Supplier Assessment Report

Jinzhou Jiutai Pharmaceutical Co., Ltd.

锦州九泰药业有限责任公司

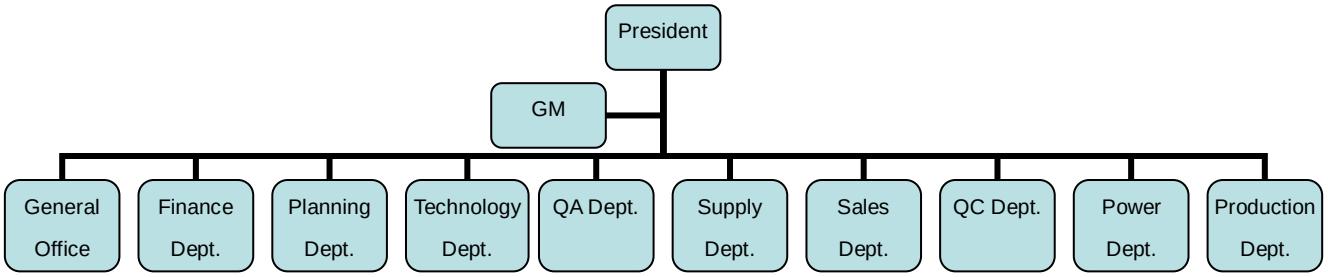
This report is issued by Hangzhou Weiku Information Technology Co., Ltd. and Bureau Veritas Certification.

Contents

Report Number:	T0010_P+T	Online Verification :	www.bvcerchina.cn
Validity Period:	19/Jun./2014 -- 18/Jun./2015		

Section 1: Company Overview

Company Overview	
1.1 Legal Entity	
Does the supplier have the following certificates to carry out business?	☒ Business license ☒ Tax Registration Certificate ☒ Organization code certificate ☒ Account opening license
Business License Number:	210700004058814
Validity Period:	2/Sep./1998 -- 23/Feb./2029
Registered Address:	No. 41, Taianli, Taihe District, Jinzhou City, Liaoning Province, China
Company Address:	No. 41, Taianli, Taihe District, Jinzhou City, Liaoning Province, China
Annual review conducted by:	Jinzhou Industrial & Commercial Bureau
Name of legal representative:	Mr. Kejun Li
Registered Capital:	RMB 40,986,462
Business Type:	☐ Manufacturer ☐ Trading Company ☒ Both
Type of Ownership:	☒ Private Owner ☐ Public Company ☐ Joint Venture ☐ Stated Owned ☐ Sole Proprietorship ☐ Other
Products Manufactured/Sold:	Lyophilized Powder for Injection, Tablet, Bulk Drug, Suppositories
Business Contact Person:	Mr. Jian Li
Phone Number:	0086-416-5169599
Fax Number:	0086-416-5178949
Email:	wmpharm@163.com
Website Address (URL):	http://www.jiutaipharm.com, http://jzjt.company.weiku.com
1.2 Company Facility Information	
Certification Type:	☒ Land Certificate ☐ Real Estate Certificate ☐ Lease Agreement
Number of Building(s)	20
Total Building Size:	58,000 m^2
1.3 Human Resources	
Company Chart	



Employee Headcount:

Department Name	Full Time Employee(s)	Part-Time Employee(s)	Total
President	1	0	1
GM	1	0	1
General Office	48	0	48
Finance Dept.	9	0	9
Planning Dept.	11	0	11
Technology Dept.	15	0	15
QA Dept.	13	0	13
Supply Dept.	12	0	12
Sales Dept.	112	0	112
QC Dept.	37	0	37
Power Dept.	38	0	38
Production Dept.	299	0	299
Total:	596	0	596

1.4 Production Capacity

Products Category	Bulk Drug	Tablet	Lyophilized Powder for Injection	Suppositories	N/A
Actual Production Capacity in the Past 12 Months	125 Tons	1,655,830,000 PCS	7,420,000 PCS	20,140,000 PCS	N/A
Max Production Capacity Based on Current Status	200Tons/Year	2,000,000,000 PCS/Year	20,000,000 PCS/Year	80,000,000 PCS/Year	N/A

