

XPURE SYSTEMS CONCEPTUAL DESIGN STUDIES & COST ESTIMATES



XPure SMB conceptual studies distinguishes 3 stages:

1. The purification process concerns a new (product) ingredient with hardly any chromatographic literature or experience present.
2. The (product) ingredient can be related to a group/family with similar properties in chromatographic purification.
3. The (product) ingredient is currently processed in batch chromatography process and will be considered to operate in continuous mode.

SEVERAL ASPECTS OF LAB STUDY FOR CONCEPTUAL SMB DESIGN

ASPECT	DELIVERABLE
Literature search for appropriate resin functionality	A number of potentially functional resins for the application (typical 3 off)
Single column tests (stages 1,2)	
Write column test plan: <ul style="list-style-type: none"> Typically 3 resin species Set of parameters for recipe Literature data and resin datasheet of supplier Note: the same procedure is applicable for a EBA (expanded bed adsorption) column tests	Report: <ul style="list-style-type: none"> Applicability of selected resins First indicative estimate of yield and purity Full scale process CAPEX $\pm 40\%$ Typical lead time: 4 weeks
Single column optimization tests (stages 1,2)	
Typically 1-2 best performing resins each resin test with 3 variables at 3 levels (based on DOE principle) <ul style="list-style-type: none"> Parameter test range, such as bed velocity, buffer strength, particle size (provided applicable) 	Report <ul style="list-style-type: none"> (sub)optimal settings for SMB configured process: conceptual SMB design (see image below) Estimated yield and purity Full scale SMB CAPEX $\pm 30\%$ Typical lead time: as previous plus 3 weeks
Lab scale SMB / alternatively pilot scale tests (stages 1,2 and 3)	
SMB runs based on conceptual design from single column tests <ul style="list-style-type: none"> Preferably realistic feed stock from client Run 1: base model Run 2: tweak adsorption zone Run 3: tweak elution zone Run 4: tweak wash/rinse Run 5: Entrainment rejection and / or consolidation run (this run max. 3 days) Note: <ul style="list-style-type: none"> Piloting can be done in our own lab (only small scale) or at client's site Both static and carousel configured SMB studies are available Same procedure applies for EBA-SMB conceptual design studies 	Report: <ul style="list-style-type: none"> Full scale SMB proposal Process conditions Product titer and purity Buffer & water consumptions CAPEX and OPEX (budget) Typical lead time: 2 months

TYPICAL CONCEPTUAL SMB DESIGN FOR BIND & ELUTE

