NAFDAC Active Pharmaceutical Ingredient (API) Regulations 2026

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NAFDAC Active Pharmaceutical Ingredient (API) 2026

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National Agency for Food and Drug Administration and Control (CAP N1 LFN 2004)

NAFDAC Active Pharmaceutical Ingredient (API) Regulations 2026

[] Commencement

In exercise of the powers conferred on the Governing Council of the National Agency for Food and Drug Administration and Control (the Governing Council') by Section 30 of the National Agency for Food and Drug Administration and Control Act, Cap. N1, LFN, 2004 and Section 12 of the Food, Drugs and Related Products (Registration, Etc.) Act. Cap. F33. LFN, 2004 and of all the powers enabling it in that behalf, the Governing Council with the approval of the Minister makes the following Regulations: -

Part I
Objective and Application

1. **Objective**

The objective of these Regulations is to provide framework for the regulation of Active Pharmaceutical Ingredients (APIs) manufactured, imported, exported advertised, sold, displayed for sale, distributed or used in Nigeria.

2. **Application**

(1) These Regulations shall apply to the
   (i) requirements for Active Pharmaceutical Ingredients (APIs) manufactured, imported, exported, advertised, sold, distributed, or used in Nigeria.
   (ii) manufacturing, processing, packaging, or handling of API for human or animal use.

(2) These Regulations shall provide the minimum.
   (i) Good Manufacturing Practice (GMP) requirements for the methods, facilities and controls to be used for manufacturing, processing, packaging or handling of Active Pharmaceutical Ingredients (APIs) for human or animal use, to ensure that such API meets safety requirements, has the identity and strength that meets the quality and purity characteristics that it purports to possess.
   (ii) provide the minimum requirements for drug substances to be used in the manufacture of finished products destined to be imported to or exported from Nigeria.

(3) Drug substances to be used to manufacture finished products meant for Nigerian market shall meet any of the following standards:
   (i) Registered by NAFDAC through the NAFDAC API registration scheme
   (ii) Prequalified by WHO
   (iii) Have certificate of suitability to the monographs of the European Pharmacopoeia (CEP)

(4) The scope of these Regulations apply to;
   (i) manufacture of APIs for use in medicinal products.
   (ii) APIs manufactured by chemical synthesis, extraction, cell culture, fermentation, by recovery from natural sources, or by any combination of these processes.
   (iii) APIs produced using blood or plasma as raw materials.
   (iv) The manufacture of sterile APIs only up to the point immediately prior to the APIs being rendered sterile.

(5) This Regulation excludes
   (i) vaccines, whole cells, whole blood and plasma, blood and plasma derivatives, plasma fractionation, and gene therapy APIs. However, it does include APIs that are produced using blood or plasma as raw materials.

(ii) medical gases, bulk-packaged drug or medicinal) products, and manufacturing or control aspects specific to radiopharmaceuticals.

Part II
Pharmaceutical Quality System, Personnel, Premises and Equipment

3. **Pharmaceutical Quality System**

(1) The manufacturer shall establish a quality system to cover organizational structure, responsibilities, policies, procedures, processes, and application of the principles of risk management, as well as appropriate resource management, compliance management, and records management.

(2) Top Management of the organization shall have the responsibility to ensure that the;

(a) quality system is in place, adequately resourced and its effectiveness is continually improved and sustained; and

(b) roles, responsibilities, and authorities are defined, communicated, and implemented in the organization.

(3) The organizational structure shall clearly define the responsibilities, authorities, interrelationships, and qualifications of personnel in the organization as well as its place in the parent organization where applicable.

(4) Procedures are in place for notifying responsible management in a timely manner of regulatory inspections, serious GMP deficiencies, product defects and related actions including quality-related complaints, recalls, and regulatory actions.

(5) Regular quality -reviews of APIs shall be conducted and documented annually. The results of the review shall be evaluated and corrective actions implemented where applicable.

4. **Personnel**

(1) The manufacturer shall have sufficient number of competent and appropriately qualified personnel to perform assigned functions and achieve the quality management objectives.

(2) Initial and continuing training shall be done in relation to the operation that the employee performs and in good manufacturing practices as they relate to the employees' functions, the effectiveness of the training shall be verified, and the records of training kept.

(3) Where the holder of a Certificate of Registration engages a Consultant to advice on the manufacture, processing, packaging, or holding of APIs, the Consultant shall have necessary education, training, and experience, or any combination thereof, to advise on the subject for which they are retained and records maintained stating the name, address, and qualifications of the consultant and the type of service provided.

