

**Ethiopian Food and Drug Authority**

**Bioequivalence Center Control Directive**

**Preamble**

WHEREAS it is necessary to demonstrate the therapeutic equivalence of generic products with the comparator products by performing a bioequivalence study.

WHEREAS it is necessary to ensure that generic products need to conform to the same standards of quality, efficacy, and safety as the comparator products.

WHEREAS it is necessary to ensure that the bioequivalence center used by the sponsor complies with good clinical practices (GCP) and good laboratory practices (GLP) requirements.

WHEREAS ensuring bioequivalence study participants’ rights, safety, and well-being are protected and bioequivalence study data are credible.

WHEREAS it is necessary to set legal provisions for organizations performing bioequivalence studies to be licensed by the Authority.

THEREFORE, this directive is issued in accordance with Article 71 (2) of the Food and Drug

Administration Proclamation No. 1112/2019.

**Part One**

**General**

1. **Short Title**

This directive may be cited as “Bioequivalence Center Control Directive No. XX/2024”.

1. **Definitions**

Unless otherwise a different meaning is given in this directive

1. **Bioequivalence:** means the absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed study.
2. **A bioequivalence study:** meansa special study where two drugs or two sets of formulations of the same drug are compared to show that they have nearly equal bioavailability and Pharmacokinetic or Pharmacodynamics parameters.
3. **Case-report form** means a document that is used to record data on each subject during the course of the trial, as defined by the protocol.
4. **A comparator product** means an innovator or a generic pharmaceutical product whose quality, efficacy and safety has been established, and which is used as a reference to ensure the quality, efficacy and safety of other generic product.
5. **Good laboratory practice** means a quality system covering the organizational process and the conditions under which laboratory studies are planned, performed, monitored, recorded and reported.
6. **Innovator product** means the first product discovered containing its specific active ingredient to receive approval for use. It is usually the product for which efficacy, safety and quality have been fully established.
7. **Internal standard** means test compound(s) added to calibration standards, quality control samples and study samples at a known and constant concentration to correct for experimental variability during sample preparation and analysis.
8. **Technical manager** means the individual responsible for the overall technical activities’ bioequivalence center.
9. **Key personnel** mean individuals assigned by a bioequivalence center for the key activities such as technical manager, bioanalytical chemist or pharmacist, quality assurance manager, biostatistician and as applicable, a physician.
10. **Person** means a natural person or juridical person.
11. **Authority** means the Ethiopian Food and Drug Authority.
12. In this directive any expression in the masculine includes feminine.
13. **Scope**

This directive shall be applicable to the establishment, renewal, change and inspection of bioequivalence center.

**Part two**

**Certificate of Competence**

1. **Issuance of Certificate of Competence**
	1. Any person who wants to establish a bioequivalence center shall first obtain a certificate of competence from the Authority.
	2. Any person who wants a certificate of competence shall submit his/her application to the authority. The application form as indicted in the annex 1 shall be accompanied by the following documents along with the cover letter and applicable service fee:
		* 1. Passport-size photo of the technical manager
			2. Employment agreement or contract of technical manager
			3. An organm of the Center including a brief CV of key personnel and list of other staff in organization
			4. House rent contract or house ownership certificate authenticated by Document Authentication and Registration Agency.
			5. Without prejudice to sub-article 3(d) of this article, for government houses, supporting letters from this organization
			6. If the applicant is a business organization other than sole proprietorship , Article of Association attested by Document Authentication and Registration Agency.
			7. major tie ups for ancillary services. The center shall have a contract agreement for outsourced services such as Hospitals, Laboratory Centers or Ambulances
	3. If the application submitted does not fulfill the requirements, the Authority shall inform the applicant with an official letter for correction and may re-apply after correction.
	4. If the application submitted fulfills the requirements, the Center shall be inspected on-site by a team having at least two appropriate inspectors.
	5. Once requirements are met, the Authority shall issue a certificate of competence within five working days. In the event of compelling circumstances, the time to provide the certificate of competence may be extended up to 5 additional working days.
	6. Where the requirements have not been met, the applicant shall be informed about the decision in writings and the Authority may carry out two-rounds of re-inspection after the appropriate service fee payment up on request by the applicant.
	7. Notwithstanding sub-Article (6) of this Article, an applicant who do not fulfill the requirements after the conduct of two rounds of re-inspections, the submitted application shall be rejected. The applicant may submit a new application up on payment of service fee.
2. **Content of the Certificate of Competence**

Any certificate of competence for bioequivalence center issued in accordance with this directive shall have the following information.