Number of Main Production Machineries by Category:	Machineries Category	Number
	Reaction Kettle	39
	Centrifugal Machine	7
	Vacuum Drying Machine	5
	Bottle Cleaning Machine	1
	Aluminum Cap Cleaning Machine	1
	Rubber Plug Cleaning Machine	1

	Sterilization Drying Machine	2
	Mixing Machine	3
	Pure Water Equipment	5
	The Lyophilizer Unit with Feeding and Discharge Automatically	2
Number of Main Testing Machineries by Category:	Machineries Category	Number
	IR Spectrophotometer	1
	Gas Chromatograph	2
	Liquid Chromatograph	6
	Ultraviolet Spectrophotometer	1
	Automatic Potential Titrimeter	4
	Electronic Scales	3
	Drug Melting Point Meter	2
	High Temperature Furnace	2
	Electrothermal Constant-Temperature Dry Box	2
	Digital Automatic Polarimeter	1

1.5 Sales Volume of Trade Goods

Sales volume in past 12 months	Bulk Drug	Tablet	Lyophilized Powder for Injection	Suppositories	N/A
	125 Tons	1,655,830,000 PCS	7,420,000 PCS	20,140,000 PCS	N/A

1.6 Trade Mark

No.	Content	Observations /Comments
1	Registered Trade Mark	JIUTAI
2	Issued By:	State Industrial & Commercial Bureau Trademark Office of R.P. China

1.7 Communication Channel

Accepted Language	Mail	Telephone	Instant communication tool	others
English	Yes	Yes	Yes	N/A

1.8 Export Situation

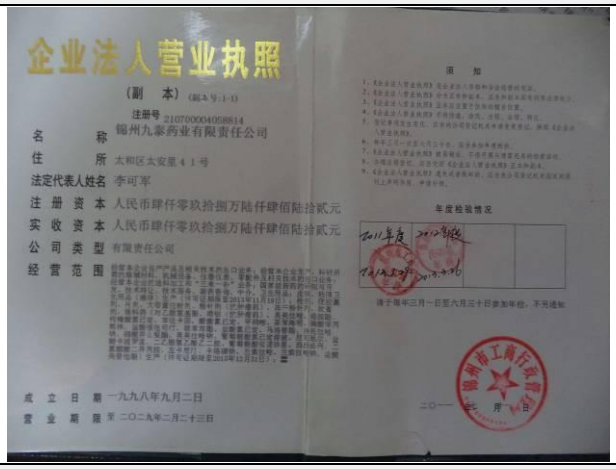
There is/are 3 international trade employee(s) in the company.	
Is there a valid export license?	☒ Yes ☐ No
Export License Registration No.:	01272304
Trade agents employed overseas:	☒ Yes ☐ No
Accepted payment terms:	☒ FOB ☒ CIF ☐ EXW ☐ CFR
Accepted payment type:	☒ L/C ☒ T/T ☐ Credit Card ☐ Cash ☐ West Union ☒ Paypal
Lead time from order confirmation to production delivery on average (products exiting the factory):	30 Days

1.9 Market Distribution (Previous 24 Months)

Products	Western Europe	Eastern Europe	North Amer-ica	South America	Asia	Africa	Mid East	Domestic
Bulk Drug	-	√	-	-	√	-	-	√
Tablet	-	-	-	-	-	-	-	√
Lyophilized Powder for Injection	-	-	-	-	-	-	-	√
Supposito-ries	-	-	-	-	-	-	-	√

