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 standard 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 documented and authorized by the LRD and the Study Director:	