Protocol Audit Checklist

Study Title:

Study Number (PR#):

Packet ID: PA-

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: