Bora Pharmaceuticals

Our Mission

About Bora

Bora Pharmaceuticals is one of the leading pharmaceutical companies in Taiwan. We cover the entire pharmaceutical supply chain from research and development to commercial manufacturing and sales and distribution. We provide contract R&D and manufacturing services as well as pharmaceutical product in-licensing for Taiwan domestic and global pharmaceutical companies around the world.

Our TFDA, USFDA, MHRA, and PIC/S certified facilities, currently provide CDMO services to over 18 countries worldwide.

Bora Pharmaceuticals has an extremely solid financial foundation and experienced management team, with over 20+ years working in the pharmaceutical industry.

Mission Statement

Our mission is to become one of the best pharmaceutical companies and contract service partners in Asia, by pushing the boundaries of research and innovation, while maintaining exceptional quality standards.

Focused on International Markets

Business Philosophy

People around the world are entitled to the best medical care sciences can offer.Bora Pharmaceuticals is a leading partner in the pharmaceutical industry, committed not only to supporting the latest advancements across the sector, but also pioneering the next generation of growth for pharmaceutical companies in Asia-Pacific.

Our Promise

Bora Pharmaceuticals is dedicated to providing the highest quality pharmaceuticals and maintaining the highest ethical standards.

We recognize our responsibility within the supply chain and have a patient-focused outlook. Our core company value is to improve the lives of the end-user and we take great pride in doing so.

Poinciana tree of Bora Tainan plant

Our Values

Bora Pharmaceuticals is driven by three values - Innovation, Quality, and Leadership.

Quality

Bora has been dedicated to maintaining world-class quality standards since its formation. Advanced quality systems, including QMS, EDMS, and ERP, are effectively utilized to ensure the highest manufacturing quality.

Innovation

Bora's R&D team is focused on innovating and developing products with minimal risk and maximum market potential. We have numerous technologies and concepts in the R&D phase.

Working with the leading academic research center has given Bora multiple technology platforms to create one of the most diverse product pipelines. We not only use these technologies to develop our own products, we also share our in-depth knowledge and findings with our partners to develop best in class products with global licensing potential.

Leadership

Our management team are focused on strengthening our leadership position in the market.
These principles are the foundation of everything we do and the core values we believe.

Milestones

Bora Pharmaceuticals has a long history of innovation and continues to be dedicated to becoming a leading, next generation pharmaceutical company in Asia.

2019
- Extended secondary five-year supply agreement with Eisai
- Exclusive in-licensing 18 CHC & OTC Boiron products
- Successfully hosted Bora's first USFDA inspection with no observations
- CommonWealth Magazine〈Fast 100〉
- HR Asia〈Best Companies to Work for in Asia 2019 Awards (Taiwan Edition)〉

2018
- Acquired Impax Laboratories Inc. Taiwan Subsidiary
- Received PIC/S GDP Certification
- BSAT-1301 Taiwan patent approved

2017
- Completed initial public offering at Taipei Exchage (GreTai Securities Market)
- Invested in Yutai Health to license CHC and OTC products of Eisai and SSP pharmaceutical in Taiwan
- Received approval from TFDA for BSAD1301

2016
- Awarded "Fast 500 Award" for top 500 fastest growing companies in Asia Pacific

2015
- Awarded " Top ten potential enterprise golden trophy" by outstanding enterprise manager association

2014
- Established official Research and Development Laboratory
- BSAT1301 is awarded government SBIR incentive
- Acquired Union Chemicals Co., Ltd.

2013
- Acquired PICS/GMP Tainan manufacturing site from Japanese Pharmaceutical, Eisai

2012
- Officially began the development of BSAT1301, new dosage form drug
- Started Licensing "Lendormin" for Boehringer Ingelheim

2011
- Immuboost launched in Taiwan market
- Received approval from TFDA for Brexa (Olanzapine)

2009
- Began development of generic drugs and CHC products Brexa, Pitavol, Denset and Immuboost

2007
- Bora Pharmaceuticals is established

No scale too large or challenge too big, we'll simplify your modified release and large-scale solvent manufacturing projects.

A CDMO with complex capabilities at its core.
FDA and MHRA approved, we can help you to save time and eliminate risk.

cGMP commercial manufacturing

Experts in oral solid dosage forms including tablets, granules, powders and capsules, Bora has the capability and flexibility to take on demanding projects which require tailored processes. We offer contract services ranging from development to large-scale manufacturing, tech transfer and stability studies. Providing specialist support through every stage of your drug life cycle from clinical trial to commercial supply.

