

# 1、Introduction

Shanghai Twisun Bio-pharm Co., Ltd. (hereinafter referred to as Twisun), founded at Shanghai Jinshan Fine Chemical Industry Park in 2007, is a leading Hi-tech manufacturer of APIs and intermediates, special chemicals and CRO, which successfully acquired the Shanghai and National Ministry of Science and Technology Innovation Fund in 2009.

Twisun mainly involves in more than 40 key intermediates of 5 major categories which are Cardiovascular, Anti-cancer, Anticoagulation, Antidiabetics, and Antidepressant etc. Our products basically relate to the newly developing API category and key intermediates that include Tenofovir, Ticagrelor, Saxagliptin, Dabigatran Etexilate, Prasugrel, Rivaroxaban, Apixaban, Dapagliflozin, Paliperidone, Brinzolamide, Dorzolomide hydrochloride, Lapatinib, Nilotinib etc. More than the above mentioned area, Twisun also has the technology and capability to provide professional services of chemistry and pharmacy effectively and efficiently.

Since its inception, Twisun has always been adhering to our "Quality Based, Customer First, Credit Management, Professional Services" business principle. Our products are exported to Europe, USA, the Middle East, India, Southeast Asia and other regions. We have built good and steady cooperation relationship with numerous pharmaceutical enterprises from both domestic and international, which making our turnover growing rapidly in double speed every year.

Twisun has more than 3,000 square meters of multi-functional R&D center for chemistry and pharmacy. Having many sets of R&D and testing equipments like NMR, HPLC, LC-MS, and GC-MS etc. Twisun production base which covers 20,000 square meters GMP plant(Anhui Twisun Hi-Tech Pharmaceutical Co., Ltd) has been built and put into production. It has got ISO9000 certificates and can supply to customer with high-quality products which apply to international standards (ICH, Q7A etc.) now.

Twisun has a professional R&D team comprised by 30 senior experts with many years experience in research and development, which is led by the professors of the Nanjing University (NJU), and PhDs of the Chinese Academy of Sciences Shanghai Organic Chemistry (SIOC). Twisun believes that a professional team with the good R&D environment can assure the high quality of products and the professional services we provided.