(4) Hygiene programmes shall include procedures relating to health, hygiene practice and clothing of personnel, adapted to the activities to be carried.

(5) Person shown at any time either by medical examination or supervisory observation to have an apparent illness or open lesions shall be excluded from activities where the health condition could adversely affect the quality of the APIs until the condition is corrected or qualified medical personnel determine that the person's inclusion would not jeopardize the safety or quality of the APIs.

5. **Premises and Equipment**

(1) Building and equipment used in the manufacture, processing, packaging, or holding of an API or starting materials shall be adequately located, designed, constructed, adapted, maintained and of suitable size to facilitate cleaning, maintenance, proper operations and safety of operators as appropriate to the type and stage of manufacture.

(2) Building used in the manufacture of intermediates and APIs shall have adequate space for the

orderly placement of equipment and materials and have orderly flow of personnel, materials and processes through the building to prevent mix-ups, contamination, cross contamination and any adverse effect on the quality of the API or starting materials.

(3) There shall be dedicated and self-contained facilities for the production of different classes of highly sensitive penicillins or cephalosporins and potent APIs including certain steroids or cytotoxic anti-cancer agents, to minimize the risk of serious medical, occupational, or environmental hazards.

(4) Production activities including weighing, milling, or packaging of highly toxic non- pharmaceutical materials, such as herbicides and pesticides, shall not be conducted using the buildings and equipment being used for the production of APIs. Handling and storage of these highly toxic non-pharmaceutical materials shall be separate from APIs.

(5) The manufacturer shall establish a program for preventive and breakdown maintenance of equipment and instruments, inclusive of GMP support facilities.

(6) Utilities including direct and indirect impact utilities that could affect product quality (e.g., steam, gas, compressed air, Heating, Ventilation and Air Conditioning (HVAC), Water for Pharmaceutical Use shall be qualified and appropriately monitored and actions taken when limits are exceeded. Water used in the manufacture of APIs shall be demonstrated to be suitable for its intended use.

(7) Measures shall be in place to mitigate environmental health and occupational safety impacts associated with API manufacture.

(8) The manufacturer shall establish a program for safe, timely, and sanitary disposal of sewage, refuse, and other waste including solids, liquids, or gaseous by-products from manufacturing and from buildings and the immediate surrounding areas.

Part III
Qualification and Validation, Documentation, Production, Materials Management

6. **Qualification and Validation**

(1) Premises and equipment to be used for manufacturing operations, which are critical to the quality of the products, shall be subjected to appropriate qualification and validation.

(2) Critical processes and GMP support systems shall be validated, continually monitored and periodically re-validated.

(3) Changes to processes, systems, equipment, or materials that may affect product quality or process reproducibility shall be requalified or re-validated prior to routine implementation.

(4) The potential for critical changes to affect established retest or expiry dates shall be evaluated.

7. **Documentation**

(1) The manufacturer of API shall

(i) establish and maintain a documentation system based upon instructions, records and reports covering the various manufacturing and control operations and all activities performed, as appropriate to the pharmaceutical quality system.

(ii) ensure adherence to good documentation practices.

(2) Pre-established procedures for general manufacturing operations and conditions shall be kept available together with specific documents for the manufacture and control of each batch and the documents shall enable the history of the manufacture of each batch of API or intermediates to be traced.

(3) Production, control, and distribution records shall be retained for at least 1 year after the expiry date of the batch. For APIs with retest dates, records shall be retained for at least 3 years after the batch is completely distributed.

(4) Data

(iii) shall be stored by means of electronic, photographic, or other data processing systems which shall first be validated to ensure that the data will be appropriately stored during the anticipated period of storage.

(iv) stored by those systems shall be made readily available in legible form and shall be provided to the Agency on request.

(5) Electronically stored data shall be protected, by methods such as duplication or back-up and transfer on to another storage system, against loss or damage of data and audit trails shall be maintained.

(6) Adequate measures to ensure data integrity, confidentiality and security shall be established, implemented, and maintained.

(7) Procedure shall be established for retaining all appropriate documents including development history reports, scale-up reports, technical transfer reports, process validation reports, training records, production records, control records, and distribution records.

8. **Production**

(1) Procedures and instructions shall be established for production and process control to ensure that an API produced has the identity, strength, quality, and purity it purports or is represented to possess, and the procedures and instructions followed and records maintained.