World-class testing laboratories

With a quarter of our workforce devoted to quality assurance (QA) or and quality control (QC), our laboratories only contain world-class instrumentsation and equipment but also operate to the highest quality standards. Our experienced team excels in analytical method validation, transfer against regulatory compendium for drug substance, drug product services (including IPC, final blending, and final goods), and compendium raw material characterization, analysis and stability programs.

Packaging and serialization

Bora's packaging lines cater for bottle, blister, pillow blister and sachet packaging of oral solid dose products and are equipped with Optel TrackSafe's Level 4 serialization and aggregation systems. We are well-versed in supplying compliant bottles, cases, and pallets to our portfolio of global customers.

We embrace your complex modified release and solvent processing challenges with expertise and diligence.

With Bora as your global CDMO partner, you receive:

1. Exceptional quality products
2. Customer-oriented service
3. Robust product knowledge and skilled scientists
4. Reassurance that we will meet your timelines
5. World-class large-scale manufacturing
6. Capabilities for a variety of oral solid dosage forms
7. Proficient packaging services
8. DSCSA compliance
9. Serialization

Your Global CDMO

Services:

- Pharmaceutical development (formulation, process, and analytical)
- Analytical and microbiological testing
- Commercial manufacturing
- Bottle, blister and sachet packaging
- DSCSA compliance

Oral solid dosage services for:

- Tablets: sugar coated and film-coated tablets
- Capsules: single and multi-component capsules
- Granules
- Powders

Specialist drug delivery technology including:

- Immediate release
- Controlled release (sustained, pulsed, modified and delayed)

Quality Units

Advanced quality systems including QMS, EDMS, and ERP

Analytical Development
Method Development,
Transfer, Verification
and Validation

Quality Control Lab
Chemistry
Microbiology
Ongoing Stability Testing
Ongoing Stability Testing

Quality System
Change Control,
Investigation,
Documentation,
Annual Product
Review, GMP Training,
Quality Agreement

Quality Assurance
Manufacturing QA
Product Disposition
Investigation
Change Control

Compliance & Audit
Internal/External Audit
Commitment Tracking Compliant
Management, Quality Council, Supplier
Quality Management

How We Help

1 **PROJECT EVALUATION**

2 **PROPOSAL & AGREEMENT**

3 **TECHNOLOGY TRANSFER**

4 **PIVOTAL BATCH MANUFACTURING**

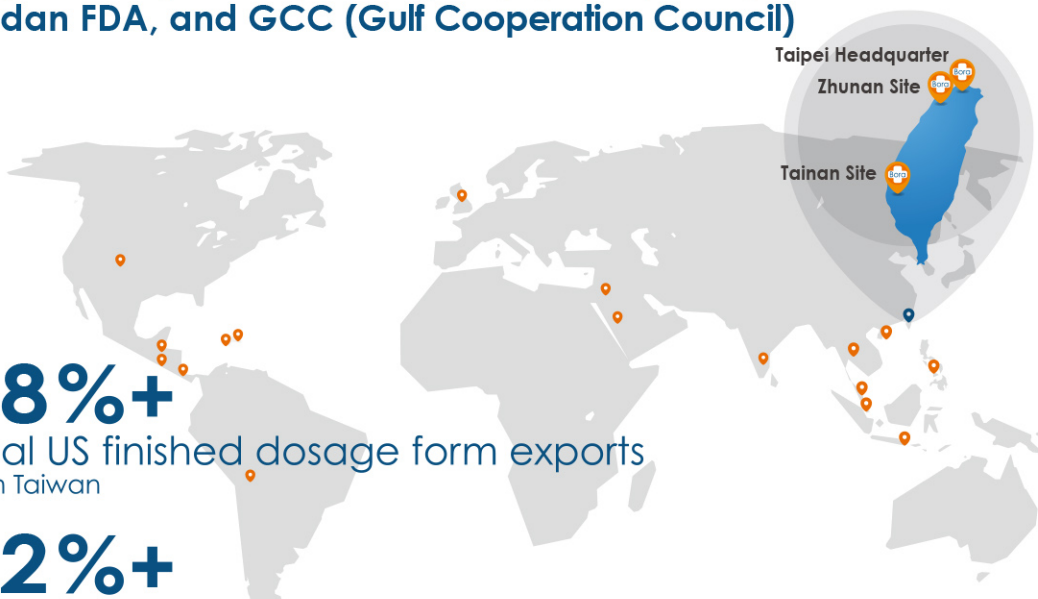
5 **SCALE-UP & PROCESS MANUFACTURING**

6 **COMMERCIAL MANUFACTURING**

Global Reach

Export to Over 17 Countries Worldwide

Approved by USFDA, MHRA, PIC/S, GMP, TFDA, Jordan FDA, and GCC (Gulf Cooperation Council)



48%+
total US finished dosage form exports
from Taiwan

12%+
worldwide finished dosage form exports
from Taiwan

Source: Taiwan Customs Administration, Ministry of Finance (2018 Jan. ~ Sep.)

