Protocol Audit Checklist

Study Title:

Study Number (PR#):

Packet ID:	PA-000
Audit Type Chem/Crop/PR#(ID) :	
Location:	
Date:	

A. General

Yes No or N/A	
1. Study title (descriptive):	
2. Purpose / objective of study:	
3. Sponsor name and address:	
4. Testing facility management name and address:	
5. Identity of study participants/test sites complete:	
6. Proposed start date:	
7. Proposed termination date:	
8. Name & dated signature of Study Director:	
10. Records/specimens to be maintained:	
9. Dated approval signature of Sponsor Representative:	
11. Archival location for raw data accurate:	
12. Description of proposed statistics:	
13. Parameters to be statistically analyzed:	

B. Test System

Yes No or N/A* GLP required element

14. Description of the test system:	
I. Field Studies:	
a. Crop/soil:	
b. Variety:	
c. Source of supply:	
d. Age of test system:	
e. Plot size and description:	
f. Greenhouse trials required:	
II. Analytical Studies:	
a. Matrix/Method described:	
b. Spiking levels assigned:	
c. Number of samples for assay:	
III. Animal Studies:	
a. Number and sex:	
b. Body weight range and/or age:	
c. Species strain and sub strain:	
d. Source of supply:	
e. Description of diet used:	

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15. *Method of plot identification:	
16. Justification for the test system selection:	

C. Test, Control & Reference Article

	Yes No or N/A
17. *Name, CAS number or code number:	
a. Test Substance:	
b. Control Substance:	
c. Reference Substance:	
18. Supplier of test, control & ref. substance:	
19. Solvent and/or adjuvant used to solubilize or suspend the test, control or reference substance:	
20. Archival of retentions sample addressed:	
21. Storage condition information for the test, control and / or ref. substance:	
22. Stability under testing conditions:	

D. Dosing

	Yes No or N/A
23 *Route or administration:	
24. Frequency of administration:	
25. Justification for route od administration:	
26. *Preparation of dosage form:	
27. *Identity of carrier or vehicle:	
28. *Concentration of test material:	
29. *Method to assure uniformity of mixture:	

E. Sample Collection and Shipment

	Yes No or N/A
30. *Interim sampling points (if applicable):	
a. # of samples per plot/ per trt. group:	
b. Number of treatments and control groups:	
31. *Terminal sampling points:	
32. *Description/number of samples required:	
33. *Method of control bias:	
34. *Handling, shipment and storage of samples:	
35. *Sample prep for analysis:	
36. *Archival/disposition of samples. :	
37. *Parameters to be statistically analyzed:	

F. Sample Analysis

	Yes No or N/A
38. Identity of analytical reference method:	
39. Method validation requirements:	
40. Analysis acceptance criteria provided:	
41. Storage stability requirements:	