Study Title:
Lab ID Number:

Form Group: Analytical Raw Data Audit
Packet ID: ARDA-
Audit Type Chem/Crop/PR#(ID) :
Location:
Date:
Closed:

A. General
Yes, No, N/A

1. Approved protocol and method included in raw data package:
2. Changes were authorized by the Study Director, as per protocol:
3. Method used for analysis was validated per protocol prior to us in analyzing study samples:
4. All modifications to the referenced method were documented, validated, signed and dated by the LRD (working method):
5. All SOP deviations listed in the raw data:
6. All SOP deviations authorized by Study Director:
7. Appropriate personnel signatures included in raw data:
8. All data corrections properly explained, initialed and dated:
9. All pages properly identified:
10. Procedures used in generating raw data were described in the SOPs, protocol and /or study raw data:

B. Sample Storage and Preparation
Yes, No, N/A

11. Samples traceable through chain of custody documentation:
a. Receipt:
b. Storage:
c. Distribution:
12. Sample preparation according to SOP:
13. Sample preparation adequately recorded:
14. Sample preparation followed validated method:
15. Sample storage location(s) documented:
16. Sample storage temperatures documented:
17. Date and times samples taken in and out of the freezer are logged and within SOP requirements:
18. Storage duration and conditions of storage of samples & stability samples are the same:

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C. Analytical Reference Standards and Fortification Solutions
Yes, No, N/A

19. Check all analytical standards used, source, batch numbers and expiration dates for acceptability:

20. Certified copy of certificate of analysis for standard(s) is in the study file:

21. Standard(s) solution was used prior to their expiration dates:

22. Accountability of reference standards:

a. Records and receipts:

b. Use logs up-to-date (distribution and disposal):

c. Storage logs:

d. Storage location(s):

e. Storage conditions:

23. Laboratory raw data documents the standard used (proper identification maintained):

24. Retention sample of the standard in the IR-4 Laboratory chemical archive or other archive facility is documented:

25. Logbook(s) for balance(s) contain calibration documentation:

26. Standard solutions documentation adequate:

a. Stock:

b. Analytical standards:

c. Fortification solutions:

D. Data Inspection
Yes, No, N/A

27. Raw data properly recorded:

a. Promptly and legibly in ink:

b. Dated on day of entry and signed or initialed:

c. Changes to entries did not obscure the original:

d. Corrections were explained, dated, and signed or initialed:

28. Computer generated data:

a. Program has been validated:

b. Input personnel identified:

c. Printout signed:

d. Printout dated:

29. Numerical results reported were consistent for significant figures, rounding-off numbers, etc. with SOPs:

30. Units of concentration were clearly identified:

31. Instrument parameters were documented for each set of runs:

a. Instrument conditions /date:

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b. Study number:	
c. Lab sample/standard concentration:	
d. Analyst(s) / operator(s) initials:	
e. Injection volume:	
32. Injection sequence. All chromatograms retained in continuous sets per run:	
33. Samples fall within standard curve range:	
34. Chromatograms and standard curves audited:	
35. Integrator chromatograms and /or computer generated chromatograms compared to data report:	
36. Analytical instrument logbooks showed proper documentation and operation:	
37. Analytical sets, including standards and fortifications according to SOPs and protocol:	
38. Limits of quantization and detection (LOQ and LOD) were clearly defined:	
39. Calculations were accurate:	
40. Recoveries outside of 70 - 120 % range	