



Welcome **to** Huayi Pharmaceuticals

Huayi Pharmaceutical (Anhui) Co., Ltd.
Professional CDMO for high-quality generics
Based in Hefei, Eastern China



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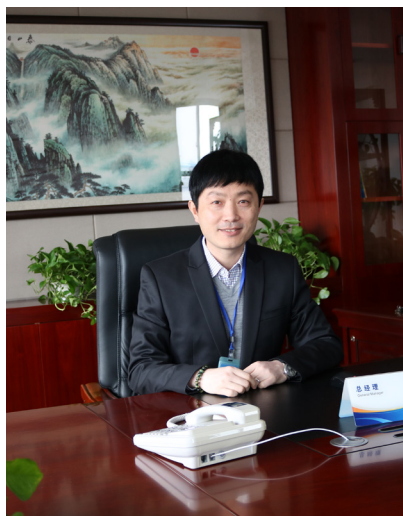
华益药业科技(安徽)有限公司

» Welcome to Hefei, China

合肥 安徽省



Huayi Pharmaceuticals
Introductory Brochure 2019



GAO YU

—
Director of Huayi
Pharmaceuticals

INDUSTRY

—
Contract manufacture
Fine Chemicals

Introduction

Huayi Pharmaceuticals was established in 2006 as a Sino-British joint venture between a UK-based generic company and a Chinese fine chemical supplier. Our goal was to create an independent export-oriented Chinese manufacturer, with the ambition of becoming the leading independent Chinese medicine supplier for customers in the European Union as well as Chinese customers.

Our facilities have passed several re-inspections by the MHRA since we were granted our EU Good Manufacturing Practice (GMP) Certificate in 2010 by the UK Medicines and Healthcare Regulatory Agency (MHRA). We continue to adhere to cGMP standards according to China and EU GMP requirements.

We can take your product through our pharmaceutical development process, with an expert quality management team to ensure your R&D project is completed on time and to the highest possible standards. To date, we are proud to have successfully transferred over 50 different products for our customers and have registered almost 100 strengths of product in the EU. From contract development, we can seamlessly scale-up to commercial manufacture and packaging, with serialisation lines fully implemented.

We will strive to provide quality service and faultless communication with our European customers. Through many years of close partnerships, we are confident that we can work effectively with new customers regardless of differences in our native languages and cultural backgrounds. We take pride in upholding our company values of quality, integrity and service in all of our interactions and projects with our customers.



- Serving a little better everyday.

We want to provide the best service to our customers, ensure continued uninterrupted supply of medicines to patients and manufacture high-quality medicines at a reduced cost.

Our Principles

— Customer-focused service

We aim to provide excellent service to our customers and partners.

— Cost-effective supply

We believe we can offer you significant cost-savings when developing and manufacturing your product in China. This does not mean that we are compromising in any aspect of our manufacturing, but we will negotiate the best possible prices for you, delivering your products to you on time and in full.

— Responsive and communicative

We work to overcome language barriers and cultural differences in our working relationships.



Huayi Pharmaceuticals

Committed to high-quality manufacturing
Dedicated to customer-focused service
Responsible for our patients, partners and employees
Prioritising innovative thinking

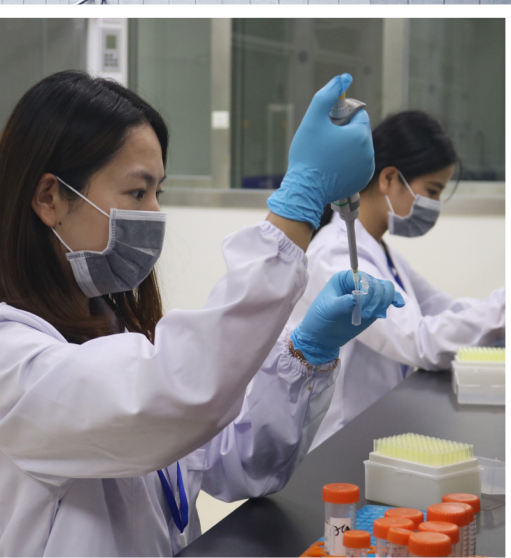


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“专业专注 · 生产高水平仿制药

Dedicated to making high-quality generic medicines



Quality

We are dedicated to maintaining the highest standards of manufacturing and producing high-quality medicines.



Integrity

We hold ourselves to a high standard of accountability.