1.10 Certification & Photos

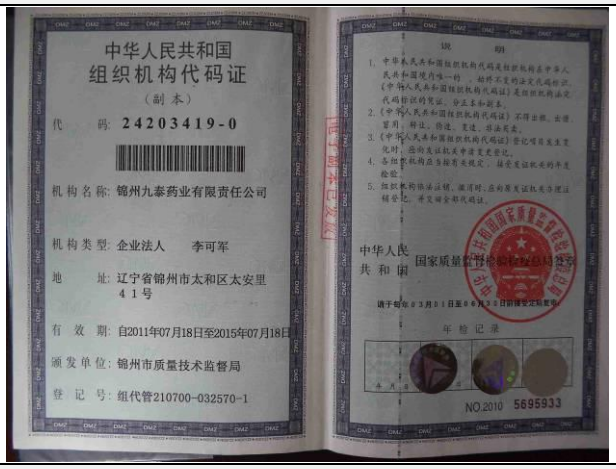
Business License (Duplicate) with Certificate / Records of Annual Inspection



Tax Registration Certificate

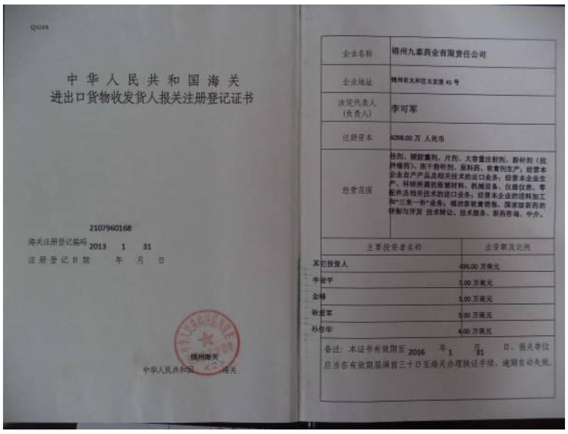
Permit for Opening Bank Account

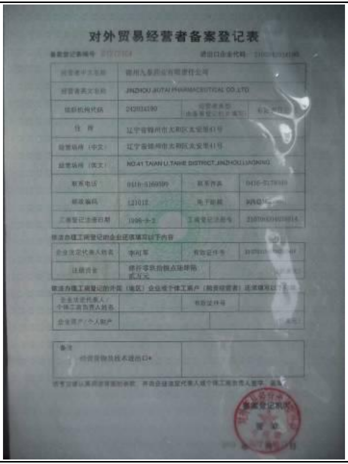
Organization Code Certificate



Custom Clearance Registration Form

Import and Export Enterprise Registration



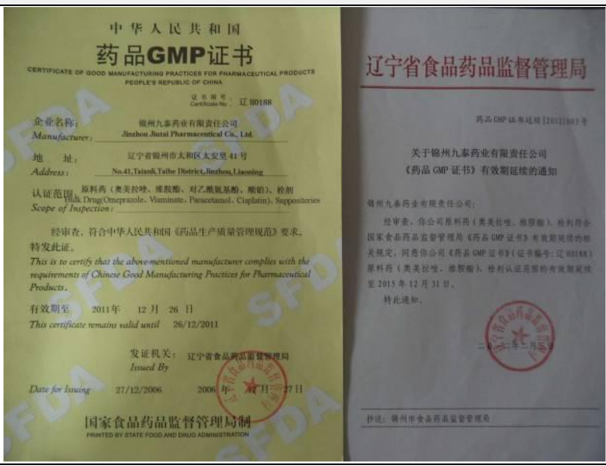


Register Trade Mark

Pharmaceutical Production License

GMP 1

GMP 2



GMP 3

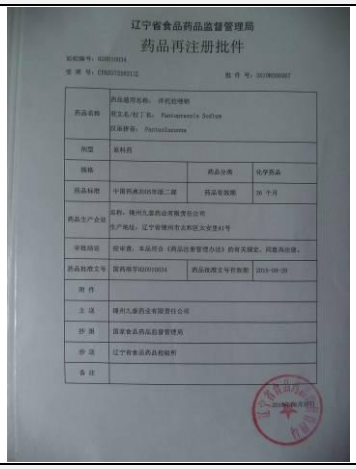
Medicine Registration Approval 1


中华人民共和国
药品GMP证书
CERTIFICATE OF GOOD MANUFACTURING PRACTICES FOR PHARMACEUTICAL PRODUCTS
PEOPLE'S REPUBLIC OF CHINA
证书编号：CN20130024
Certificate No.:
企业名称：锦州九泰药业有限责任公司
Manufacturer: Jin Zhou Jiu Tai Pharmaceutical Co., Ltd.
地址：锦州市太和区太安里41号
Address: No.41,Taian li,District Taihe,City Jinzhou,Province Liaoning
认证范围：冻干粉针剂
Scope of Inspection: Lyophilized Powder for Injection
经审查，符合中华人民共和国《药品生产质量管理规范》要求。
特发此证。
This is to certify that the above-mentioned manufacturer complies with the requirements of Chinese Good Manufacturing Practices for Pharmaceutical Products.
有效期至 2018 年 01 月 27 日
This certificate remains valid until 27/01/2018
发证机关：
Issued By
Date for Issuing 28/01/2013 2013 年 01 月 28 日
国家食品药品监督管理局制
PRINTED BY STATE FOOD AND DRUG ADMINISTRATION

Medicine Registration Approval 2


辽宁省食品药品监督管理局
药品再注册批件

Medicine Registration Approval 3


辽宁省食品药品监督管理局
药品再注册批件

Medicine Registration Approval 4


辽宁省食品药品监督管理局
药品再注册批件

Medicine Registration Approval 5


辽宁省食品药品监督管理局
药品再注册批件

Medicine Registration Approval 6


辽宁省食品药品监督管理局
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Medicine Registration Approval 7


辽宁省食品药品监督管理局
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Medicine Registration Approval 8


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Medicine Registration Approval 9


