PQS HPLC System Suitability Worksheet

Pre-run readiness • SST data capture • failure evidence review • documented decision

Educational use: This worksheet supports structured review and training. It does not replace an approved analytical procedure, laboratory SOP, pharmacopoeial requirement, regulatory filing or quality-system decision.

1. Analysis and Method Identification

Product / material		**Test**	
Method / SOP no.		**Version**	
HPLC system ID		**Column ID / lot**	
Analyst		**Date / sequence ID**	

2. Pre-Run Readiness Check

Check	Yes	No	Notes / evidence
Correct approved method and current version verified	■	■	
Instrument qualification / required calibration status acceptable	■	■	
Required maintenance status / system readiness acceptable	■	■	
Correct qualified reference standard / lot verified	■	■	
Standard preparation, calculations and solution use period verified	■	■	
Mobile phase composition / pH / preparation verified	■	■	
Correct column chemistry, dimensions, ID and installation verified	■	■	
Required equilibration / conditioning completed per procedure	■	■	
Sequence, vial positions, injection volumes and acceptance criteria verified	■	■	

System Suitability Data Record

Record the criteria exactly as defined by the approved procedure. Do not replace method-specific limits with memorized “universal” numbers.

3. Predefined SST Criteria

Parameter	Approved criterion	Observed result	Pass / Fail
Repeatability / %RSD			
Resolution (critical pair)			
Tailing / symmetry			
Theoretical plates / efficiency			
Sensitivity / S:N (if applicable)			
Retention / other method-specific control			

4. Replicate Injection Data

Injection	Peak area / response	tR	Tailing	Plates (N)	Comments
1					
2					
3					
4					
5					
6					
Mean					
SD					
%RSD					

%RSD calculation: %RSD = (sample standard deviation ÷ mean) × 100	**Critical-pair Rs / other calculation:** _____

Failed SST Evidence Review and Decision Record

Use evidence to support conclusions. A later passing SST does not erase the original failure or justify selective data removal.

5. Initial SST Decision

All predefined SST criteria passed? ■ Yes ■ No

Were any product samples injected before suitability was established or after suitability became uncertain? ■ Yes ■ No ■ N/A

If SST failed: sequence/sample status and immediate controlled action:
_____
_____
_____

6. Evidence Review Matrix

Evidence area	What to verify	Evidence / finding
Approved method / sequence	Method version, predefined criteria, sequence design, permitted adjustments	
Reference standard	Qualification, lot, potency correction, weighing, dilution, stability, storage	
Mobile phase / reagents	Composition, pH, lot/grade, preparation time, filtration/degassing	
Column	Chemistry/dimensions, ID/lot, history, conditioning, pressure behavior	
HPLC modules	Pump/mixing, leaks, detector, temperature, autosampler, qualification status	
Sequence / injections	Order, vial identity, injection volume, aborted/repeated/unexpected injections	
CDS / audit trail	Method edits, integration changes, sequence edits, deletions, reprocessing, user actions	
Complete raw data	Chromatograms, calculations, logs, instrument messages, review records	

7. Data Integrity and Controlled-Retest Check

Item	Yes	No / N.A.	Notes
All original chromatograms and electronic raw data retained	■	■	
Aborted, failed, repeated or unusual injections accounted for	■	■	
No product-sample trial injection used to obtain an unofficial result	■	■	
Any reprocessing / reintegration scientifically justified and traceable	■	■	
Any corrective action approved before SST repetition, as required	■	■	
Repeat SST, if performed, followed the approved method / SOP	■	■	

8. Documented Conclusion / Disposition

Assignable cause supported by evidence? ■ Yes ■ No ■ Not determined

Evidence-based conclusion:

_____
_____
_____
_____
_____
_____

Approved corrective action / follow-up:

_____
_____
_____
_____

Final SST status: ■ Suitable for defined analysis ■ Not suitable / further action required ■ Other: _____

Analyst / investigator: _____	**Date:** _____
Reviewer / approver: _____	**Date:** _____

Regulatory basis used for this educational tool: FDA Laboratory Controls Q&A; (system suitability / trial injections); USP <621> Chromatography framework; Health Canada quality guidance; ICH Q2(R2) and Q14. Always use the current approved versions applicable to your site and product.