* 1. Name and address of the bioequivalence center
		1. Name and address of Clinical site
		2. Name and address of bioanalytical site
	2. Name of the owner of the bioequivalence center
	3. The bioequivalence center’s technical manager name, 3x4 photo and professional license number
	4. Date of issue and expiry date of the certificate of competency
	5. Signature of the authorized person who issued the certificate of competence and stamp of the Authority
	6. Certificate of competency number
	7. Taxpayer identification numbers (TIN)
	8. Detail condition and notice on the license
1. **Renewal of Certificate of Competence of Bioequivalence center**
	1. Any bioequivalence center shall renew a certificate of competence every 3 years.
	2. Without prejudice to sub-article (1) of this article, if any force majeure supported by objective evidence, the certificate of competence may be renewed within 3 months after the lapse of 3years period.
	3. To renew a certificate of competence of bioequivalence center, the applicant shall apply three months before expiry of the service period.
	4. In accordance with sub-article (1) of this article, a certificate of competence shall be renewed.
		1. Based on the inspection report,
		2. Confirmation of payment of required service fee
	5. If the certificate of competence of the bioequivalence center is not renewed in accordance with sub-article (1) of this article, the certificate of competence shall be considered as canceled.
	6. Where the Authority deny the renewal of Certificate of Competence, it shall notify the applicant by stating the reasons in writing.
2. **Changes**
3. Any bioequivalence center shall not change location, ownership, technical manager, modify or partition the rooms without prior permission of the Authority.
4. Any person who wants to make a change shall apply using application form Annex 2
5. without prejudice sub-article 2 of this article, the applicant shall fulfill the following requirements to make changes as per the application form in annex 2.
6. The new site, facility and personnel shall fulfill similar requirements with the previous one.
7. Pay service fee and duly fill the application form
8. **Replacement of Certificate of Competence**

Any person whose certificate of competence has been damaged or lost shall request for replacement by fulfilling the following:

* 1. Presenting damaged certificate of competence and receipt of service fee payment
	2. If lost or burnt, present proof of evidence from justice organ and receipt of service fee payment
1. **Return of Certificate of Competence**
	1. Where any bioequivalence center wants to return the certificate of competence granted by the Authority due to different reasons, it shall submit a letter of declaration that describes status of the center, availability of active bioequivalence study , the availability and status of investigational products, medical devices, previously issued certificate of competence and application letter.
2. **Displaying Certificate of Competence**

Any bioequivalence center shall display the original certificate of competence in the technical manager’s office of the organization in a conspicuous place where it can be easily seen.

