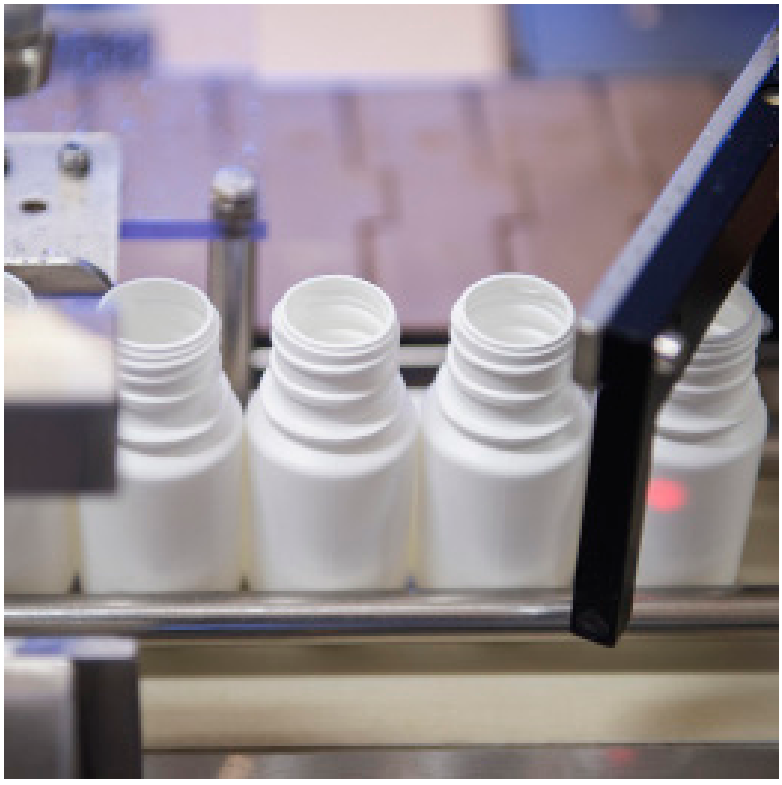
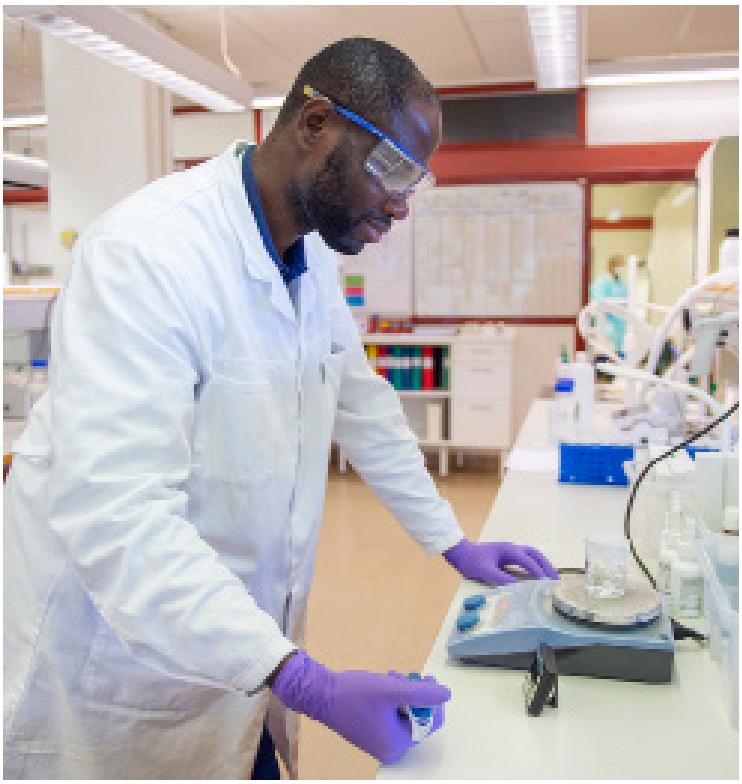


APL:s service offering



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PHARMA·SPECIALS

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

Manufacturing capabilities		Class*	Malmö	Umeå	Stockholm
Solids	Wet granulation	D	x		x
	Dry mixture in capsules	D	x		x
	Modified release capsules	D	x		x
	Granules, powders	D	x		x
Semi solids	Suppositories	D	x		
	Gels	B, D	x	x	
	Ointments	B, D	x	x	
	Creams	B, D	x	x	
Liquids	Emulsions	B, D	x	x	
	Suspensions	B, C, D	x	x	
Primary packaging	Vials 1.5 to 1 000 mL	B, C		x	
	PFS 1 and 3 mL	B, C		x	
	Tubes 5 g to 30 g	B, C, D	x	x	
	Ampoules 2-10 mL	B, C		x	
	Infusion bag 100, 300, 500 and 1000 mL	B		x	
	Sachets	D	x		
	Bottles	B, C, D	x	x	
Certifications	FDA (US)		x	x	x
	EU GMP		x	x	x
	Clinical Trial Material (IMP)		x	x	x
	Veterinary Products		x	x	x
	Anvisa (Brasil)		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.	Small molecules
		Biologics
		Peptides
		Protein
		Light-sensitive compounds
	Oral dosage forms	Wet granulation
		Dry mixture in capsules
		Modified release capsules
		Granules, powders
		Oral dissolving films
		Suspensions, emulsions
		Solutions
	Topical dosage forms	Suppositories
		Gels
		Ointments
		Creams/Lotions (sterile and non-sterile)
		Eye drops
		Ear drops
		Sprays
	Parenteral dosage forms	Injectable solutions (aseptic and sterile manufacturing)
		Injectable suspensions
		Pre-filled syringes
	Specials	Placebo and dosage form strategies
		Pediatric dosage forms
		Controlled release
		Inhalation
Analytical development	Analytical offers	Assay
		Degradation
		Uniformity of Dosage
		Dissolution and disintegration
		Particle count, distribution and size
		Ph Eur limit tests (EP and USP)
		Viscosity
		Rheology
		Polarimetry
		Forced light degradation
		Light scattering
		pH
		Density
		Titrations (potentiometric, volumetric, coulometric, KF)
		Microbiological tests e.g. sterility, TAMC, TYMC, specific microorganisms
		Endotoxins
	Analytical techniques	HPLC/UPLC - UV, PDA, MS and refractometer
		GC - Headspace and MS
		FTIR
		UV
		IC
		ICP
		DSC
		TGA
		Microscopy
		Suntest
	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

Apotek Produktion & Laboratorier (APL) is one of Europe's leading companies in extempore manufacturing and stock preparation, and we work on behalf of society and other pharmaceutical companies. We are also established contract manufacturers within Life Science in Scandinavia where we provide development and analysis. With approximately 500 employees and five manufacturing units, we develop medicines that improve and save lives.
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