Facilities

- 36,133 m² (316,000 ft²)
- USFDA, MHRA, and the TFDA-approved
- 2 billion units of solid-dosage form (IR and ER)
- Bottle packaging
- Serialization

- 24,000 m² (258,000 ft²)
- PIC/S certified and TFDA-approved
- 700 million units of solid-dosage form including tablet, capsule, granule, and sugar coated tablet
- Packaging lines: Blisters, granules sachets, tablet/capsule bottle

Bora Pharmaceuticals

Manufacturing Process

	Bora Zhunan 保瑞竹南廠	Bora Tainan 保瑞官田廠	
High Shear Granulation	Super Mixer Comil Integrated Extruder/Spheronizer	Super Mixer HATA Cylindrical Granulator	
Drying	Circulation Tray Dryer Gruenberg Oven Fluid Bed Dryer	Freund Fluid Bed Dryer	
Milling & Blending	Fitzmill x3 sets Slant Cone Blender Column Blender	Tumbling Mixer	
Tablet Compress	Fette Jcmco Rotary Tablet Press	Fette HATA Rotary Tablet Press Jcmco Rotary Tablet Press	
Coating	Film Coating: Super Coater Solvent Coating: Glatt Wurster Coating	Sugar & Film coating: Freund Hi-Coater	
Low Shear Granulation	Ross Mixer Hobar Mixer		
Capsule Encapsulation	MG2 MFG2 x2 sets IMA x2 sets Machine IMA Precisa/Anritzu	Chin Yi	
Fluid Bed Granulation	Glatt GPCG Plus YenChen		
Packaging	Bottle Packaging Serialization	Bottle Packaging Sachet Packaging Blister Packaging Face-to-face Pillow-shape blister packaging	

Analytical Testing

Lab Technical Service

Assay/Impurities

HPLC/UV/RI/FLD, GC-FID/COD, UPLC/MS, CE

Dissolution Behavior

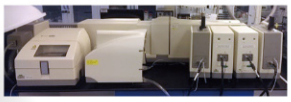
Dissolution System

Environmental Monitoring

TOC, Conductivity, Microbial

Basic Physical / Chemical property

DLS, Density, KF, FTIR, Disintegrator, Hardness, Friability Tester, TGA



Microbial

Microbial Limit Testing, Purified Water Testing

Lab Control Center
Computer System Validation

Research & Development

Formulation Development

Our formulation development team provides formulation development and ssolutions from an early stage of new chemical entities (NCE) to generic products. Our formulation design starts from early feasibility through development, and formulation screen all the way to clinical trials and technical transfer to commercial batch manufacturing.

Process Development

Our expertise in technology transfer and scale up ensures we can provide small-scale proof of concept prototype batches, manufacture clinical trial materials; perform scale up manufacturing and registration batch manufacturing as well as perform product transfer and validation services in preparation for commercial manufacturing.

Analytical Development

Bora provides customized analytical solutions for small molecules. Depending on product development phases, and global relevant regulatory guidance (ICH, FDA, USP, EP, JP etc.), Bora designs customized analytical solutions utilizing state of the art equipment, following GMP standards. Bora is also equipped with Empower 3 software to ensure data integrity.

bora

Explore Develop Optimize

Bora
Pharmaceuticals

bora
保瑞藥業

股票代號：6472
USFDA、MHRA、PIC/S Certified

BORA

CDMO-borapharma

http://www.bora-corp.com
https://cdmo.bora-corp.com

Zhunan Plant
USFDA, MHRA and TFDA - approved
Sales to Taiwan, US, UK, and EU countries

Tainan Plant
TFDA, Jordan FDA, and GCC
(Gulf Cooperation Council) - approved
Sales to Asia, Middle East, and Americas

Bora Taipei Headquarter
E-mail : info@bora-corp.com
Tel : +886-2-27901555 Fax : +886-2-27906595
Add : 6F., No.69, Xing'ai Rd., Neihu Dist.,
Taipei City 114, Taiwan