**Part Three**

**Organization and Required Facilities, Personnel and Equipment**

1. **Organization and management**
	1. The bioequivalence center shall have an organization chart depicting key positions and the names of responsible persons. The organization chart shall be dated, authorized and kept up to date.
	2. There shall be job descriptions for all personnel, including a description of their responsibilities. Every job description shall be signed and dated by the staff member to whom it applies.
	3. There shall be a list of signatures of the authorized personnel performing tasks during each study.
	4. For the bio-analytical part of the study, the bioequivalence center shall abide to the principles of good laboratory practice.
	5. For the clinical part of the study, the bioequivalence center shall comply with the principles of good clinical practice.
2. **Computer Systems**
	1. The bioequivalence center shall have appropriate hardware and software for the proper run of its operation.
	2. The bioequivalence center networks shall be appropriately designed, qualified, managed and controlled.
	3. The bioequivalence center shall have appropriate data management system including backups, secured and access-controlled and procedures.
3. **Quality Management**
	1. The bioequivalence center shall have appropriate data entry procedures, quality assurance and quality control systems with written standard operating procedures.
	2. Quality management system, quality assurance personnel, planning and performing self-inspections, and both in-process and retrospective quality assurance verifications shall operate and performed according to the regulatory guideline.
	3. Quality assurance personnel shall not be directly involved in trial-related activities. Quality assurance personnel shall not replace the oversight role to be undertaken by another appropriate person.
	4. The quality assurance unit shall be responsible for:
		1. verifying all activities undertaken during the study,
		2. ensuring that the quality management systems are followed, reviewed and updated,
		3. determining that the protocol and SOPs are made available to study personnel and are being followed,
		4. checking all the study data for reliability and traceability,
		5. planning and performing self-inspections (internal audits) at regular and defined intervals in accordance with an SOP,
		6. following up on any corrective action as required, to determine if all studies are conducted in accordance with GCP and GLP,
		7. ensuring that contract facilities adhere to GCP and, if applicable, to GLP,
		8. verifying that the trial report accurately and completely reflects the data from the study and the methods and procedures followed,
		9. promptly reporting audit findings in writing to management, to the investigator and to the study director, as applicable,
	5. The bioequivalence center shall allow the sponsor to monitor the studies and to perform audits of the clinical and analytical study and sites and shall provide suitable office space for these activities.
	6. Both in-process and retrospective quality assurance verifications including preparation and test of bioanalysis, as the samples and standards shall be performed.
	7. The quality management system shall include root cause analysis, tracking for trends, ensuring all aspects of data integrity and the implementation of appropriate corrective and preventive action (CAPA).
4. **Archive Facilities**
	1. The Bioequivalence Center shall have sufficient and appropriately secured storage space, which should be fireproof, relative humidity-controlled and pest-controlled, for archiving of the trial-related documentation and shall be protected from flooding.
	2. Archiving, documentation, both paper and electronic versions shall be easy to retrieve and traceable.
	3. Access to archive storage areas shall be controlled and restricted to authorized personnel.
	4. Records of document access and return shall be maintained.
	5. The length of time for which study documentation, including raw data, shall be kept in the archive for at least 10 years.
	6. An SOP shall be in place for archiving
5. **Premises**
6. The facilities shall be kept clean and shall have adequate lighting, ventilation and floors, walls and if applicable environmental control. Working bench surfaces shall be easy to clean and to decontaminate.
7. The site selected shall be appropriate to the potential risk involved and it shall ensure adequate safety for the subjects.
8. First-aid equipment and appropriate rescue medication shall be available and ready for emergency use at the study site.
9. There shall be adequate procedures in place to protect personnel from accidental infection while handling or disposing of infectious waste.
10. The bioequivalence center shall have sufficient space to accommodate the personnel and activities required to perform the studies in a logical order.
11. Entry to the facility shall be restricted and controlled and there shall be alarm systems to detect the exit of subjects from clinical facilities, or the doors shall always be locked except required for emergency evacuation. Any entry to and exit from the facility shall be recorded.
12. Sites where clinical activities take place shall include dedicated room where investigational products stored under appropriate conditions with entry and exit restricted by access control. Appropriate entry or exit records of each visit to the dedicated room shall be maintained.
13. Utilities such as water, air, gas and electricity shall be adequate, stable and uninterrupted.
14. Access to telephone and internet facilities shall be available to ensure proper communication.
15. The bioequivalence center shall have office with necessary equipment to perform the required activities.
16. Laboratory premises shall be designed to suit the operations to be carried out in them, with sufficient space and shall be provided to avoid mix-ups, contamination and cross-contamination, including adequate storage space suitable for samples, standards, solvents, reagents. Records shall be available in laboratory premises.
17. Laboratory premises shall be designed to provide adequate protection to all employees and authorized external personnel, including inspectors or auditors, by ensuring their safety while handling or working in the presence of chemicals and biological samples.
18. The general rules for safe working shall be congruent with national regulations, regulatory guidelines and shall be specified in appropriate SOPs include the following requirements.
19. Premises shall have suitable systems in place to dispose of waste, to treat fumes and to protect the environment in conformance with local or national regulations, guidelines and detailed in implementation SoPs.
20. The bioequivalence center shall have both bio-analytical center and clinical center. However, the clinical site may be outsourced. The outsourced clinical center shall fulfill all the requirements set forth in this directive.
21. The clinical and bio-analytical centers may be placed in the same premise or in different premises.
22. The admission part of the clinical center shall fulfill the national requirements for internal medicine specialty center and as indicated in the Annex 4.
23. **Personnel**
24. The bioequivalence center shall be directed by a technical manager who is a licensed physician or pharmacist with a minimum of five years clinical research experience.
25. The technical manager shall be responsible for the overall management of all technical activities.
26. There shall be Technical Manager, Pharmacologists, Biostatisticians, Quality Assurance Personnel, Clinical Investigators, Laboratory Technicians, Data Managers, Physicians, Nurses and Pharmacy Professionals, and Clerical Staff with the appropriate qualifications, training and experience to support the bioequivalence activities and to respond effectively to all reasonably foreseeable emergencies.
27. All the Bioequivalence center personnel shall adhere to the regulatory requirements stated in this directive and other regulatory guideline.
28. The number of members of staff required shall be determined depending on the number and complexity of the bioequivalence activities performed by the center.
29. At all stages of the activities, including at night, there shall be enough appropriately qualified and trained personnel to ensure that the rights, safety and well-being of the subjects are safeguarded, and to care for the subjects in emergency situations.
30. All workers who have access to bio analytical areas or who are performing bioequivalence related activities shall be provided with adequate information and training.
31. All the personnel involved in bioequivalence activities shall be provided job descriptions and contract workers shall sign their contracts before commencing their work.
32. Current curricula vitae and training records should be kept for full-time and contract workers.
33. **Technical Manager**
	1. Any technical manager who wants to leave the bioequivalence center shall notify the employer and the Authority at least one month before release.
	2. When the technical manager is absent from work without any notice to the employer.
		1. The organization shall notify the Authority immediately
		2. After doing required verification and conducting appropriate inspection the Authority shall order the organization to replace the technical manager within 30 days.
	3. When the organization ceases its operation without knowledge of the technical manager and the Authority.
		1. The technical manager shall notify the Authority immediately
		2. As appropriate, the Authority may verify the information from concerned government offices and by conducting inspection activities and other necessary verification activities, the Authority may revoke the certificate of competence; and the same shall inform concerned bodies.
	4. When the bioequivalence center refuses to provide a release letter to the technical manager while it is operating within the specified time frame, the Authority may approve the technical manager's request after verification activities are completed. If the bioequivalence center fails to replace its technical manager on time, the Authority shall take necessary administrative action.
34. **Bioequivalence Center Equipment**
35. All mandatory equipment required for the conduct of the bioequivalence activities shall be maintained in the center.
36. The Bioequivalence center shall have the equipment listed in Annex 6 to be authorized by the Authority.