(2) Deviation from the procedures and the instruction shall be reported, investigated, recorded, and justified.

(3) API defect shall be documented and thoroughly investigated.

(4) There shall be adequate in-process controls for production operations which shall be sufficiently resourced. Critical in-process controls and critical process monitoring, including control points and methods, shall be stated in writing and approved by the quality unit(s).

(5) Measures shall be taken to mitigate risks of contamination, cross-contamination and mix-ups of API or intermediates.

(6) Materials to be reprocessed or reworked shall be appropriately controlled to prevent unauthorized use.

(6) Containers used for packaging APIs shall not be reactive, additive, or absorptive to alter the quality of the intermediate or API beyond the specified limits.

(7) Residual materials can be carried over into successive batches of the same intermediate or API if there is adequate control. Such carryover shall not result in the carryover of degradants or microbial contamination that may adversely alter the established API impurity profile.

(8) Precautions to avoid contamination shall be taken when APIs are handled after purification.

9. **Materials Management**

(1) Manufacturers of intermediates and APIs shall have a system for evaluating the suppliers of critical materials and the manufacturer shall maintain a list of all materials and services approved suppliers.

(2) Adequate measures shall be taken to ensure that materials meet established specifications before use, only materials released by the quality unit and within their shelf-life shall be used for manufacturing and control activities.

(3) Material and product shall be stored under the appropriate conditions established by the manufacturer and in an orderly fashion, to permit batch segregation and stock rotation.

(4) Cleaning, lubricating, fumigating, sanitizing, and pest control materials shall not contaminate equipment and materials.

(5) Materials shall be re-evaluated, as appropriate, to determine their suitability for use including after prolonged storage or exposure to heat or humidity.

Part IV
Packaging and Identification Labelling of APIs and Intermediates, Laboratory Control, Contract Manufacture and Analysis

10. **Packaging and Identification Labelling of APIs and Intermediates**

(1) There shall be written procedures and records in place describing the receipt, identification, quarantine, sampling, examination, testing, release, and handling of packaging and labelling materials.

(2) Container shall

(a) be clean and suitable for their intended use.

(b) provide adequate protection against deterioration or contamination of the intermediate or API that may occur during transportation and recommended storage.

(3) Manufacturer shall ensure access to the label storage areas which shall be limited to authorised personnel and Controls put in place to ensure stringent controls of labels.

(4) Packaging and labelling facilities shall be inspected immediately before use to ensure that only needed materials for operation are present and adequate documentation carried out.

(5) Packaged and labelled intermediates or APIs shall be examined to ensure that containers and packages in the batch have correct labels.

11. **Laboratory Control**

(1) Manufacturer of APIs shall establish and maintain a distinct organizational quality control department which functions and reports to management independent of other functional unit.

(2) For each batch of intermediate and API, appropriate laboratory tests shall be conducted to determine conformance to specifications.

(3) The quality control department shall be under the authority of a person with appropriate qualifications and experience with access to one or more control laboratories.

(4) Control laboratories specified in regulation 10 (3) shall be adequately resourced to carry out the necessary examinations and testing of materials and comply with good practices for pharmaceutical quality control laboratories.

(5) Materials shall not be released for use, sale, or distribution unless their quality has been adjudged satisfactory and approved by the authorized person.

(6) Manufacturer of APIs shall retain samples of each batch of API and starting materials for at least 1 year after the expiry date of the batch assigned by manufacturer, or for 3 years after distribution of the batch, whichever is longer. For APIs with retest dates, similar reserve samples shall be retained for 3 years after the batch is completely distributed by the manufacturer.

(7) Appropriate specifications shall be established for APIs in accordance with accepted standards. The specifications shall include control of impurities including organic impurities, inorganic impurities, and residual solvents. If the API has specifications for endotoxins or microbiological purity, appropriate action limits shall be established and met.

(8) An impurity profile describing the identified and unidentified impurities present in a typical batch produced by a specific controlled production process shall be established for each API.

(9) The impurity profile shall include the identity or some qualitative analytical designation including retention time, the range of each impurity observed, and classification of each identified impurity including inorganic, organic, solvent.

(10) API expiry or retest date shall be assigned based on an evaluation of data derived from stability studies.

(11) Certificates of analysis shall be issued for each batch of intermediate or API on request.

(12) A documented on-going stability testing program shall be established to monitor the stability characteristics of APIs, and the results used to confirm appropriate storage conditions and retest or expiry dates.

