

Developing with expertise

Cambrex is dedicated to offering the broadest of small molecule development capabilities to effectively advance your products to market.

Specializing in executing all aspects of the CMC dosage form section of the NDA, our laboratories, pilot facilities, and experts are with you at every stage of the development process. We can take your product through excipient iterations, pre-formulation and formulation activities, through to the manufacture of clinical trial materials and registration batches.

Our analytical services provide the method development and validation support you need for your registration package – flexibly, efficiently and with an excellent FDA, EMEA and Health Canada inspection record.

Agile at every stage

- **Handling DEA controlled drugs, Schedule I to IV, in addition to non-controlled drugs**
- **Manufacturing sterile and non-sterile ointments, gels and creams, in addition to suppositories, liquids and a wide range of solid oral dosage forms**
- **Specializing in extended and immediate release formulations, pellets and micro-dose tablets**
- **Offering variety with advanced equipment – such as fluid bed Wurster coaters, instrumented tablet presses, Gerteis roller compactor and a state-of-the-art Bosch encapsulator**

Project management

Experienced Project Managers serve as the primary point of contact. They will interface with you and each of the sub-teams, overseeing activities and the progress of your project.

Formulation development

Our formulation scientists will work with you to design and execute all excipient interaction, pre-formulation and formulation studies to their timescales. We look to accelerate the process of bringing projects to registration by efficiently and successfully identifying a lead formulation.

Mitesh Avlani
Operator,
Product Development



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 to 150kg in development, and a full range of complementary solid dose, semi-solid and liquid commercial scale equipment. Our development experts will work closely with you to generate a robust and optimal process.

The table below is just a sample of the drug product equipment and capacity we have available:

- Solid oral dose
- DEA Schedule I to IV drugs
- Sterile ointments, gels & creams
- Non-sterile ointments, liquids & creams
- Suppositories

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 tailored to your phase of development, complying with ICH guidelines.

Services include:

- Chemistry method development, optimization & validation
- Microbiology testing, USP qualification
- Cleaning verification method development/validation
- Residual solvent method development/validation
- Elemental impurities testing
- ICH stability testing & storage
- Warehousing of drug substances & finished products

Development equipment for tablet dosage forms

| Batch size (kg) | HS Granulator | Drying | Roller compactor | Milling | Blending | Compression |
|-----------------|-----------------------------------|---------------------------|----------------------|---------------------------------|--|---------------------------------|
| 0.3-3 | Lodige MGT 1, 5L Bowls (Vertical) | Mid Glatt | Gerteis Mini-Pactor | Quadro Comil, Fitzmill | Globe 4, 8, 16qt Bin or "V" | Korsch XL 100 Pro |
| 0.5-3 | Roto J 10L | Huttlin FBSTREA 1 FB | Gerteis Macro-Pactor | Quadro Comil, Fitzmill | 4, 8, 16qt V-shells 0.2, 0.6, 0.9ft ³ tote Bins | Korsch XL 100 |
| 3-15 | Roto J 10L Roto E 100L | Huttlin FBSTREA 1 FB | Gerteis Macro-Pactor | Quadro Comil, Fitzmill | 8, 16qt V-shells 0.6, 0.9 and 3ft ³ tote Bins | Korsch XL 100 |
| 5-15 | Fluid Air PharmX 25L (Vertical) | Glatt GPCG15 27L Bowl | Gerteis Mini-Pactor | Quadro Comil Fitzmill | Globe 16qt 1, 3ft ³ | Korsch XL 100 Pro |
| 15-30 | Roto E 100L | Vector Fluid bed FL-3N-60 | Gerteis Macro-Pactor | Quadro Comil Fitzmil | Bin or "V" 7.5, 12 and 14ft ³ tote Bins | Korsch XL 200 |
| 18-30 | Lodige MGT 70L (Vertical) | Glatt GPCG15 68L Bowl | Gerteis Mini-Pactor | Quadro Comil Fitzmil | 3 and 7.5ft ³ tote Bins | Korsch XL 100 Pro |
| 30-55 | Roto E 100L | Vector Fluid bed FL-3N-60 | Gerteis Macro-Pactor | Quadro Comil Fitzmil | Globe 2, 3, 5ft ³ Bin or "V" | Korsch XL 200 |
| 30-55 | Lodige MGT 125L (Vertical) | Despatch Tray Dryer | Gerteis Mini-Pactor | Quadro Comil, Fitzmill, Frewitt | Globe 3, 5ft ³ Bin or "V" | Korsch XL 100 Pro |
| 55-80 | Roto E 100L Kevin 600L | Vector Fluid bed FL-3N-60 | Gerteis Macro-Pactor | Quadro Comil Fitzmil | 3 and 7.5ft ³ tote Bins | Korsch XL 200 |
| 80-140 | Lodige FKM 300L (Horizontal) | Despatch Tray Dryer | Gerteis Mini-Pactor | Quadro Comil, Fitzmill, Frewitt | Globe 10ft ³ Bin or "V" | Korsch XL 100 Pro, Fette 2090IC |
| 80-140 | Kevin 600L | Vector Fluid bed FL3N-120 | Gerteis Macro-Pactor | Quadro Comil Fitzmil | 7.5, 12, 14 and 24ft ³ tote Bins | Korsch XL 400 |