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药品再注册批件

1.11 Company Overview and Product Samples

Company Overview

Workshop

Office Building

Workshop

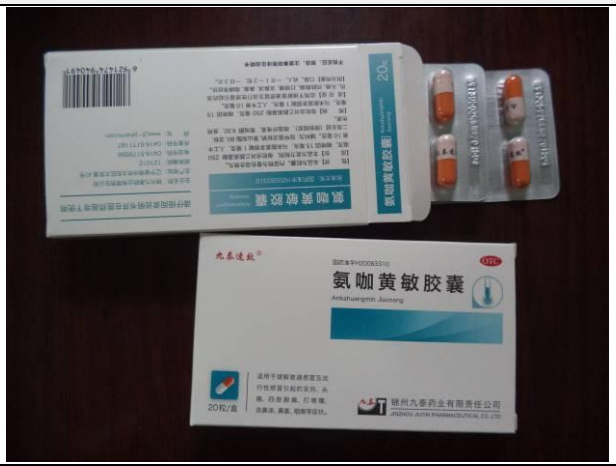
Warehouse

Product Quality Testing Center

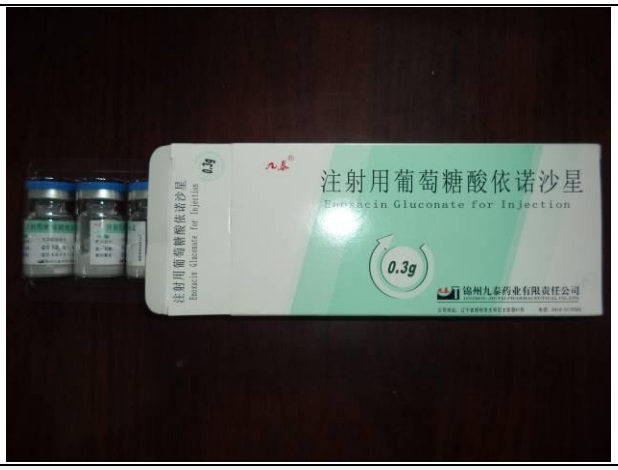
Product Sample

Product Sample

Product Sample



Product Sample



Product Sample

Product Sample

Product Sample

Product Sample

Product Sample

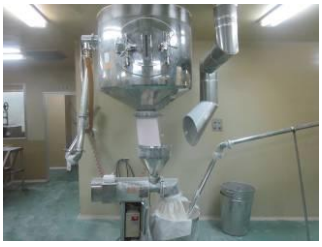
Section 2: Production Management

2.1 QA/QC and Purchasing Management		
	Content	**Observations /Comments**
2.1.1	How many full time inspectors?	37
2.1.2	Is the QA/QC inspectors work independent from the production line?	☒ Yes ☐ No ☐ Comments:
2.1.3	Does the company have written inspection criterion?	☒ IQC ☒ IPQC ☒ FQC ☐ Comments:
2.1.4	Does the company keep written inspection records?	☒ IQC ☒ IPQC ☒ FQC ☐ Comments:
2.1.5	What is the type of finished products inspected?	☐ 100% of products with detailed inspection ☒ Random sampling inspection ☐ No inspection ☐ No inspection necessary
2.1.6	Have calibration of various instruments and equipments been done periodically Records are maintained?	☒ Yes ☐ No ☐ Comments:
2.2 Production Process Management		
	Content	**Observations /Comments**
2.2.1	Can mainly material be traced?	☒ Yes ☐ No ☐ Comments:
2.2.2	Are WI/SOP provided in production line? Are they updated in time?	☒ Yes ☐ No ☐ Comments:
2.2.3	Does the company subcontract any production process?	☐ Yes ☒ No ☐ Comments:
2.2.4	Do machinery maintain periodically?	☒ Yes ☐ No ☐ Comments:
2.3 After Sales Service		
	Content	**Observations /Comments**
2.3.1	Are there any clear procedures for handling customer complaints?	☒ Yes, with clear procedures and written records ☐ Yes, with clear procedures but no written records ☐ Yes, with written records but no clear procedures ☐ No
