



PRE-FORMULATION
& FORMULATION
ACTIVITIES



PHARMACEUTICAL
DEVELOPMENT



ANALYTICAL
SERVICES



CLINICAL TRIALS
MATERIAL



*(see reverse for
more details)*



The Development Experts.

At Halo Pharmaceutical, we offer an array of fully integrated cutting-edge Pharmaceutical Development capabilities. From either of our two locations, we can bring your products through Development to the market quickly and effectively.

- ▶ Specializing in fulfilling all aspects of the CMC dosage form section of the NDA, our laboratories, pilot facilities, and highly skilled technicians can assist at every stage of the development process. We can take your product through excipient interactions, pre-formulation and formulation activities, to the manufacture of clinical trial materials. Our analytical services provide the method development and validation support you need for your Registration Package.

We pride ourselves on having large company capabilities combined with small company agility. We also take pride in our excellent FDA inspection record.
- ▶ When it comes to Development, there's a lot of flexibility in what we can do. We handle DEA controlled drugs, Schedule I-V, as well as non-controlled drugs. We manufacture both sterile and non-sterile ointments, gels and creams, in addition to suppositories, liquids and a wide range of solid oral dosage forms. Our specialized capabilities include, highly potent compounds, controlled and immediate release formulations, pellets and micro-dose tablets. Our advanced equipment - like our Glatt Fluid Bed Coaters, instrumented tablet presses, Gerteis roller compactor and our state-of-the art Bosch encapsulator - allow us to handle a wide variety of Pharmaceutical Development projects.

PHARMACEUTICAL DEVELOPMENT SERVICES:

▶ **PROJECT MANAGEMENT**

Experienced Project Managers serve as the primary point of contact for the client. The Project Manager appointed to your project will interface with the client and each of Halo sub-teams, overseeing the activities and the progress of your project.

▶ **FORMULATION DEVELOPMENT**

Working together with the client, our formulation scientists will design and execute all Excipient Interaction, Pre-formulation, and Formulation Studies in a timely manner. They work to accelerate the process of bringing your project to Registration by efficiently and successfully identifying a lead formulation.

▶ **SCALE UP AND TECHNICAL TRANSFER**

We provide Scale Up, Tech Transfer, and Validation services in preparation for Commercial Manufacturing - with equipment suitable for 0.3Kg-130Kg in Development, and a full range of complementary solid dose Commercial scale equipment. Our Development scientists will work closely with you to generate a robust and optimal process.

▶ **ANALYTICAL DEVELOPMENT**

Experienced in analytical method development and validation for all phases of product development and commercial manufacture, our expert chemists ensure customers receive robust, transferable, stability-indicating methods that are tailored to their phase of development and comply with ICH guidelines. Services include method optimization... cleaning verification method development/ validation... residual solvent method development/ validation...ICH stability testing...storage of drug substances and finished products.

SAMPLE OF CURRENTLY AVAILABLE DEVELOPMENT EQUIPMENT FOR TABLET DOSAGE FORMS:

BATCH SIZE (KG)	HS GRANULATOR	DRYING	ROLLER COMPACTOR	MILLING	BLENDED	COMPRESSION
.3 - 3	Lodige MGT 1, 5L Bowls (Vertical)	Midi Glatt	Gerteis Mini-Pactor	Quadro Comil, Fitzmill	Globe 4, 8, 16qt. Bin or "V"	Korsch XL100 Pro
5-15	Fluid Air PharmX 25L (Vertical)	Glatt GPCG15 27L Bowl	Gerteis Mini-Pactor	Quadro Comil, Fitzmill	Globe 16qt., 1, 2 ft3 Bin or "V"	Korsch XL100 Pro
18-30	Lodige MGT 70L (Vertical)	Glatt GPCG15 68L Bowl	Gerteis Mini-Pactor	Quadro Comil, Fitzmill	Globe 2, 3, 5 ft3 Bin or "V"	Korsch XL100 Pro
30-55	Lodige MGT 125L (Vertical)	Despatch Tray Dryer	Gerteis Mini-Pactor	Quadro Comil, Fitzmill, Frewitt	Globe 3, 5 ft3 Bin or "V"	Korsch XL100 Pro
80-140	Lodige FKM 300L (Horizontal)	Despatch Tray Dryer	Gerteis Mini-Pactor	Quadro Comil, Fitzmill, Frewitt	Globe 10 ft3 Bin or "V"	Korsch XL100 Pro, Fette 2090IC

NOTE: We are continually updating our equipment and capacity capabilities. Equipment for additional dosage forms available upon request.

- Solid Oral Dose
- Highly Potent Compounds
- DEA Schedule I-V Drugs
- Sterile Ointments, Gels and Creams
- Non-Sterile Ointments, Liquids and Creams
- Suppositories

LOCATIONS

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