Warmly Welcome to Rainbow Laboratories!

Rainbowlabs

We Care about Healthier Lives

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Rainbowlabs

1. Company Introduction公司概况

Shijiazhuang Rainbowlabs Pharmaceutical Technology Co., Ltd (Rainbowlabs), founded in 2009.

石家庄润柏医药科技有限公司2009年成立；

Rainbowlabs is a high-tech enterprise located on the 9th Floor, Tech Centre, No. 136, Huanghe Boulevard, High-Tech Development Zone, Shijiazhuang, China, occupying an area of 1,400m^2.

位于石家庄高新区科技中心九楼，总面积为：**1400m^2**

1. Company Introduction公司概况

Major Milestones

Company founded and Facility Construction

2009/2010

Obtain ISO9001&UKAS

2011/2017

Inspected by FDA

2013/2016

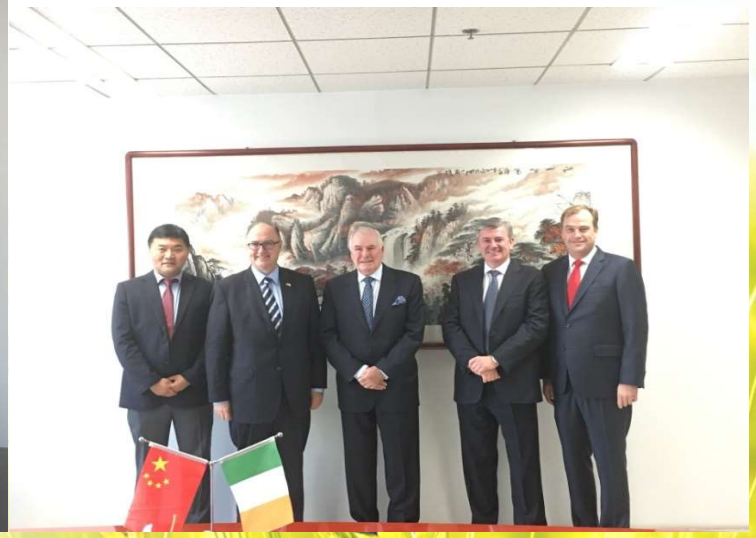
Obtain CNAS certificate

2014/2017

2011 Ireland Ambassador
Visit Rainbowlabs
2011年爱尔兰大使为中欧联合实验室揭牌

1. Company Introduction公司概况

2016 September Ireland Ambassador Visit Rainbowlabs
2016年9月 爱尔兰大使参观润柏实验室



1. Company Introduction公司概况

Rainbowlabs

◆*Main Services主要服务*

1. Contract Testing Services
   委托检测服务
2. Provide International Regulatory Affairs
   国际法规注册服务
3. Formulation Research and Development
   制剂研究及开发

