Highest Standards of Assurance in Compliance with Pharmaceutical GMP

We have worked with European pharmaceutical companies since our foundation. In 1996, we began contract manufacturing of monograph drugs, generic drugs and quasi-drugs in our GMP facility. With quality, cost and speed in mind, we are dedicated to delivering stable supplies of high-quality products through our long-standing experience in production technology. From liquids, ointments, granules, and powders to other forms of products, our systematic production system is capable of full integration of manufacturing with dispensing, inspection, packaging, testing, storage and delivery for all kinds of needs, from small-scale manufacturing of multiple products to mass manufacturing.

FRAMEWORK OF OUR PHARMACEUTICAL BUSINESS

- **Factory I**: Topical disinfectants, ointments, powder dispensing
- **Factory II**: Granules
- **Factory III**: Packaging [primary and secondary packaging, specialty packaging for high pharmacological activity drugs]
  - Tablets (sorting, filling and packaging)
  - Secondary packaging for injectables (vials, ampules, syringes)
  - Infusions (in bags), injectives (PTP and strip packaging), secondary packaging for anesthetics (in glass containers)
  - Specialty packaging for drug samples (1- to 6-tablet PTP cards and booklets)

- **Packaging Equipment**
  - PTP blister line, laser carton printer/inspector (G6S1-128 compatible)
  - Table cartoner, image processor for printing and GS1-128 testing, X-ray detector for foreign materials
  - Vial labeling system (15 to 100 mm in diameter, 35 to 150 mm in height)
  - Vial cap labeling system
  - Card and booklet packaging system (with laser printer and image inspector)

- **Pharmaceutical Storage**
  - 2600-pallet storage (room temperature), cold storage (2 to 8°C), ICH stability study storage

- **Testing and Analysis**
  - Physicochemical testing, stability testing, sterility (isolator) testing, other studies
**MANUFACTURING**

**PACKAGING**

- **Inspection and Packaging (Primary Packaging)**
  Tablets and capsules are blister-packed in a humidity- and temperature-controlled facility (alu-alu available) from loading (capable of both even and odd numbers) to pillow packing.

- **Inspection and Packaging (Secondary Packaging)**
  Tablets, fine granules, granules, injectables and infusions are inspected and packed in secondary packages while going through inspection image processors and X-ray foreign object detectors.

- **Visual Inspection Line**

- **Specialty Processing Room for High Pharmacological Activity Products**

**INTEGRATED MANUFACTURING**

- **Topical Antiseptics**
  From ethanol-based rubs to surfactant-, biguanide- and detergent-based antiseptics, we are offering manufacturing, dispensing, packaging and distribution services for various types of disinfectants that are marketed as drugs or quasi-drugs.

- **Medical Ointments**
  A vacuum emulsifier is used for the manufacture of pharmacopoeia-grade and other types of topicals in vegetable oil base, mineral oil base, aqueous base and O/W and W/O emulsions. Manufacturing, filling, packaging and shipping are all integrated.

- **Powders and Granules**
  We offer dispensing, packaging and shipping of pharmacopoeia-listed powders and granules. Various shapes and sizes of containers are available. We also offer manufacturing of pharmacopoeia-listed products using a double cone mixer.
Key Systems
- Isolator
- Infrared spectrophotometer
- Liquid chromatography
- Gas chromatography
- Potentiometric titrator
- UV spectrophotometer
- Dissolution tester
- Sterility tester

Storage
We offer complete storage solutions for raw materials, intermediates and final products. Cold storages for 2°C to 8°C and dedicated storages for ICH stability studies are among our key facilities. These facilities are equipped with a backup power system to ensure quality even during an electric outage.

Distribution
We are ideally positioned just a 30-minute drive away from Kansai Airport and 5 minutes away from a highway, promising speedy delivery of contract manufactured products. Our pharmaceutical manufacturing facilities are integrated with a distribution system that allows a smooth transition from testing and packaging to distribution of not only domestically manufactured products but also imported products, which are in increasing demand in this age of pharmaceutical globalization.

WE ARE FULLY LICENSED TO DELIVER A WIDE RANGE OF PRODUCTS SAFELY AND SECURELY.

Our national and prefectural registration/certification for safe and reliable delivery:

1. Registered pharmaceutical manufacturer
2. Registered exempt narcotic manufacturer
3. Registered psychotropic preparations manufacturer
4. Registered stimulants raw materials handler
5. Marketing license for quasi-drugs
6. License for Repairs of Medical Devices
7. Registered general dangerous goods handler
8. Certified hazardous materials storage underground alcohol storage
9. Veterinary pharmaceutical manufacturing and marketing license
10. Quasi-drug manufacturing and marketing license
11. Registered medical device manufacturer
12. License for Leasing Operation for Specially-Controlled Medical Devices

OUR SPECIALTY SAMPLING ROOM FOR SAFE HANDLING OF HIGH ACTIVITY DRUGS.

To ensure safety, our facility is equipped with a specialty sampling room to handle even the most sensitive products.