Updated Requirements for Centers Conducting Bioavailability, Bioequivalence, and In-Vitro Dissolution Studies Year 2024

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Content for Notice to applicant
Requirements for Centers Conducting Bioavailability, Bioequivalence, and In-Vitro Dissolution Studies

1. The premises shall be dedicated exclusively to conducting the relevant studies (bioavailability, bioequivalence, and In-Vitro Dissolution studies).
2. The premises shall be adequate in terms of space, with a minimum total area of 500 m², appropriately divided to facilitate workflow within the center. The center shall have a separate emergency exit independent from the volunteers' accommodation area and the clinical study area.
3. The center shall be fully air-conditioned (either by means of a central air-conditioning system or air-conditioning units installed in all rooms).
4. The center may occupy one or more floors above ground level, provided that all occupied floors are consecutive and located within the same building.
5. A sign displaying the center's name in both Arabic and English shall be installed in a clearly visible location outside the center at an appropriate height for visibility.
6. A system shall be available to ensure uninterrupted electrical power supply to the center for an appropriate period following any power outage (e.g., an electrical generator installed in a safe and separate location and equipped with a suction system).
7. Signboards in both Arabic and English shall be affixed to all rooms within the center. In the event that the center occupies more than one floor, a floor plan for each floor showing the contents of each floor shall be displayed, with all rooms appropriately numbered.
8. A fire protection system covering all rooms shall be available. Alternatively, fire extinguishers shall be provided adjacent to each room. Fire extinguishers shall be valid for use and bear labels indicating the date of the next maintenance or calibration.

9. Surveillance cameras shall be installed throughout the center, excluding volunteers' accommodation rooms and toilets. Appropriate signs indicating the presence of surveillance cameras shall be displayed.
10. Requirements for Center Rooms

No.	Center Room	Requirements
1	Reception	Shall contain: • One desk and a number of chairs. • One synchronized wall clock.
2	Screening Area	Shall contain: • One desk and at least 24 chairs. • A display screen for presenting all necessary instructions.
3	Administration Room	Shall contain: • A desk equipped with a computer dedicated to all administrative activities, including an electronic archiving system and data backup system. • A library or filing cabinets for storing paper and electronic records, including records documenting the receipt date, type, quantity, and all related documents concerning pharmaceutical products. • A paper waste bin. • A synchronized wall clock.
4	Data Processing Room	Shall contain: • A sufficient number of desks equipped with computers dedicated to data processing, study report preparation, statistical analysis, and all related calculations. All computer software used shall be

		updated and validated. The room shall also include an electronic archiving system and data backup system. • An Access Control system with a list of personnel authorized to access the database. • A waste bin. • A synchronized wall clock.
5	Archive	Shall contain: • Adequate shelving for orderly storage of study files to facilitate retrieval whenever required. • Fire-resistant doors and an internal fire suppression system. • An Access Control system.
6	Subjects' Housing Room	Shall contain: • A minimum of 40 beds. • The room shall be well ventilated, with adequate spacing between beds and sufficient ceiling height to ensure safe movement and humane accommodation of volunteers. • Where bunk beds are used, the distance between the upper bed and the ceiling shall not be less than one meter. • An adequate number of lockers for volunteers' personal belongings and separate lockers for bed linens. • Windows shall be fitted with wire mesh and metal bars. • A synchronized wall clock. • A nurse call system installed adjacent to every bed.
7	Dining Room	Shall contain: • A well-ventilated area separate from the blood sampling rooms.

		• A minimum of 40 chairs and dining tables. • A synchronized wall clock. • A waste bin for food and beverage waste.
8	W. Cs (Toilets)	An adequate number of toilets shall be provided outside the volunteers' accommodation rooms and shall include: • Exhaust fans of suitable capacity according to the area. • Waste bins. • An emergency door-opening alarm/system allowing opening from outside in emergency situations.
9	Clinic	The clinic shall be well ventilated and have a minimum area of 2 m × 3 m, allowing adequate movement and prompt emergency management. It shall be located adjacent to the volunteers' accommodation rooms and the blood sampling room, and shall contain: • An examination bed. • A cabinet dedicated to emergency medications, with a list affixed showing all medication names and expiry dates. • Blood pressure monitor. • Blood glucose meter. • Pregnancy test strips. • Drug abuse screening test strips. • Thermometer. • Height and weight measuring device for volunteers. • First-aid supplies and all essential study-related medical supplies. • Two waste containers: one for biohazardous waste and one for general paper waste. • A synchronized wall clock.