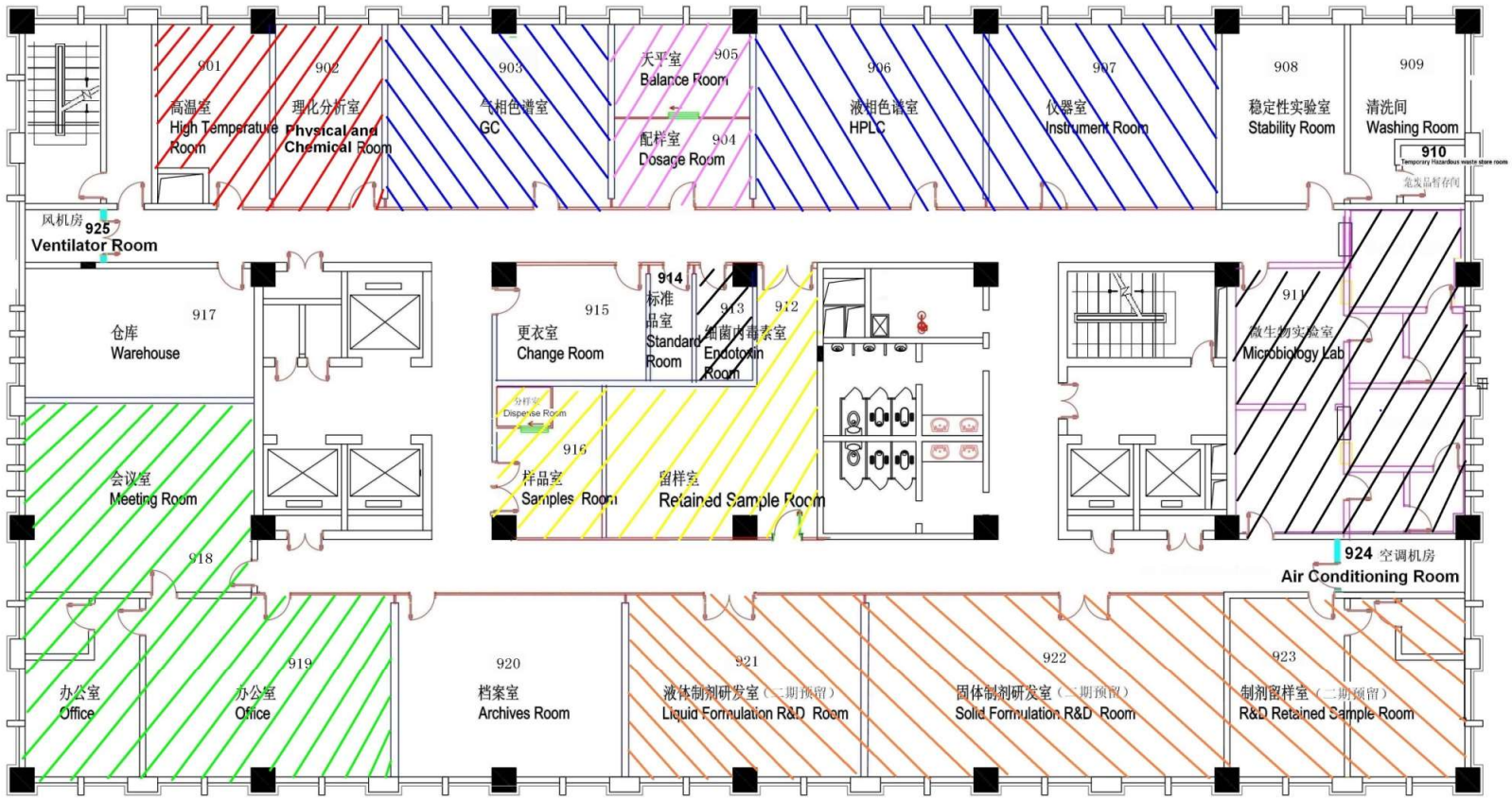
1. Company Introduction公司概况

Shijiazhuang Rainbowlabs Pharmaceutical Technology Co., Ltd
General Manager

- **General Manager Assistant**
- **Corporate Affairs Department**
- **Financial Department**
- **Quality Department**
- **R&D Department**
- **Regulatory Affairs Department**



1. Company Introduction公司概况



润柏实验室布局图

The Layout of Rainbow Labs

2.Contract Testing Services
委托检测服务

2. Contract Testing Services委托检测服务

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Rainbowlabs

2. Contract Testing Services委托检测服务

◆*Instruments*

Rainbowlabs possesses the advanced testing equipment including but not limited to

HPLC (2 Agilent),

GC (1Agilent,1 PE),

IR (Nicolet), Automatic Titrimeter (Mettler),

Karl Fischer Moisture Titrator (Mettler),

UV, AAS, Laser Particle Size Tester, etc.

Total： More than 200 instruments.

Rainbowlabs

2. Contract Testing Services委托检测服务

Testing ability

The list of Rainbowlabs Testing Ability	
Method Development /Validation/ Verification （CP, EP, USP, FCC, Customer method, etc.）	Assay of HPLC analytical methods
	Impurities of HPLC analytical methods
	Residual solvent of GC analytical methods
Physical and Chemical Testing （CP, EP, USP, FCC, Customer method, etc.）	ID, UV, pH, Practical size distribution Heavy metal, Melting point, etc.
Microbiology Testing （CP, EP, USP, FCC, Customer method, etc.）	Bacterial Endotoxin test
	Total bacterial count determination
	Total mold count determination
	Bio-assay

2. Contract Testing Services委托检测服务

2. Contract Testing Services委托检测服务


Titratoin Testing


Endotoxin Testing

Class 10,000 area
微生物限度检查实验室剪影


GC Testing

3. International Regulatory Affairs
国际法规注册服务

Our regulatory strength

- Regulatory Affairs & Quality Platform
- DMF / EDMF filling and submission;
- FDA/EDQM application and cGMP auditing, training
- Contract auditing

FDA inspection Project FDA认证项目

2014/2016 Ningxia Tairui pass FDA inspection.

