



## Pharmaceutical Sciences

### FACTSHEET



### Aseptic Manufacturing – UK

#### Sterile Manufacture of Clinical Supplies

At our GMP Sterile Manufacturing facility in Glasgow, we specialize in parenteral drug formulation development and manufacture. Our clean room suites have integrated lyophilizers as well as dedicated facilities for manufacture of non-cytotoxic and cytotoxic drug products. Our experienced teams can fill small molecule drugs and biologicals into vials, syringes, or dropper bottles.

#### Formulation Development

Using our expertise in pharmaceutical development, Aptuit's formulation and manufacturing services are optimized to facilitate and accelerate your drug development program. We can develop liquid or lyophilized formulations of biological or small molecule drugs including proteins, peptides and cytotoxics.

- Liquid formulations
- Lyophilized formulations
- Cytotoxic formulations
- Liposomes, emulsions and hydrogels
- Supporting analytical services – solubility and stability studies, including photostability

#### Clinical Supplies Manufacture

Aptuit's manufacturing facilities are MHRA approved and operate to cGMP standards. Our clean room suites have a manufacturing capacity of up to 3,000 units per batch. Small molecule drugs and biologicals can be filled into vials, syringes, or dropper bottles to support phase I and II clinical trials.

#### Supporting Service Offerings

To support your development program, Aptuit offers analytical services on-site in Glasgow. Our staff can provide preformulation services, analytical development and testing, consultancy services, and QA support:

- Analytical method development
- API synthesis
- Pre-formulation
- Lyophilization cycle development

- Stability studies per ICH guidelines
- Clinical packaging and labeling
- Release testing of clinical materials
- QP batch release
- Clinical supplies storage and distribution
- Formulation development strategy and consultancy
- Regulatory strategy consultancy

#### Global, Integrated Approach

With facilities worldwide, including Aptuit Laurus in India, Aptuit provides development services to clients on a truly global scale. Our services span the drug development continuum from discovery through commercialization, we provide clients the option to choose an integrated suite of services or individual modules to complement existing resources. With centralized project management to manage your program from inception through clinical development, we are able to integrate services and manage activities between sites. Such integration is critical to reducing time to clinic and then to market.

#### Additional Aptuit Capabilities

Aptuit offers a comprehensive suite of drug development services that range from candidate selection through to market, including consultancy services, API development and manufacture, preclinical and clinical technologies, pharmaceutical services, large and small scale manufacturing, IVRS, and clinical packaging and logistics, across a wide range of compounds, dosage forms and delivery systems.

For information about Aptuit's services, please call or email:

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**Engineering a better drug development process.**