10	Samples' Withdrawal Room	Shall contain: • An adequate number of chairs. • An adequate supply of cannulas of different sizes. • An adequate supply of sterile syringes. • Two waste containers for biohazardous waste and general paper waste. • A safety box for used syringes. • An ice box or a refrigerator equipped with a thermometer and a nearby temperature recording log for temporary storage of samples. • One bench-top centrifuge. • A white board or electronic board displaying sample collection times. • A synchronized wall clock.
11	Sample Separation Room	Shall be well ventilated and contain at least two bench-top centrifuges.
12	Chemical Store	Shall contain: • Adequate ventilation and lighting. • Separate storage for liquid and solid chemicals. • Fire-resistant doors and an internal fire suppression system. • Cabinets and shelves with labels indicating the names and expiry dates of stored chemicals. • A data logger for temperature and humidity monitoring, with records displayed nearby. • One or more exhaust fans appropriate to the room area. • Sand buckets for acid spills. • A refrigerator equipped with a thermometer and temperature records for chemicals requiring refrigerated storage.

		• An Access Control system.
13	Drug Samples Store	Shall contain: • Cabinets for storage of reference and test pharmaceutical products intended for the study, with labels indicating product name, manufacturing date, expiry date, and date of receipt. • A data logger for monitoring temperature and humidity, with records displayed nearby. • A dehumidifier. • An exhaust fan. • Adequate lighting. • A refrigerator equipped with a thermometer and temperature records for products requiring refrigerated storage. • An Access Control system.
14	Wastes' Disposal Area	A separate room shall be designated within the center for the centralized collection of study-generated waste. The room shall have an entrance and exit separate from the main entrance and exit of the center. It shall contain: • Two waste containers for biohazardous waste (including used syringes) and general waste. • An exhaust fan of suitable capacity according to the room area. • Log sheets documenting the dates of waste receipt and disposal, to be updated periodically.
15	Offices for the Center Organizational Staff	----------

16	Deep Freezer Rooms (-80°C & -20°C)	It is preferable that the deep freezer rooms: 1. Be located close to the laboratories. 2. Be well ventilated and adequately illuminated. 3. Be equipped with a temperature and humidity monitoring device (Data Logger), with monitoring records maintained nearby. 4. Be provided with an Access Control system. 5. Be connected to an Uninterruptible Power Supply (UPS). 6. For the -80°C deep freezer room, an advanced alarm system shall be available to alert in case of door opening or power failure. 7. Calibration certificates and maintenance contracts shall be available for each freezer, with a label indicating the next calibration due date affixed to each unit. 8. A Log Book shall be maintained adjacent to each freezer documenting its contents as well as sample receipt and removal dates.
17	Laboratory(ies) One or more laboratories shall be available, with identification labels displayed on each laboratory door. Laboratories shall comply with the World Health Organization (WHO) Good Laboratory Practice (GLP) requirements	1. Walls and ceilings shall be constructed of inert materials and shall not contain wooden lining or any combustible material. 2. Flooring shall be rough, non-slip, and suitable for laboratory work. 3. Adequate natural and mechanical ventilation shall be provided (e.g., HEPA filters and/or air ventilation systems). 4. A sufficient number of easily operable windows shall be distributed to provide proper ventilation and lighting.

		5. High-quality laboratory exhaust systems specifically designed for laboratories shall be available. 6. The laboratory shall contain all equipment necessary for conducting the study and shall be equipped with an Access Control system. 7. The drainage system shall be independent. 8. Walls shall be coated with plastic paint. 9. Laboratory bench tops shall be constructed of smooth, chemical-resistant materials. 10. A fume cupboard shall be available for handling hazardous chemicals and concentrated acids after opening. 11. Every chemical container or bottle shall be labeled with the opening date immediately after first use. 12. Standard powders (Working Standards and USP Standards) shall be stored in a refrigerator, with an inventory list indicating all stored standards and their expiry dates. 13. A temperature and humidity monitoring device (Data Logger) shall be available, with monitoring records maintained nearby. 14. Appropriate storage areas shall be provided for laboratory glassware. 15. A Log Book shall be available beside each instrument, documenting the user's name, date of use, and purpose of use. 16. Standard Operating Procedures (SOPs) or operating instructions shall be available adjacent to each instrument. 17. All accessories and components required for proper operation of each instrument shall be available.

		18. Calibration certificates and maintenance contracts shall be available for each instrument, with a label indicating the next calibration due date affixed to each instrument. 19. A waste management plan shall be available. 20. A list of general laboratory safety rules shall be displayed in both Arabic and English. 21. A dedicated room shall be provided for sensitive instruments (e.g., sensitive digital balances). Balances shall be routinely calibrated before use. The room shall contain stable, level benches fixed to the floor, adequate lighting, and a temperature and humidity monitoring device (Data Logger), with monitoring records maintained nearby.

11. Essential Laboratory Equipment:

1. HPLC with different detectors, equipped with the most updated validated software, connected to an UPS Supply, and provided with an Access Control.
2. LC-MS or LC-MS/MS (If any), with the most updated validated software, connected to an UPS, and Access Control.
3. Double-Beam UV Spectrophotometer.
4. Sample Concentrator with vacuum and temperature control.
5. Filtration Kit with vacuum pump.
6. Sonicator.
7. Oven.
8. pH Meter.
9. Bench-Top Centrifuge.
10. Micropipettes with holder.
11. Magnetic Stirrer.
12. Vortex Mixer.

13. Deep Freezer (-80°C), equipped with the most updated alarm system and connected to an UPS.
14. Refrigerator with a thermometer and connected to an UPS.
15. Sensitive Digital Balance with a minimum 4 digits accuracy.
16. Analytical Balance.
17. Water Purification System (Deionizer).
18. USP Dissolution Apparatus with a minimum of six vessels.
19. Disintegration Apparatus.
20. Cooling Centrifuge.

12. Organizational Structure (Organogram)

1. Center Manager (full-time), holding a Bachelor's degree in Pharmaceutical Sciences and having not less than five years of relevant experience in the same field.
2. Technical Manager (full-time), holding a Ph.D. in Pharmaceutical Sciences with specialization in Pharmaceutics, Pharmacology, or Clinical Pharmacy only.
3. Quality Assurance Manager (full-time), holding an appropriate university degree with at least one year of relevant experience in the same field, and shall be independent from the other members of the center.
4. Chief Analyst (full-time), holding a Master's degree in Analytical Chemistry or a Diploma in Analytical Chemistry, with at least one year of relevant experience in the same field.
5. Analysts, holding a Bachelor's degree in Pharmaceutical Sciences or Basic Sciences.
6. Physician, a Specialist or Consultant in Internal Medicine, who shall be present throughout the volunteers' stay at the center.
7. At least two qualified nurses trained in blood sample collection.
8. Administrative personnel and secretarial staff.
9. Housekeeping staff.
10. Security personnel.

The center shall ensure that all members of its organizational structure are Egyptian nationals or hold a valid license to practice their profession in the Arab Republic of Egypt. The center shall maintain the curricula vitae (CVs), organizational chart, employment contracts, full-time declarations, and copies of all academic qualifications and professional certificates of its staff members.

13. General Rules

1. A license shall be granted to a Bioavailability and Bioequivalence Center upon fulfillment of all applicable health and technical requirements. For Bioavailability and Bioequivalence Centers affiliated with governmental authorities, research centers (specialized in pharmaceutical sciences), or Faculties of Pharmacy, the license shall be issued in the name of the legal entity applying for the license (e.g., the Special Unit of the Faculty of Pharmacy, … University, or the relevant authority or research center). The entity shall designate a licensed pharmacist to represent it in all matters related to the center. Bioavailability and Bioequivalence Centers affiliated with pharmaceutical companies shall not be licensed, whether located inside or outside the company's premises or manufacturing site.
2. All instruments and equipment shall be calibrated and maintained periodically in accordance with contracts concluded with competent service providers, based on the requirements of ISO/IEC 17025. Such providers shall either comply with the standard or be accredited by the National Accreditation Council. Calibration certificates issued by the official agent of the equipment may also be accepted.
3. All biological samples collected from volunteers (including plasma and urine samples) shall be analyzed within the center's premises, and analysis outside the center shall not be permitted.
4. No biological samples related to studies not conducted by the center shall be present within the center.
5. An Ethics Committee / Institutional Review Board (IRB) shall be established in accordance with the applicable Regulatory Guideline.
6. The center shall comply with the international standards of Good Laboratory Practice (GLP) and Good Clinical Practice (GCP).

7. A complete file of Standard Operating Procedures (SOPs) shall be prepared in accordance with the applicable Regulatory Guideline.
8. A contract shall be concluded with a nearby hospital to receive and manage any emergency cases involving volunteers that may arise during the conduct of a study.
9. A contract shall be concluded with a hospital or another competent authority for the disposal of waste generated during the study.
10. A contract shall be concluded with a licensed laboratory accredited by the relevant accreditation bodies to perform laboratory investigations for volunteers.
11. An insurance policy shall be obtained from an insurance company licensed to operate in the Arab Republic of Egypt for the benefit of study volunteers, covering any study-related injuries or damages. The insurance policy shall provide coverage for an adequate number of volunteers, not fewer than thirty-six (36) volunteers.
12. Study files, reference and test product samples, and all study-related records and data shall be retained for a minimum period of five (5) years from the date of approval of the study by the Committee for Evaluation of Bioavailability and Bioequivalence Studies for Human Pharmaceutical Products.
13. A Center Master File shall be prepared and maintained in accordance with the applicable Regulatory Guideline.