FDA inspection Project

2012/2015，Inner Monogolia Changsheng passed FDA inspection with 0 483.

4. Qualification and Certificate
公司资质

US FDA inspection(2013)

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
Food and Drug Administration

CENTER FOR VETERINARY MEDICINE

Office of Surveillance and Compliance
Division of Compliance, HFV-230
Post-Market Compliance Team
7519 Standish Place
Rockville, MD 20855

TELEPHONE: (240) 276-9239
FAX: (240) 276-9241

DEC 02 2013

Mr. Oliver Wang
General Manager
Shijiazhuang Rainbowlabs Pharmaceutical Technology Co., Ltd.
9th Floor, Rech Centre No. 136 Huanghe Ave
Gaoxin District, Shifianzhuang, China

FEI: 3010177917

Mr. Oliver Wang:

On July 15, 16, and 17, 2013, Investigator Kham Phommachanh with the U.S. Food and Drug Administration (FDA) conducted an inspection of your contract testing laboratory facility located in 9th Floor, Rech Centre No. 136 Huanghe Ave, Gaoxin District, Shifianzhuang, China. At the conclusion of the inspection, an Establishment Inspection Report (EIR) was written for the inspection. The Division of Compliance in the Center for Veterinary Medicine (CVM) reviewed the EIR as well as your September 6, 3013 response.

Based on the inspection and the EIR and your response, your facility is classified as acceptable. This letter is not intended as an endorsement or certification of the facility. We remind you that it is your responsibility to assure continued compliance to current good manufacturing practices.

Please be advised that all manufacturers must register annually as required by 21 C.F.R. § 207.40. Information on how to register is available at http://www.fda.gov/cder/drls/registration_listing.htm

The Agency is working to make its regulatory process and activities more transparent to the regulated industry. Enclosed is a copy of the Establishment Inspection Report (EIR) for the inspection. It is being provided to you for information purposes only and may reflect some redactions made by FDA in accordance with the Freedom of Information Act and Title 21 of the Code of Federal Regulations, Part 20. Copies provided to other requestors may have additional redactions of trade secret and confidential commercial information. You may request additional information under the Freedom of Information Act.

Please send any questions regarding the enclosed EIR to Kham.Phommachanh@fda.hhs.gov. If you have any questions regarding this letter, you may contact me at the above address or telephone number.

Sincerely,
Marea Harmon
Marea Harmon
Consumer Safety Officer
Division of Compliance
Office of Surveillance & Compliance
Center for Veterinary Medicine

◆*FDA inspection with 0-483（2016 ,June）*

US FDA letter (2016)

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
Food and Drug Administration

CENTER FOR VETERINARY MEDICINE

Office of Surveillance and Compliance
Division of Compliance, HFV-230
Post-Market Compliance Team
7519 Standish Place
Rockville, MD 20855

June 1, 2017

Mr. Kelvin Ma, General Manager
Shijiazhuang Rainbowlabs Pharmaceutical Technology Co., Ltd.
9th Floor, Tech Centre No. 136 Huanghe Ave
Gaoxin District, Shijiazhuang, 050035 China

Reference: Inspection Date(s): 6/27-30/16
Location: Shijiazhuang Rainbowlabs Pharmaceutical Technology Co., Ltd.
No 136 Huanghe Blvd. 9th Floor, Tech Centre, Hi tech Dev. Zone
Shijiazhuang, Hebeisheng, 050035 China
FEI: 3010177917

Dear Mr. Kelvin Ma,

We are enclosing a copy of the establishment inspection report (EIR) for the inspection that the U.S. Food and Drug Administration (FDA) conducted at your premises on the referenced locale and date(s). When the Agency concludes that an inspection is "closed" under 21 CFR 20.64(d)(3), it will release a copy of the EIR to the inspected establishment. This procedure is applicable to EIRs for inspections completed on or after April 1, 1997.

The Agency continually works to make its regulatory process and activities more transparent to the regulated industry. Releasing this EIR to you is part of this effort. The copy being provided to you comprises the narrative portion of the report; it may reflect redactions made by the Agency in accordance with the Freedom of Information Act (FOIA) and 21 CFR Part 20. This, however, does not preclude you from requesting additional information under FOIA.

