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| |  |  | | --- | --- | | **Form Group:** | Contributing Scientist Report/Data Audit | | **Packet ID:** | CSRA- | | **Audit Type Chem/Crop/PR#(ID) :** |  | | **Location:** |  | | **Date:** |  | | **Closed:** |  | |
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| |  |  | | --- | --- | |  |  | |  |  | | **A. Cover Page**  **Yes, No, N/A** | | | **Study Title:** |  | | **Lab/Processing/Seed Treatment ID#:** |  | | **1. PR# on Report:** |  | | **2. Title of Report Accurate:** |  | | **3. Author (s) Presented:** |  | | **4. Report Date:** |  | | **5. Sponsor Named:** |  | | **6. Study Director (Name):** |  | | **7. Research Director (Proc, Seed Trt., etc) (Name &** **Location):** |  | | **8. Study Timetable:** |  | | **a. Initiation Date:** |  | | **b. Experimental Termination Date:** |  | | **B. Good Laboratory Practice (GLP) Statement**  **YES,NO,N/A** |  | | **9. Exceptions to the GPL Standards listed:** |  | | **10. Research Director’s Signature (s):** |  | | **C. Quality Assurance Statement**  **YES,NO,N/A** |  | | **11. QA Statement Complete:** |  | | **a. Date (s) of Inspection (s):** |  | | **b. Name of Person (s) Inspecting:** |  | | **c. Date Reported to SD and TFM:** |  | | **d. Signed and Dated:** |  | | **12. Signed & dated:** |  | | **D. Study Participants**  **YES,NO,N/A** |  | | **13. All Study Participants Listed:** |  | | **E. Table of Contents**  **YES,NO,N/A** | | | **14. Table of Contents to contain all Sections of Report:** | | | **a. List of Tables:** |  | | **b. List of Figures:** |  | | **c. Appendices:** |  | | **d. Page numbers included and accurate:** |  | | **F. Archive Statement** |  | | **15. Data Archive Location Provided & According to the Protocol:** |  | | **G. CSR Content**  **YES,NO,N/A** | | | **16. Objective(s) / Introduction included:** |  | | |  | | --- | | **17. Materials/Methods:** | | **a. Methods of Trt. /Processing, etc. Presented :** | | **b. Test/Reference substance(s) (Name, Source, lot#, Purity, Expiration Date, Storage:** | | **c. Reagents:** | | **d. Equipment (s) used Identified:** | | **e. Preparation of Test/Reference Substance(s) and Fortification Solutions Adequately Documented:** | | **f. Preparation of Reagents Described:** | | **g. Description of Sample Preparation (sub-samples, chopping or grinding used for analysis):** | | **h. Analytical Procedure Named and Available:** | | **i. Instrument(s) and Parameters Used:** | | **j. Limits of Detection and Quantitation (defined in SOP):** | | **k. Method of Quantitation (e.g., software) Sample Calculation Presented. :** |   **18. Sample Inventory and History:** |  | | **a. Test System:** |  | | **i. Commodity (ies) of Fractions:** |  | | **ii. Field ID#s:** |  | | **iii. Field Research Director name(s):** |  | | **iv. Total # of Samples:** |  | | **v. Form(s) of Sample (whole, ground, etc.):** |  | | **b. Storage (storage period and temp.) for Samples & Extracts:** |  | | **C. Relevant Dates (e.g., harvest, sampling, application(s), Processing, Fortifications, Extractions, Analyses, etc.):** |  | | **d. Were samples stored in appropriate form :** |  | | **19. Results and Discussion** |  | | **a. Processing flow chart/mass balance presented, as applicable:** |  | | **b. Results have been accurately transcribed to the study report:** |  | | **c. All relevant raw data were presented:** |  | | **d. Use of correction factors clearly presented.** |  | |  |  | | **e. Explanation/Description of Calculation Technique Presented (if automated?) are formulas visible:** |  | | **f. Sample Calculations for Fortified Control Presented (at a minimum):** |  | | **g. Calibration curves or bracketing standard(s) values presented:**  **h. Clearly labeled and representative chromatograms/spectra presented:** |  | | **i. If corrected values reported are the apparent values are also presented?:** |  | | **H. Appendices**  **YES,NO,N/A** | | | **20. Test/Reference Substance Characterization:** |  | | **a. Contains GLP Status and Archival Location:** |  | | **b. Copy of Certificate of Analysis Presented:** |  | | **I. Data**  **YES,NO,N/A** |  | | **21. Data properly signed/initialed and dated:** |  | | **22. Data changes GLP compliant:** |  | | **23. Data Pages is Identified by Study # and Paginated:** |  | | **24. Raw Data Complete:** |  | | **J. Protocol/SOP**  **YES,NO,N/A** | | **25. Protocol and all Applicable Changes Present:** |  | | **26. Protocol Followed or All Deviations Issued and Approved:** |  | | **27. All SOPs Followed or Deviations Issued and Approved:** |  | |  |  | |