LIST OF REOUIRED SOPS AT BA/BE STUDIES CENTER

The following is an example list of the standard operating procedures (SOPs) that should be used at BA/BE Studies Center. This list is not exhaustive as additional procedures may be necessary depending on the functional and compliance requirements at the facility concerned.

All of the documents at the BA/BE Studies Centers related to a bioequivalence (BE) clinical trial should be controlled (e.g. version date, date approved, etc.) documents. This control is easier if the documents are in the SOP format or are appended to SOPs.

SOPs should be in place at least for all the critical and major operations in the BE/clinical trial.

NUMBERAND NAME OF SOPs

1. Conduct of BE study
2. Archiving and retrieval of documents related to a BE study
3. Quality assurance of a BE study; audits of clinical and bioanalytical part of the study and the study report.
4. Study files
5. Preparation and review of the protocol for the study
6. Amendment to the protocol for the study
7. Protocol deviations/violation recording and reporting
8. Sponsor/CRO quality assurance agreement on conducting the BE study
9. Process for approval of study by ethical committee
10. Bioavailability (BA)/BE report
11. Study report
12. Written informed consent
13. Obtaining written informed consent for screening from study volunteers
14. Allocation of identification numbers to volunteers at various stages in BE study
15. Investigator's brochure
16. Case report form (CRF)
17. Preparation of CRF, review and completion
18. Data collection and CRF completion
19. Adverse/serious adverse event monitoring, recording and reporting
20. Organizational chart for the study

21. Training of personnel
22. Responsibilities of the members of the research team
23. Monitoring of the study by the sponsor
24. Conduct of pre-study meeting.
25. Study start-up
26. Subject management
27. SOP on mobilization of individuals for registration in volunteer bank
28. Eligibility criteria for registration and registration of individuals in volunteer bank
29. Handling of subject withdrawal
30. Allocation of identification numbers to volunteers at various stages in the biostudy
31. Screening of volunteers enrolled for the study
32. Collection of urine samples from subjects for detection of drugs of abuse and transportation of samples to pathology laboratory
33. Custodian duties
34. Payments to research subjects for BE studies
35. Procedures for entry into and exit from clinical unit
36. Handling of subject check-in and check-out
37. Housekeeping at clinical unit
38. Planning, preparation, evaluation and service of standardized meals for bio-studies
39. Distribution of meals to study subjects
40. Operation and maintenance of nurse call system
41. Administration of oral solid dosage form of the investigational product to human subjects during BE study
42. Cannulation of study subjects
43. Collection of blood samples from study subjects
44. Identification of biological samples
45. Recording of vital signs of subjects
46. Operation and verification of fire alarm system
47. Administration of oxygen to subject from medical oxygen cylinder
48. Emergency care of subjects during BA/BE study
49. Availability of ambulance during BA/BE study
50. Centrifugation and separation of blood samples
51. Storage of plasma and serum samples

52. Segregation of bio-samples
53. Transfer of plasma and serum samples to bioanalytical laboratory
54. Procedures for washing glassware
55. Recording temperature and relative humidity of rooms
56. Instructions on operation and maintenance procedures for all the equipment in the clinical unit
57. Numbering the equipment and logbooks for use in the clinical unit
58. Control of access to pharmacy
59. Pharmacy area requirements
60. Authorization related to investigational product storage, dispensing and retrieval from storage for BE study
61. Investigational product receipt, return and accountability documentation
62. Investigational product receipt and return procedures
63. Storage of investigational products in the pharmacy
64. Line clearance before and after dispensing
65. Documentation of line clearance and dispensing; packaging records and release of dispensed products
66. Retention of samples of investigational products
67. Disposal of archived investigational products
68. Disposal of biological materials
69. Procedures for bioanalytical laboratory (SOPs for the different items of equipment, analytical methods, reagent preparation)
70. Out-of-specification in the laboratory
71. Acceptance criteria for analytical runs: acceptance of calibration curves, acceptance of the runs based on quality control samples results
72. Chromatographic acceptance criteria and chromatogram integration
73. Sample re-assay
74. Pharmacokinetic data from bioanalytical data
75. Procedure for statistical analysis in a BE study