Study Title:
Lab ID Number:

Form Group: Lab Critical Phase Inspection
Packet ID: LCPI-
Audit Type Chem/Crop/PR#(ID) :
Location:
Date:
Closed:

A. General
Yes, No, N/A

1. Protocol and method available to appropriate personnel:
2. Discovered changes/revisions of approved protocol documented:
3. Procedures, as listed in the protocol, being followed:
4. Modifications to the validated method documented and approved by the LRD and Study Director:
5. Lab operations relating to study conducted according to SOPs:
6. SOPs available to lab personnel:
7. SOP deviations documented in the raw data:
8. SOP deviations approved by the Study Director:
9. Adequate number of trained personnel:
10. Observed procedures relating to study:
11. Observed procedures conducted for protocol:

B. Equipment/Instrument
Yes, No, N/A

12. Equipment calibrated/standardized:
13. Equipment cleaning/maintenance is documented:
14. Logbooks up-to-date:
15. SOP for equipment in place and current:

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C. Samples
Yes, No, N/A

16. Sample is uniquely identified to::
a. Protocol:
b. SOP:
17. Sample ID appears on container:
18. Sample container is identified by:
a. Test System:
b. Field ID Number:
c. Nature of the sample:
d. Date of collection/ site:
Test Substance:
19. Samples are maintained under proper storage:
a. Sample storage location documented:
b. Temperature and maintenance records up-to-date:
20. Sample preparation (ie, processing, extraction, analysis, etc.) is properly recorded:
21. Sub-samples are properly identified during:
a. Sample Processing/grinding:
b. Weighing/subsampling:
c. Sample extraction(s) and cleanup(s):
22. Sample integrity maintained during preparation:

D. Reagents, Solvents and Solutions

23. Reagents, Solutions, Solvents are labeled:
a. Identity/concentration/storage requirements:
b. Expiration date:
24. Standard Solutions:
a. Have been prepared according to SOPs/method:
b. Have been properly labeled:
i. Identity/concentration:
ii. Date prepared/prepared by (if applicable):
iii. storage conditions/expiration date:
c. Are not out-of-date:
d. Are properly stored:

Study Title:

Lab ID Number:

E. Recording of Data

25. Hand generated data are properly recorded:

a. Directly, promptly, legibly:

b. In indelible ink:

c. On an appropriate form or in lab raw data:

26. Entries are dated and initialed appropriately:

27. . Analytical standards used are properly identified in the raw data:

28. . Changes to raw data. Do not obscure the original entry:

a. Explained:

b. Dated:

c. initialed:

29. . Computer generated data:

a. Program has been validated:

b. Input personnel identified:

c. Data calculation verified:

30. Lab raw data stored according to SOP: