

STANDARD OPERATING PROCEDURES

Review and Release of Results from the Analytical Laboratory Notebooks.

REVIEWER CHECKLIST - LAB NOTEBOOK

NOTEBOOK	YES	NO
1. Analytical Method: Test Test Number Edition #: Same as the one used for testing Date of Edition	<input type="checkbox"/>	<input type="checkbox"/>
2. Full and correct name of sample tested	<input type="checkbox"/>	<input type="checkbox"/>
3. Description of operating conductors according to the analytical method.	<input type="checkbox"/>	<input type="checkbox"/>
4. Compatibility of actual work with the analytical method.	<input type="checkbox"/>	<input type="checkbox"/>
5. Inserts of Weights (date, number of notebook, pH, titration results, name of analyst), spectra graphs and chromatograms.	<input type="checkbox"/>	<input type="checkbox"/>
6. Standards: Assay Water content RLB Specifications as in valid Certificate of Analysis Use before retest date	<input type="checkbox"/>	<input type="checkbox"/>
7. Standard Solutions: Repeatability of injections Repeatability of control injections Used within time permitted	<input type="checkbox"/>	<input type="checkbox"/>
8. Results: Difference between duplicates Questionable result and OOS Repeated significant figures	<input type="checkbox"/>	<input type="checkbox"/>
9. System Suitability Graphs: Compatible with method Compliance with method (tailing factor, resolution, no. of theoretical plates) Appropriate concentrations Appropriate running conditions (time of run, RRT)	<input type="checkbox"/>	<input type="checkbox"/>
10. Interrupted Work: Reason noted Signature	<input type="checkbox"/>	<input type="checkbox"/>
11. Retest: According to SOP (investigation, etc.)	<input type="checkbox"/>	<input type="checkbox"/>
12. Erasure of the test - signature and date	<input type="checkbox"/>	<input type="checkbox"/>

ED. N0: NEW	Effective Date: DD / MM / 200Y	APPROVED:	http://www.iagim.org		
Ed. Status : ORIGINAL		_____	_____	_____	_____
		Laboratory	QC	QA	HEAD

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RAW DATA	YES	NO
Name of sample	<input type="checkbox"/>	<input type="checkbox"/>
Dates compatible and in chronological order with dates in notebooks, raw data and documents	<input type="checkbox"/>	<input type="checkbox"/>
Conformity of successive graphs	<input type="checkbox"/>	<input type="checkbox"/>
Running time and RRTs according to method and edition	<input type="checkbox"/>	<input type="checkbox"/>
Canceled Chromatograms and spectra with signed explanation	<input type="checkbox"/>	<input type="checkbox"/>
Graph of system suitability compatible with method	<input type="checkbox"/>	<input type="checkbox"/>
Discrepancies between original data (area responses, absorbance values) and those reported in notebook, computer sheets and documents.	<input type="checkbox"/>	<input type="checkbox"/>
Extraneous peaks in standard and sample solutions:	<input type="checkbox"/>	<input type="checkbox"/>
Number of peaks found	<input type="checkbox"/>	<input type="checkbox"/>
Size of peaks (less or more than QL)	<input type="checkbox"/>	<input type="checkbox"/>

EQUIPMENT	YES	NO
- Calibrated at the time of use	<input type="checkbox"/>	<input type="checkbox"/>
- Performance check of dissolution bath	<input type="checkbox"/>	<input type="checkbox"/>

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				_____ HEAD