**Part Four**

**Clinical and Bioanalytical Practice**

1. **Clinical Section**
	1. All the clinical study activities performed in the premises of a bioequivalence center or by contracted licensed premises in a licensed hospital shall adhere to the regulatory requirements stated in the clinical study directive and guidelines.
	2. At least 12 beds shall be available for the subjects in the clinical site. The necessity for beds and for overnight stays depends on the type of trial and investigational product and shall be specified in the trial protocol.
	3. There shall be an arrangement for urgent transportation of subjects to a hospital or clinic equipped for their emergency care, if required.
	4. The adequate function and performance of emergency-use equipment such as defibrillators shall be verified at appropriate intervals.
	5. Equipment used shall be appropriately calibrated at predefined intervals.
	6. Access to key documents, such as the randomization list, shall be restricted to specific personnel, such as the pharmacist in charge of the study. Such documents shall be password-secured (if electronic) or kept under lock and key (if in the form of a hard copy) and their distribution should be documented.
	7. All the clinical laboratory activities performed in the premises of a bio-equivalence center shall adhere to the regulatory requirements stated in this directive and GLP guideline.
2. **Ethical Requirements**

All the ethical requirements required to be observed during a clinical study in the premises of a bioequivalence center or by a contracted premises shall be observed as per the regulatory requirements stated in this directive.

1. **Informed consent**
	* 1. There shall be standard operating procedure for taking informed consent.
		2. Informed consent shall be taken and recorded as of clinical trial directive.
2. **Monitor**
	* 1. The bioequivalence center shall have appropriately qualified monitor as per the clinical trial directive during the conduct of study
		2. The main responsibility of the monitor is to ensure that the studies conducted in the bioequivalence center is conducted in accordance with the protocol, Good Clinical Practice, Good Laboratory Practice and applicable ethical and regulatory requirements and has the responsibilities mentioned on clinical trial directive.

