

## Commercial Scale API Manufacturing SAFC Pharma™ – Arklow

SAFC Pharma-Arklow, Ireland is the company's primary center for cGMP production of commercial and late-stage APIs and advanced intermediates. The 64,000 m<sup>3</sup> complex supports customers with expertise in new process evaluation, process development validation and technology transfer. The site is also equipped with one of the few large-scale simulated moving bed (SMB) chromatography units for chiral separation.



### Manufacturing

Fully validated cGMP site for commercial-scale API manufacturing, SAFC Pharma's Arklow facility features four separate plants, and has a total reactor capacity of over 90,000 L.

- cGMP, FDA and IMB inspected
- 14 glass-lined reactors (250-8,000 L)
- 6 stainless steel reactors (4,000-8,000 L)
- 3 centrifuges (1 stainless steel, 2 Hastelloy®)
- 8 stainless steel high vacuum distillation units (200-6,000 L), stainless steel filter dryer
- Hastelloy® filter dryer, stainless steel fluidized bed dryer, glass tumbler dryer (4,000 L)
- Vacuum tray drying oven (200 kg)
- Controlled environment sieving, delumping and packaging

### Core Technologies

- Alkylation
- Esterification
- Ester Condensation
- Reduction
- Suzuki Coupling

### Core Competencies

- Large-scale SMB chromatography capabilities
- High vacuum fractional distillation
- Salt formation - crystallization
- Powder handling - milling and sieving
- Grignard chemistry

## Commercial Scale API Manufacturing

### SAFC Pharma™ – Arklow



#### SMB Chromatography

Quick, cost efficient continuous purification and separation of intermediates and APIs, SAFC Pharma-Arklow is one of a few sites in the world able to provide large-scale SMB purification:

- Licosept 6-450 SMB unit
- Purity specification to customer demand (up to 99.9%)
- Scalable – from grams to tons



#### Analytical Services

With well-equipped and experienced analytical support from raw material QC and release to method development and validation. SAFC Pharma's analytical teams provide a comprehensive range of services for cGMP operations.

The latest in analytical testing, including:

- LCMS
- GC
- NMR
- DSC
- Particle Size Analysis
- HPLC
- FTIR
- UV
- IR
- Wet Chemistry



#### Quality Management

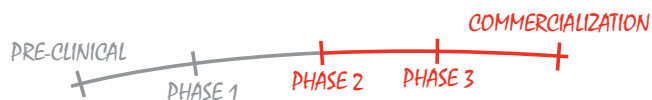
Experienced regulatory teams oversee all FDA and IMB related activities and are responsible for quality control, quality assurance and regulatory affairs. The site's history includes successful Drug Master File submissions in numerous countries.

- Skilled quality/regulatory group with track record of successful submissions
- Site capability for all aspects of QC/QA and regulatory affairs
- FDA and IMB inspected and approved-work to ICH Q7A, FDA 21 CFR Parts 11, 210 & 211 standards
- Testing to USP, EP, BP and customer requirements-pharmacopoeial certification
- DMF/COS/CTD preparation and maintenance
- Process validation
- Six Sigma quality system philosophy

#### Product List

SAFC Arklow has the expertise to manufacture custom and generic APIs, to the highest level of quality:

- Amitriptyline hydrochloride USP/BP/EP
- Acepromazine maleate USP/BP Vet
- Brompheniramine maleate USP29/BP/EP
- Butoconazole nitrate USP
- Clomipramine hydrochloride USP/BP/EP
- 4-Chloro-N-methyl-piperidine
- 8-Chlorotheophylline
- Diethylcarbamazine citrate USP/BP/EP
- Doxylamine succinate USP/BP/EP
- Imipramine hydrochloride USP/BP/EP
- Nortriptyline hydrochloride USP/BP/EP
- Orphenadrine citrate USP/BP/EP
- Orphenadrine hydrochloride BP/EP
- Promethazine hydrochloride USP/BP/EP
- Lofepiramine hydrochloride BP/EP



SAFC Pharma-Arklow specializes in development and manufacturing of late-stage custom and generic APIs to commercial-scale quantities.