

HPLC System Suitability Checklist

Reference: USP General Chapter <621> Chromatography — System Suitability

1. Method / Run Information

Method / SOP No.	_____	Analyst	_____
Instrument ID	_____	Column ID / Lot	_____
Run Date	_____	Number of Replicate Injections (n)	_____

2. System Suitability Parameters

Parameter	USP <621> Typical Requirement	Method-Specific Criterion	Measured Value	Pass / Fail	Analyst Initials
Resolution (R_s) between critical peak pair	$R_s \geq 1.5$ (baseline resolution; some methods require ≥ 2.0)				
Tailing Factor (T)	$T \leq 2.0$				
Theoretical Plates (N)	N per method requirement (commonly $N \geq 2000$)				
% RSD of Replicate Injections (Area or Response)	$\%RSD \leq 1.0\%$ (n=5) or $\leq 2.0\%$ per method-specific requirement (USP <621> RSD-vs-n relationship)				
Capacity Factor (k')	$k' > 2.0$ (typical; method- dependent)				
Relative Retention (α)	Per method-specific requirement				
Signal-to-Noise Ratio (S/N) at LOQ level	$S/N \geq 10:1$ (for quantitation limit verification, where applicable)				

Note: Method-specific acceptance criteria must be defined in the validated analytical method / SOP and take precedence over the USP <621> typical requirements shown above where a tighter or method-specific limit applies. Calculate N, T, and R_s using the equations specified in USP <621>.

3. Replicate Injection Data (for %RSD calculation)

Injection No.	Retention Time (min)	Peak Area / Response	Peak Height
1			
2			
3			
4			
5			
Mean			
Std. Dev.			
% RSD			

4. Overall System Suitability Determination

- ☐ System suitability PASSED — all parameters meet acceptance criteria; proceed with sample analysis.
- ☐ System suitability FAILED — do not proceed; investigate per site OOS/deviation procedure before re-testing.

5. Sign-Off

Role	Printed Name	Signature	Date
Analyst			
Reviewer			

Template reference: USP General Chapter <621> Chromatography (System Suitability). This checklist is a general-purpose template; confirm exact numeric acceptance criteria against the specific validated method before use. Lab-Training.com — free educational template, no login or fee required.