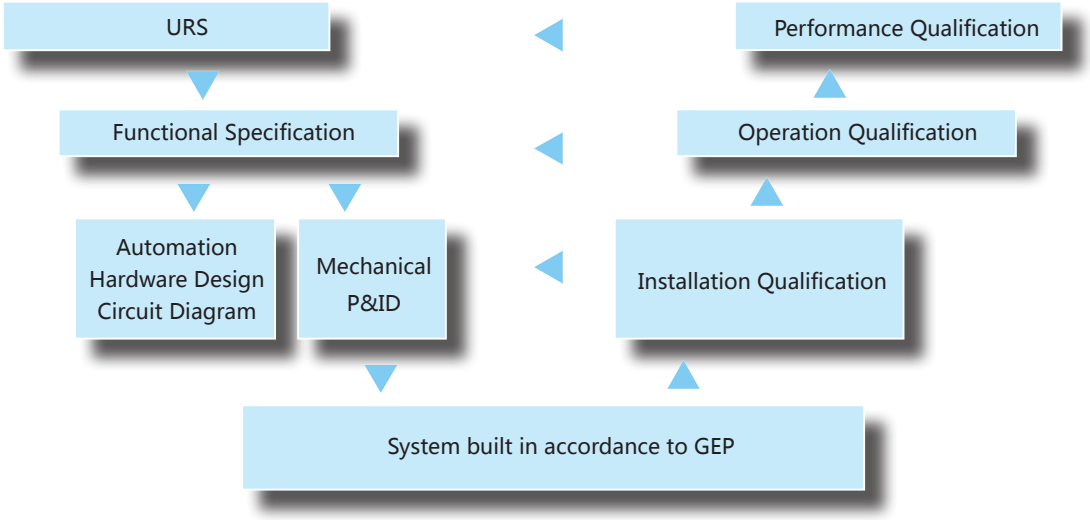
Endoscope

Surface roughness detector

Quality Control

Validation

- Whole project conforms with the V model from planning to operation
- Documentation system can meet the validation requirement
- Automatic control system can fulfill the requirements of GAMP

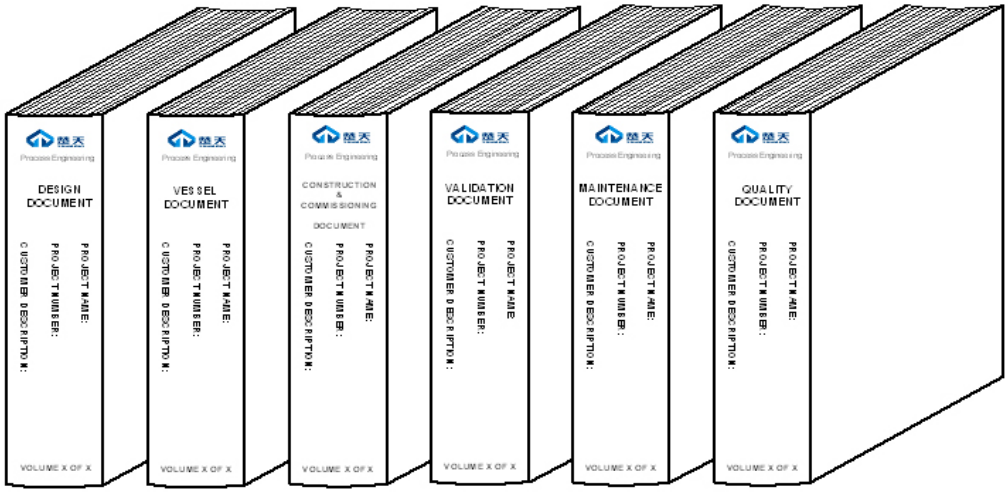


Quality

- Latest technology, high standards configuration and manufacture, world-class quality
- Full compliance with the regulations of WHO , EU GMP FDA and cGMP.
- Development and project management team with rich experienced and world-class technology could provide the high quality products and highstandard project management service to our customers.
- High standard equipment files and validation documents
- Fast delivery and rapid response
- Professional project service and validation support
- Large-scale and highstandard manufacture, abundant spare parts supply
- Global, large-scale, professional and efficient after-sales service

Documents

Phase 1: **Validation Plan**	• Validation Plan • Test Matrix
Phase 2: **Design Review**	• Design Review Protocol • Requirement Traceability Matrix • Design Review Report
Phase 3: **Risk Assessment**	• Component Criticality Assessment • Automation Risk Assessment
Phase 4: **Validation Tests**	• Vendor Internal Test Protocol & Report • Factory Acceptance Test Protocol & Report • Site Acceptance Test-1 Protocol & Report • Site Acceptance Test-2 Protocol & Report • Installation Qualification Protocol & Report • Operational Qualification Protocol & Report
Phase 5: **Handover**	• Design Document • Vessel Document • Construction & Commissioning Document • Validation Document • Maintenance Document • Quality Document



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