APL:s service offering

PHARMA · SPECIALS

Services		Malmö	Umeå	Stockholm	Strängnäs
Project Management	Dedicated project managers for CTM and CDMO	x	x	x	x
	Established project model	x	x	x	x
Development work	Drug formulation development			x	x
	Placebo strategy and development			x	x
	Production process development			x	x
	Analytical method development and validation			x	x
	Stability studies			x	x
	Process scale up and tech transfer	x	x	x	x
	Construction of primary and secondary package	x	x	x	x
Clinical Trial Material	CMC documentation support			x	x
	Manufacturing of IMP and placebo	x	x	x	x
	Labelling			x	x
	Packaging and randomization			x	
Manufacturing	Antibiotics				x
	Aseptic/sterile		x		
	Clinical trials and commercial scale	x	x	x	x
	Dry, liquid and semi-solid preparations	x	x	x	x
	Non sterile	x		x	x
	Quality Control and QA GMP release	x	x	x	x
	Serialization and aggregation			x	x
	Small scale GMP production	x	x	x	x
Approved suppliers	API:s	x	x	x	x
	Excipients	x	x	x	x
	Packaging materials	x	x	x	x
Analytical Services	Chemical analysis	x	x	x	x
	Microbiological analysis	x	x		

Manufacturing capabilities		Class*	Malmö	Umeå	Stockholm	Strängnäs
Solids	Capsules	D	x		x	x
	Coating					x
	Granules, powders	D	x		x	x
	Modified release capsules	D	x		x	x
	Tablets and mini-tablets					x
	Wet granulation	D	x		x	x
Semi solids	Gels	B, D	x	x		
	Ointments and creams	B, D	x	x		
	Suppositories	D	x			
Liquids	Emulsions	B, D	x	x		
	Suspensions	B, C, D	x	x		
Primary packaging	Ampoules 2-10 mL	B, C		x		
	Blisters (PVC/PVDC/Alu/Alu strips)					x
	Bottles, plastic and glass	B, C, D	x	x		x
	Infusion bag 100, 300, 500 and 1000 mL	B		x		
	PFS 1 and 3 mL	B, C		x		
	Sachets	D	x			x
	Tubes 5 g to 30 g	B, C, D	x	x		
	Unit dose presentations (hospitals)					x
	Vials 1.5 to 1 000 mL	B, C		x		
Certifications	Anvisa (Brasil)		x		x	
	Clinical Trial Material (IMP)		x	x	x	x
	EU GMP		x	x	x	x
	FDA (US)		x	x	x	x
	ISO 14001, ISO 45001					x
	Veterinary Products		x	x	x	

*Aseptic (class B). Sterile (class C). Non sterile (class D)

Development Capabilities		
Pharmaceutical development	Handling of different API´s and compounds e.g.	Antibiotics
		Biologics
		Light-sensitive compounds
		Peptides
		Protein
		Small molecules
	Oral dosage forms	Capsules
		Coating
		Granules, powders
		Modified release capsules
		Oral dissolving films
		Solutions
		Suspensions, emulsions
		Tablets and mini-tablets
		Wet granulation
	Topical dosage forms	Ear drops
		Eye drops
		Creams/Lotions (sterile and non-sterile)
		Gels
		Ointments
		Sprays
		Suppositories
	Parenteral dosage forms	Injectable solutions (aseptic and sterile manufacturing)
		Injectable suspensions
		Pre-filled syringes
	Specials	Controlled release
		Inhalation
		Pediatric dosage forms
		Placebo and dosage form strategies
Analytical development	Analytical offers	Assay
		Degradation
		Density
		Dissolution and disintegration
		Forced light degradation
		Light scattering
		Microbiological tests e.g. sterility, TAMC, TYMC, specific microorganisms, Endotoxins
		Particle count, distribution and size
		Pharmacopoeia limit tests (EP and USP)
		Polarimetry
		Rheology including viscosity
		Titrations (potentiometric, volumetric, coulometric, KF)
		Uniformity of Dosage
	Analytical techniques	HPLC/UPLC - UV, PDA, RI, MS and QToF
		GC - Headspace and MS
		FTIR
		UV
		IC
		ICP
		DSC/TGA
		Microscopy
	Stability studies	According to ICH guidelines
		Controlled climates between -80C/AMB to 40C/75%RH

APL offers a wide range of services that covers the entire development and manufacturing chain

Project Management
- Experienced project leader
- Project documentation

Supply Chain Services
- Sourcing and procurement of raw materials and API's
- Supplier qualifications
- S&OP Management

Product Development
- Preformulation/Formulation
- Dosage form design
- Process development
- Analytical method development
- Registration documentation

Analytical Services
- Chemical analysis
- Microbiological analysis

Clinical Trials
- Manufacturing
- Randomization
- Coding
- Packaging and labeling

Manufacturing
- Process scale up and tech transfer
- Large and small GMP production
- QC and QA release
- Aseptic/steriles
- Non steriles
- Dry preparations
- Antibiotics

Apotek Produktion & Laboratorier AB (APL) is one of Europe's leading companies in the manufacture of extemporaneous medicines and stock preparations, working on behalf of society and other pharmaceutical companies. We are also an established contract manufacturer within the Life Science industry, providing development, analysis, and manufacturing services. With approximately 600 employees and five manufacturing units, we produce medicines that improve and save lives.

Please read more at www.apl.se