#  **Investigators**

* 1. The sponsor or the bioequivalence center shall select the principal investigator for the conduct of specific bioequivalence study.
	2. If the bioequivalence center carry out bioequivalence study, the principal investigator shall have the responsibility to conduct the bioequivalence study as per the clinical trial directive.
1. **Safety, Adverse Events and Adverse Event Reporting**
	1. The Bioequivalence center shall provide first-aid services and appropriate rescue medication at the study site.
	2. The bioequivalence center shall have appropriate adverse event registration and reporting forms.
2. **Bioanalytical Section**
	1. The measurement of analyte concentrations of API or metabolites shall be performed by the same bioequivalence center as conducted the clinical study, or this work may be contracted to another nationally or internationally accredited laboratory or bioequivalence center.
	2. The bioanalytical laboratory shall provide a detailed description of how a bioanalytical method was developed, justify the internal standard by sound scientific principles and procedure for method development shall ensure that methods are created in a manner that will minimize any potential human error.
	3. The laboratory shall keep a copy of any publications used in developing the bioanalytical method. The modifications and adaptations to the published method made by the laboratory shall be documented.
	4. All the validation requirements for the analytical method shall be described in the protocol and shall be stated in separate SOPs for analytical method validation, as indicated in the regulatory bioequivalence guideline.
	5. Selection of the internal standard shall be justifiable by sound scientific principles as indicated in the bioequivalence studies’ guideline.
	6. The procedure for method development shall ensure that methods are created in a manner that will minimize any potential human error.
3. **Good laboratory practices**
	1. Principles of GLP shall be followed during the bio-analytical part of bioequivalence studies.
	2. There shall be clear procedure for sample transfer from bioequivalence center to bio analytical laboratories.
	3. There shall be SOPs for the operation, use, calibration, checks and preventive maintenance of equipment.

**Part Five: Investigational Product**

1. **Receiving, Storage and Handling of Investigational Products**
	1. Bioequivalence centers shall have separate SOPs for receipt, storage, handling and accountability of investigational products, dispensing, administration, reconciliation, disposal, keeping records of information about the shipment, delivery and labeling requirements of investigational products as per the regulatory guideline.
	2. The bioequivalence center shall have SOP for randomization and records including the randomization list.
	3. There shall be appropriate labeling on the investigational products. The labeling shall include the following information:
		* 1. name of the sponsor,
			2. a statement reading “for clinical trial use only”,
			3. trial reference number or study number,
			4. batch number,
			5. subject identification number (to whom the product is destined to be given),
			6. study period,
			7. active ingredient and dosage,
			8. the storage conditions,
			9. expiry date (month/year) or retest date,
			10. identification of the product (i.e., test or reference).

**PART SIX**

**ADMINISTRATIVE MEASURE AND COMPLAINT HANDLING PROCEDURE**

1. **Written Warning**
	1. Corrective notification shall be given by the Bioequivalence Canter Inspection and Enforcement Lead Executive Office when violations are significant enough for the issuance of a corrective notification letter and reasonable expectation exists that the inspector will correct the violation.
	2. Corrective measures shall be given by the Bioequivalence Canter Inspection and Enforcement Lead Executive Office in written form immediately after completion of the inspection.
2. **Warning Letter**

The Regulatory authority shall issue warning letters to bioequivalence studies center or sponsors for violates the provisions of regulatory requirements in following conditions.

* 1. When the staff members are not trained to all relevant regulatory requirements
	2. When the key personnel are not found during the inspection time for the first time
	3. When the premises are not clean and well organized
	4. When there is no dated and signed job description for any of the key personnel.
	5. When there are no stable and uninterrupted utilities such as water, power, light…
	6. When minor violation of work place discipline
	7. When the quality assurance activities are not conducted in well-organized reporting system during verification.
1. **Suspension**

The Regulatory authority shall suspend the bioequivalence studies center or sponsors for violates the provisions of regulatory requirements in following conditions.

* 1. Impedes the work of inspectors during inspection or during discernment of inspectors for inspection or removing or hiding of study related information, products during the inspection or other similar violations
	2. When entry to the facility or access to data is not restricted and controlled
	3. Refusal to replace the leaving Technical Manager within 30 days
	4. Repeated violation of the rules despite receiving written warning for the same violation
	5. When the bioequivalence center changes key personnel without notification to the authority
	6. The bioequivalence center doesn’t respond to ethical violation of the subjects involved in the trial observed by the inspectors or confirmed report received by the Ethics committee
	7. The bioequivalence center fails to reports serious adverse events to the Authority
	8. Inadequate documentation and record-keeping practices
1. **Cancelation**
2. The Regulatory authority shall cancel the bioequivalence studies center or sponsors for violates the provisions of regulatory requirements in following conditions.
3. Any form of data falsification, fabrication, or selective reporting
4. Conducting bioequivalence study not approved by the Authority in the bioequivalence center.
5. Changing the facility address without prior notification to the Authority
6. Non-compliance with Protocols
7. Engaging in practices that create conflicts of interest, such as financial ties between the CRO and the sponsor that could influence study outcomes
8. Failing to ensure the safety and well-being of study participants, including inadequate monitoring for adverse events
9. Non-compliance with Good Clinical Practices (GCP), Not adhering to GCP guidelines, which cover ethical and scientific quality standards for designing, conducting, recording, and reporting trials
10. Conduct of any illegal activities which are against laws and adversely affect the safety, well-being and right of the participants
11. When the center involved in conduct of the activities which are not under the scope of license, unscientific and unethical issues.
12. Failure to renew the COC in proper time
13. The COC shall be revoked when the inspection findings are critical and this happens repeatedly after serious of warnings/suspensions
14. **Complaint Handling**