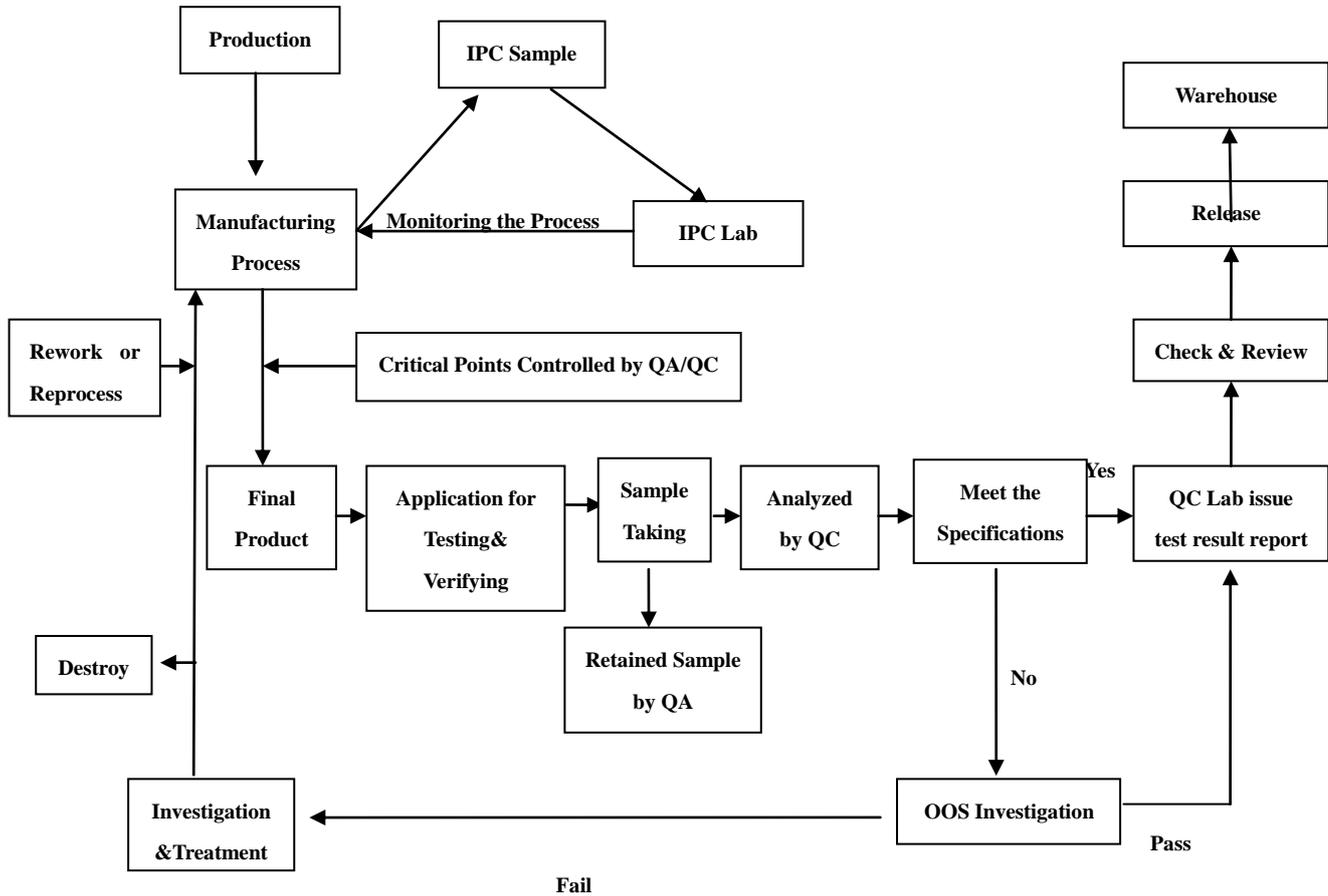
Just as our slogan, "We see things from the customer's perspective, and strive to exceed customers' expectations". We are willing to cooperate with domestic and international friends for a Win-Win future.

## 2、QA

The Quality Principles are:

- ICH Q7: GMP Compliance
- ISO 9001/2000: Quality Management System

The Quality Control of Release Flow Chart for Finished Products:



### 3. Quality Control System

1) We have built a professional and experienced QC team that has regular and standardized training. QC system covers from R&D to manufacture process of the production, including procurement of raw materials, manufacturing process, and finished product testing control as well as the management of QC documents.

2) In order to meet the requirements of all APIs and intermediates testing in the process of R&D and manufacture, we will use the advanced equipments in company analysis center.

HPLC	GC	Melting point apparatus
Stability Chambers	IR	UV
NMR	LC/MS	GC/MS
Polarimeter	Titration	KF water meter



## 4、 R&D and Services

- 1) Application of database: We use Beilstein and Crossfire organic synthesis database, Chemistry patent database and pharmaceutical industry database for R&D data and legal basis supporting.
- 2) 3000 square meters R&D center is designed to develop several pharmaceutical researches in a comprehensive way at the same time.
- 3) In our chemistry lab, besides the routine experiment instruments, we also equipped high pressure reactor, hydrogenation reactor, microwave reactor equipments and etc.
- 4) By closely cooperate with famous academy and research institutions as well as the professional coordinate with high quality teams, we enhanced and ensured our human resource for the developing of new projects.

### Service

- 1) Technology development and quality research on APIs and intermediates;
- 2) Developing and researching on new drugs & Customer research outsourcing (CRO);
- 3) Customer synthesis service;
- 4) FTE cooperation system;
- 5) Drug registration & Regulation consultation.

## 5、 Production Capacity

The GMP factory(Anhui Twisun Hi-Tech Pharmaceutical Co., Ltd)which is a new production base raised and built by Twisun Pharm has been completed and put into production. It satisfies not only production requirements of APIs and intermediates but also certification requirement of API.