If there is any question about the released information, feel free to contact me at Marea.Harmon@fda.hhs.gov.

For more information on the U.S. FDA, please visit our website at www.fda.gov.

Sincerely,

Marea K. Harmon -S

Marea Harmon
Consumer Safety Officer

Enclosure: Establishment Inspection Report (EIR)

CNAS

China National Accreditation Service for Conformity Assessment

LABORATORY ACCREDITATION CERTIFICATE

(Registration No. CNAS L7572)

Shijiazhuang Rainbowlabs Pharmaceutical Technology Co., Ltd.

No.136, Huanghe Boulevard, High-Tech Development Zone,

Shijiazhuang, Hebei, China

is accredited in accordance with ISO/IEC 17025: 2005 General Requirements for the Competence of Testing and Calibration Laboratories(CNAS-CL01 Accreditation Criteria for the Competence of Testing and Calibration Laboratories) for the competence to undertake the service described in the schedule attached to this certificate.

The scope of accreditation is detailed in the attached schedule bearing the same registration number as above. The schedule form an integral part of this certificate.

Date of Issue：2015-04-21

Date of Expiry：2018-03-25

Date of Initial Accreditation：2015-03-26

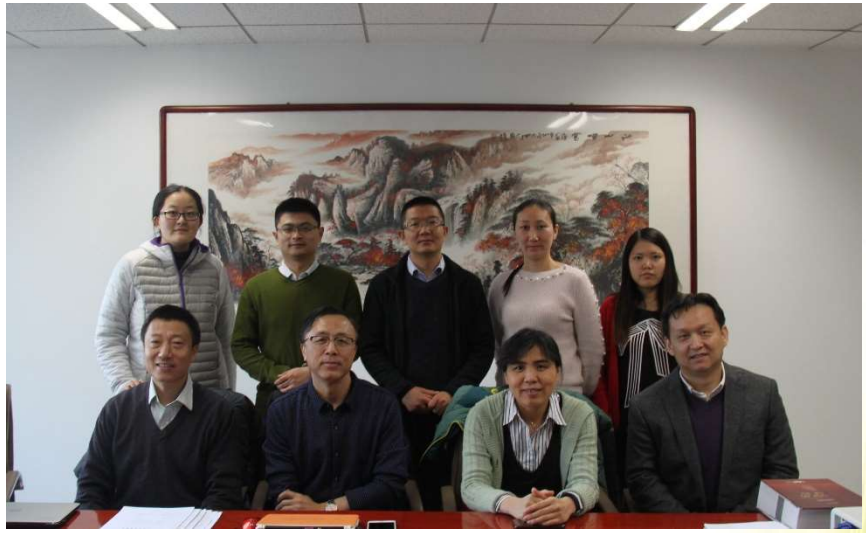
Signed on behalf of China National Accreditation Service for Conformity Assessment

CNAS （China National Accreditation Service for Conformity Assessment) inspected Rainbowlabs according to ISO 17025:2005 in November, 2014.

CNAS L7572

◆*CNAS inspection（2016，March）*

CNAS **re-*inspection*（*2017，Dec.*）**



ISO and Canada Health Department approved

QUALITY MANAGEMENT SYSTEM CERTIFICATE

Certificate No.: 18517Q10693R0S

We hereby certify that the organization:

Shijiazhuang Rainbowlabs Pharmaceutical Technology Co.,Ltd.

Unified social credit code: 91130101688227827W

is in conformity with Quality Management System Standard:

GB/T19001-2016 idt ISO9001:2015

The certificate is valid to the following product(s)/service:

Testing, R&D, technology transfer and technology consulting services for pharmaceuticals and chemicals.

Registration Address/ Audit Address: 9F,Tech Centre, No.136 Huanghe Avenue, Shijiazhuang High-tech Zone, Hebei,P.R.China

Date of Issue: 25-12-2017

Date of Expiry: 25-12-2020

Issued By:

IAF CNAS 中国认可 国际互认 管理体系 MANAGEMENT SYSTEM CNAS C185-M

National Standard Integration (Beijing) Certification Co., Ltd.

NO: IY 0003314

Rainbowlabs obtained the ISO9001 certificate from 2011 .
2011年获得ISO9001认证。

We received the approved letter from Canada Health Department in 2014.
2014年得到加拿大卫生部认可信。

Health Canada

Rainbowlabs

Thank you!