



APL:s service offering



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.

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