***Table of Contents mapping [INSERT COMPANY NAME] TOC to BioCelerate NCPT TOC***

*Versions Compared:* ***[INSERT COMPANY NAME] [DATE] to BioCelerate [INSERT VERSION]***

| 1. BioCelerate nCPT Heading
 | 1. Section IN toc
 | 1. Comments/GAPS
 |
| --- | --- | --- |
| 1. Biocelerate nCPT SECTION #
 | 1. [Company NAME]

**SECTION #** |
| 1. Instructional Page
 | 1. X
 |  |  |
| Table of Contents | X |  |  |
| Approval  | X |  |  |
| Objective | 1. 1
 |  |  |
| Proposed Study Schedule | 1. 2
 |  |  |
| Sponsor/Test Facility/Test Site Information | 3 |  |  |
| Key Personnel | 4 |  |  |
| Test Item/Article and Vehicle Control Item/Article | 5 |  |  |
| Test Item/Article | 5.1 |  |  |
| Vehicle Control Item/Article | 5.2 |  |  |
| Bulk Test Item/Article Analysis | 5.3 |  |  |
| Dose Formulation | 6 |  |  |
| Analysis of Dose Formulations | 6.1 |  |  |
| Test System and Husbandry | 7 |  |  |
| Characterization of Test System | 7.1 |  |  |
| Justification for Test System Selection | 7.2 |  |  |
| Justification for Number of Animals | 7.3 |  |  |
| Selection, Assignment and Replacement of Animals | 7.4 |  |  |
| Pretest Handling/Acclimation | 7.5 |  |  |
| Housing and Environmental Conditions | 7.6 |  |  |
| Veterinary Care | 7.7 |  |  |
| Experimental Design | 8 |  |  |
| Dose Interval/Frequency | 8.1 |  |  |
| Justification for Dose Selection | 8.2 |  |  |
| Route of Dose Administration | 8.3 |  |  |
| Justification for Route | 8.4 |  |  |
| In-life Observations and Procedures | 9 |  |  |
| Safety Pharmacology | 9.1 |  |  |
| Cardiovascular | 9.1.1 |  |  |
| Respiratory | 9.1.2 |  |  |
| CNS | 9.1.3 |  |  |
| Clinical Pathology | 10 |  |  |
| Sample Collection | 10.1 |  |  |
| Hematology | 10.2 |  |  |
| Coagulation | 10.3 |  |  |
| Clinical Chemistry | 10.4 |  |  |
| Urinalysis | 10.5 |  |  |
| Bioanalysis | 11 |  |  |
| Bioanalytical Sample Collection | 11.1 |  |  |
| Toxicokinetic Evaluation | 12 |  |  |
| Other Testing | 13 |  |  |
| Terminal Procedures | 14 |  |  |
| Unscheduled Euthanasia and Decedents | 14.1 |  |  |
| Scheduled Euthanasia | 14.2 |  |  |
| Necropsy | 14.3 |  |  |
| Bone Marrow Smears | 14.4 |  |  |
| Organ Weights | 14.5 |  |  |
| Tissue Collection and Preservation | 14.6 |  |  |
| Histology and Histopathology | 15 |  |  |

| 1. BioCelerate nCPT Heading
 | 1. Section IN toc
 | 1. Comments/GAPS
 |
| --- | --- | --- |
| 1. Biocelerate nCPT SECTION #
 | 1. [Company NAME]

**SECTION #** |
| Histology | 15.1 |  |  |
| Histopathology | 15.2 |  |  |
| Pathology Peer Review | 16 |  |  |
| Data Evaluation and Statistical Analysis | 17 |  |  |
| Regulatory Information | 18 |  |  |
| Good Laboratory Practice | 18.1 |  |  |
| Regulatory Testing Guidelines | 18.2 |  |  |
| Quality Assurance | 19 |  |  |
| Animal Welfare | 20 |  |  |
| Major Computer Systems | 21 |  |  |
| Amendments and Deviations | 22 |  |  |
| Retention of Records, Samples and Specimens | 23 |  |  |
| Study Classification | 24 |  |  |
| Reporting | 25 |  |  |
| References | 26 |  |  |
| ATTACHMENT A | X |  |  |
| ATTACHMENT B | X |  |  |
| APPENDIX | X |  |  |
| SUPPORTING INFORMATION | X |  |  |
| SUMMARY OF CHANGES AND JUSTIFICATIONS | X |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |