Notice to applicant

Central Administration of Pharmaceutical Products
General Administration For Stability

Technical requirements of the stability centers and units

Year 2024

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1- Organization and management organogram (For stability centers)

a- Full-time director holds a bachelor's degree in Pharmacy / Pharmaceutical Sciences / Bachelor of Pharmacy (PharmD), and must be Egyptian.

b- Full-time physical and chemical analysis supervisor holds a diploma or master's degree in pharmaceutical/medicinal chemistry from faculty of Pharmacy / Pharmaceutical Sciences or holds a diploma or master's degree in analytical chemistry from faculty of Pharmacy / Pharmaceutical Sciences or from faculty of Sciences.

c- Analysts hold a bachelor's degree in Pharmacy / Pharmaceutical Sciences / Bachelor of Pharmacy (PharmD) or a bachelor of Science.

d- Quality assurance manager holds a bachelor's degree in Pharmacy / Pharmaceutical Sciences / Bachelor of Pharmacy (PharmD) provided that be independent and report directly to the stability center / unit director.

e- In case of presence of microbiological testing laboratory:

Full-time microbiological analysis supervisor holds a diploma or master's degree in microbiology from faculty of Pharmacy / Pharmaceutical Sciences or from faculty of Science.

2- Equipment and other devices

A- General mandatory equipment and other devices

i. Stability cabinets / chambers

a- There must be – as minimum - an accelerated stability cabinet/chamber and a long-termstability cabinet/chamber achieve the specified conditions limits for temperature and relative humidity.

b- The cabinets should be equipped with an alarm system (audible sound or appropriateelectronic system) automatically works when the cabinets conditions are out of the specified limits.

c- The cabinets should be supplied with an alternative electric current source as electricgenerator or Uninterruptible Power Supply (UPS).

d- There must be -as minimum - a calibrated external data logger in each stabilitycabinet/chamber to monitor and record the worst location for temperature and humidity.

ii. Physical and chemical laboratory equipment

The stability center / unit must have - as minimum - the following equipment needed in the stability testing of the products:

- High performance liquid chromatography apparatus connected to UPS, (at least one HPLC with PDA detector)
- 4-digits analytical balance (preferably a 5-digit balance), with standard testweights.
- Double beam spectrophotometer (connected with software for data retrieval)
- pH meter, with standard certified buffer solutions
- Karl fisher

- Oven or IR moisture analytical balance
- Sonicator
- Magnetic stirrer
- Vortex mixer
- Water bath
- Water distillator
- Refrigerator with external data logger
- Photostability cabinet
- Presence of fuming hoods for the use of hazardous chemicals.
- Glasswares

iii. Microbiological laboratory equipment

The microbiological laboratory is involved in:

- sterility testing;
- detection, isolation, enumeration and identification of microorganisms (bacteria, yeast and moulds)
- testing for bacterial endotoxins
- assay using microorganisms
- serological assays

The microbiological laboratory must have - as minimum – the following equipment:

- Hot air oven
- Bunsen burner
- Water bath or hot plate with magnetic stirrer
- Two autoclaves one for preparation & another for destruction
- 3 Incubator for bacteria, fungi and bio-indicator
  (The incubators should be supplied with an alternative electric current source aselectric generator or Uninterruptible Power Supply (UPS))
- Thermometer
- Membrane filter set
- Auxiliary tools as (micropipette – cuvettes – loops – autoclavable glasses)
- Microscope
- pH meter
- Analytical balances
- Dynamically interlocked pass box (pass-through hatches (PTH)) for media entryto the LAF clean room
- Laminar Airflow (LAF) unit / Unidirectional Airflow (UDAF) unit
- Biosafety cabinet (at lease class 2)
- Refrigerator with external data logger
- Mechanical freezer
- Source of purified or distilled water should be supplied

B-Specialized function – dependent equipment

i. For solid dosage forms stability studies:

- Dissolution apparatus
- Disintegration apparatus
- Hardness tester
- Friability tester

ii. For sterile dosage form stability studies:

- Particulate matter counter

iii. For liquid and semisolid dosage forms stability studies:

- Rotational viscometer

C-Requirements for equipment

a- Equipment and stability cabinets / chambers should be regularly calibrated by accredited calibration laboratory (ISO 17025) in the scope of the calibration of equipment /cabinets or the official representative/agent of the equipment/cabinets, otherwise shall be investigated by General Administration of Stability, adequate records of such tests (calibration certificates) should be maintained.

b- Records should be kept for the maintenance plan of equipment and the maintenance carried out containing history of any damage, malfunction, modification or repair

c- Equipment / cabinets should be labelled, to indicate the status of calibration and the date when recalibration is due.

d- The laboratory should establish, implement and maintain authorized, written SOPs at the relevant locations near instruments for the use, verification and calibration of equipment.

e- Specific requirements should be established for some measuring equipment, forexample, but not limited to:

- pH meters are verified with standard certified buffer solutions before use.
- balances are to be checked daily using internal calibration and regularly usingstandard test weights.

f- The microbiological testing of products should take place in a controlled environment,zones in which operations could be carried out as the following grades (see table (1))

g- The qualification of cleanrooms:

- The maximum time interval for requalification of grade A and B areas is6 months.
- The maximum time interval for requalification of grade C and D areas is 12months.

Table (1)

Zone & Operation	Grade
Sample receipt, autoclave, media preparation before sterilization	Unclassified
Sterility testing — LAF/UDAF	Grade A

Sterility testing — background to LAF/UDAF	Grade B
Sterility testing — isolator (Optional)	Grade A
Sterility testing — background to isolator	Unclassified
Microbial limit test - LAF/UDAF	Grade A
Microbial limit test – background to LAF/UDAF	Grade C

3- Documentations & Records

Operation logbooks (apparatus, analyst and cabinet logbook) should be organized, inseparable (not lose or coiled), paginated, has unique identifier (coded/serial number) andcontaining the following data:

- For cabinet logbook: (cabinet type & its storage conditions - model name & number - name of product & its concentration - dosage form - batch number – manufacturing and expiry date - batch type - applicant name - manufacturer name - number of samples - date of samples entry - dates of samples withdrawal - name of operator).
- For analyst logbook: (name of analyst - name of product - names of active constituents and its concentration - dosage form - batch number - manufacturing and expiry date - type of study - steps that followed - standard details - calculations in details).
- For apparatus logbook: **(**apparatus name - model number - date of any operation -name of product - dosage form - batch number - type of study - name of analyst).

4- Data Integrity

a- Date and time control shall be locked on computers connected with laboratory apparatus.

b- No PDF Editor applications shall be present on laboratory apparatus.

c- Chromatography equipment should have validated chromatography data systems with complete audit trail.

5-Outsourced activities and contracts

Outsourcing testing such as microbiological analysis or photostability studies, the stability center / unit set a written, legalized and signed contract with EDA licensed organizations for the type of tests required which clearly defines the subcontracted test