Service

Our business is about supply and we should deliver our products and services in full, on time, every time



Resourcefulness

We prioritise good decision-making and seek to overcome challenges with new ideas.



**Hello,
Let us introduce
Huayi Pharmaceuticals**

Professional CDMO

Huayi Pharmaceuticals is a contract development and manufacturing organisation (CDMO). Our facilities are based in China, serving customers from all over Europe. We are fully certified to manufacture in China and Europe and are familiar with the EU regulatory process, allowing us to produce dossiers that can be filed in both China and in the EU.

We manufacture solid oral dosage generic medicines in many different forms, including tablets (film-coated, sugar-coated, enteric-coated, effervescent, soluble, chewable, buccal) and capsules filled with powders or pellets. We are confident in our ability to offer you cost-effective solutions whether it comes to contract development or contract manufacturing. While we offer significant cost-savings on your product, we will always ensure that what we manufacture is made in full, sent out on time and is of high-quality.

Our in-house team is made up of technical and regulatory experts, with rich expertise in project management. We

also have access to specialist technical consultants through our innovative R&D department, the Huayi China-Europe Pharmaceutical Research Institute.

Along with R&D and commercial production, we are also excited to offer integrated services that will allow our customers to conduct biological testing of their products in China. Customers will also have access to our clinical trial facilities through our partner Weida Clinical Research. We feel that conducting the necessary bioequivalence studies in China would be very beneficial in terms of registering the product in the country.

Our ambition to become a leading independent Chinese medicine supplier. We are committed to upgrading and developing our facilities to provide better services for our customers. Our high-potency and liquid preparation workshop will be completed in 2020. We are eager to try new technologies, develop new products and manufacture for our customers to the highest quality possible.

One Stop Solution for pharmaceutical development, contract manufacture



Technology Transfer

Over 50 products transferred
Almost 100 strengths registered



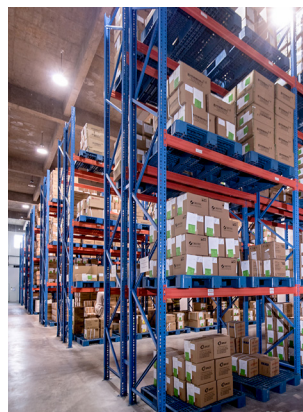
Service Structure

Development - Quality - Manufacture -
Packaging

Let our team at Huayi China-Europe Research Institute develop your next product. We have a complete project management system to ensure your product will be developed on time according to your specifications. Our R&D team have an independent GMP Development Workshop where we prepare our pilot and scale-up batches.

We can seamlessly scale-up your product from small batches to commercial production. Our production capacity currently sits at 3 billion units. In 2018, we manufactured 1.3 billion tablets and 30 million capsules. Our capacity will be increased in the future in order to meet demand. Our packing lines have had serialisation and tamper-evident closures fully implemented.

Our partners Velocityte and Weida Clinical Research provide an integrated service for any bioequivalence studies you might require.





Research

Pharmaceutical Development

1. Preformulation
2. Formulation development
3. Tablets: sublingual, dispersible, effervescent
4. Capsules: hard gel, pellets



Quality

Contract Manufacture

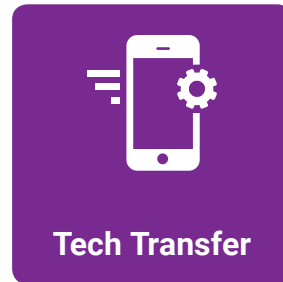
1. Clinical GMP Supply
2. Commercial Manufacture

GMP Development

1. Our GMP workshop is capable of manufacturing batch sizes from 10,000 up to 100,000 tablets for pilot batches, clinical trial batches and process validation batches



GMP



Tech Transfer

Technology Transfer

1. We have over 50 products are commercially manufactured for several European countries including some products developed from scratch by our R&D team.

Integrated Services

We are partnered with Weida Clinical Research (Hefei) Ltd. and Velocity Analytical Technology (Hefei) Co., Ltd. to offer clinical trials and biological testing of samples.



Integrated Services



Weida

Weida

1. Weida Clinical Research is run by an experienced clinical trials team and nurses. We are able to recruit participants from Hefei and our neighbouring provinces easily, due to our central geographic location.

Velocity

1. Bioequivalence studies can be completed in Velocity, which is located in the same facility as the rest of Huayi. This ensures seamless communication between different departments.



Velocity

**Thank you
for reading
about Huayi
Pharmaceuticals.**

**Let's make your
project happen.**



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