2.3.2	Does the company have a written procedure for product alert and recall?	☒ Yes ☐ No
2.4 R&D Capacity		

	Content	Observations /Comments
2.4.1	Number of special R&D engineer(s) in the company	10
2.4.2	Does the company have a standard R&D procedure?	☐ Yes, with clear procedure and written instructions ☒ Yes, with procedure but no written instructions ☐ No
2.4.3	Does the company have records of R&D processes?	☐ Yes ☒ No ☐ Comments: (typical process)
2.4.4	Has the R&D product been internally tested and verified?	☒ Yes, with written record ☐ Yes, only partly have written record ☐ Yes, but no written record ☐ No
2.4.5	Were the R&D product inspected by the third party organizations?	☒ Yes, all products were inspected by third party organizations ☐ Yes, only partly ☐ No
2.4.6	Is there a confirmation with client for the R&D product?	☐ Yes, all product were confirmed with client ☐ Yes, meet client requirements, but partly confirmed ☒ No
2.4.7	If any, list all certifications and/or qualifications of the R&D department	N/A
2.4.8	List special equipments for R&D purposes	Gas Chromatograph, Liquid Chromatograph, Drug Melting Point Meter, Electronic Scales

2.5 Production Flow

No	Production Process	No	Production Process	No	Production Process
1		2		3	
	Addition (Bulk Drug)		Refining (Bulk Drug)		Salifying (Bulk Drug)

4	 Separating (Bulk Drug)	5	 Drying (Bulk Drug)	6	 Packaging (Bulk Drug)
7	 Preparing (Lyophilized Powder for Injection)	8	 Mixing (Lyophilized Powder for Injection)	9	 Cleaning (Lyophilized Powder for Injection)
10	 Drying (Lyophilized Powder for Injection)	11	 Freezing (Lyophilized Powder for Injection)	12	 Cap Cleaning (Lyophilized Powder for Injection)
13	 Packaging (Lyophilized Powder for Injection)	14	 Pelletizing (Tablet)	15	 Drying (Tablet)
16	 Whole Grain (Tablet)	17	 Mixing (Tablet)	18	 Tableting (Tablet)

19		20		N/A	N/A
	Mixing (Suppositories)		Filling (Suppositories)		N/A

-- End of Report –