Any person who is dissatisfied with the administrative decisions of the Authority shall lodge his/her complaint to the grievance handling committee of the Authority.

**PART SIX**

**MISCELLANEOUS**

1. **Confidentiality and Conflicts of Interest**
	1. The selected inspector shall declare and sign the conflicts of interest and confidentiality agreement before participating in the Bioequivalence Centre inspection and shall follow respective SOPs and directions
	2. The inspector shall properly maintain confidential information of the Bioequivalence Center unless the bioequivalence Center discloses it.
	3. The inspectors shall properly maintain confidential information unless the judiciary body requires it.
2. **Record Handling**

The Bioequivalence Centre Inspection and Enforcement Lead Executive Office shall keep all relevant documents pertaining to Bioequivalence Centre inspection activities including inspection report for at least until re- inspection done and shall fulfil the requirements on Record Handling Directive.

1. **Service Fee**

Any person who seeks regulatory service under this directive may be required to pay applicable service in accordance with current rate of service fees regulation.

1. **Inapplicable laws**

1) With respect to matters provided by this directive, the Pharmaceutical bioequivalence Centre Inspection Directive --------------, is hereby repealed.

1. **Effective date**

This directive shall enter into force on the date of October 2024.

**Heran Gerba**

**Director General**

**Ethiopian Food and Drug Authority**

**Annex 1: Application Form**

**Annex 2: Application form for change location, ownership, technical manager**

**Annex 4. premises for clinical**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Sr.no  | Premise required  | Number of rooms require  | Minimum area of a room required  | Total area of rooms required  |
| 1 | Reception, Registration/ Recording | 1 | 16 sq. m | 16 sq. m |
| 2 | Screening and consenting room  | 1 | 12 sq. m | 12 sq. m |
| 3 | Emergency and treatment room  | 1 | 12 sq.m  | 12 sq.m  |
| 4 | Admission room with beds  | 2 | 48 sq.m | 96 sq.m |
| 5 | Nursing room | 1 | 12 sq.m | 12 sq.m |
| 6 | Physicians room | 1 | 12 sq.m | 12 sq.m |
| 7 | Clean utility room | 1 | 6 sq.m | 6 sq.m |
| 8 | Soiled utility room | 1 | 6 sq.m | 6 sq.m |
| 9 | Archive room | 1 |  |  |
| 10 | Room for storage of investigational product | 1 |  |  |
| 11 | Office  | 1 |  |  |
| 12 | Canteen  | 1 |  |  |
| 12 | Toilet (male and female) | 2 | 4sq. m | 8 sq.m |

**Annex 5. Premises for Bioanalytical**

|  |  |  |  |
| --- | --- | --- | --- |
| Sr.no  | Premise required  | Number of rooms require  | Area required  |
| 1 | bioanalytical room  | 1 | 16 sq. m |
| 2 | Screening and consenting room  | 1 | 12 sq. m |
| 3 | Emergency and treatment room  | 1 | 12 sq.m  |
| 4 | Admission room with beds  |  |  |

**Annex 6: List of Equipment**

|  |  |
| --- | --- |
| No. | Equipment  |
| 1 | HPLC + Photodiode Array detector + Fluorescence detector |
| 2 | UP LC / MS - MS |
| 3 | Dissolution Apparatus |
| 4 | Spectrophotometer |
| 5 | Analytical Balance (4 digits) |
| 6 | Analytical Balance (3 digits) |
| 7 | pH meter |
| 8 | Deep Freezer (-80) |
| 9 | Vortex Mixer |
| 10 | Water Distiller |
| 11 | Cooling Centrifuge |
| 12 | Hot Plate & magnetic stirrer |
| 13 | Disintegration Tester |
| 14 | Hardness Tester |
| 15 | Friability Tester |
| 16 | Drying Oven |
| 17 | Rotary evaporator |
| 18 | Sonicator |