12. **Contract Manufacture and Analysis**

(1) Where the whole or part of the manufacturing process or analysis of materials or products is contracted, the contract shall be in written form, clearly spelling out the responsibilities of each party.

(2) The contract shall clearly state the observance of good manufacturing practice, good practices for pharmaceutical quality control laboratories and registration requirements to be followed by the contract acceptor and the manner in which each batch is to be released by the authorized person.

(3) The contract acceptor shall be subject to inspections carried out by the Agency and the contract giver.

(4) The contract acceptor shall not subcontract any of the work entrusted to him under the contract without written authorization from the contract-giver.

(5) Manufacturing and laboratory records shall be kept at the site where the activity occurs and be readily available.

(6) Changes in the process, equipment, test methods, specifications, or other contractual requirements shall not be made unless the contract giver is informed and approves the changes.

Part V
Rejection and Re-use of Materials, Complaints and Product Recall, Good Distribution Practice

13. **Rejection and Re-Use of Materials**

(1) Intermediates and APIs that fail to meet established specifications shall be identified as such and quarantined. These intermediates must be reprocessed or reworked.

(2) The final disposition of rejected materials shall be recorded.

(3) Recovery such as from mother liquor or filtrates of reactants, intermediates, or the API shall be considered acceptable, provided that approved procedures exist for recovery and the recovered materials meet specifications suitable for their intended use.

(4) Solvents can be recovered and reused in the same processes or in different processes, provided that the recovery procedures are controlled and monitored to ensure that solvents meet appropriate standards before reuse or commingling with other approved materials.

(5) Fresh and recovered solvents and reagents can be combined if adequate testing has shown their suitability for all manufacturing processes in which they may be used.

(6) The use of recovered solvents, mother liquors, and other recovered materials shall be adequately documented.

(9) Returned intermediates or APIs shall be identified as such and quarantined.

(10) If the conditions under which returned intermediates or APIs have been stored or shipped before or during their return or the condition of their containers cast doubt on their quality, the returned intermediates or APIs shall be reprocessed, reworked, or destroyed, as appropriate.

14. **Complaints and Product Recall**

(1) Complaints and other information concerning potentially defective products shall be carefully investigated, recorded, and reviewed according to written procedures by the manufacturer.

(2) The manufacturer shall establish and maintain a system to recall from the market or companies, promptly and efficiently, products known or suspected to be defective.

(3) The manufacturer shall inform the Agency of any defect that could result in the recall or abnormal restriction on supply of an API within and outside the country as well as any regulatory action taken against the company by relevant authorities by virtue of non-compliance with requirements.

15. **Good Distribution Practice**

Distribution of APIs or intermediates shall be in accordance with the current Agency's Good Distribution Practice Regulations.

16. **Self -Inspection**
    (1) The manufacturer shall establish a routinely implemented self-inspection program designed to monitor the implementation of GMP.
    (2) The recommended corrective and preventive actions shall be implemented and records maintained.

17. **Sampling and Testing**
    The Agency shall implement appropriate procedures, methods, and sampling plans to conduct sampling at designated locations, including ports of entry, warehouses, and distribution points throughout the supply chain, for the purpose of verifying and ensuring the quality of Active Pharmaceutical Ingredients (APIs).

Part VI
API Registration Scheme, Agent, Broker, Trader, Distributor, Repacker and Relabeller, Non-Compliance with GMP Requirements

18. **API Registration Scheme**
    (1) There shall be an API registration scheme in NAFDAC for manufacturers, marketers, importers, distributors and brokers starting with known APIs used to manufacture finished products that are used in the treatment, management or control of diseases considered or identified as having high public health impact or high disease burden in Nigeria. The list of these Drug substances shall be reviewed time to time by NAFDAC to reflect current realities in the public health.
    (2) Registration of drug substances shall be undertaken following satisfactory assessment of the Drug Master File (DMF) and satisfactory GMP inspection of the API manufacturing facility.
    (3) A drug master file (DMF) or Active Pharmaceutical Ingredient Master File (APIMF) for the drug substance or Active Pharmaceutical Product intended for registration shall be prepared by the API manufacturer and submitted to NAFDAC for assessment in line with NAFDAC guideline for the preparation of Drug Master File.
    (4) The information in the DMF provided in support of an active pharmaceutical ingredient (API) shall be assessed by the API assessors to determine whether the drug substance meets the requirements and standards for NAFDAC registration.

19. **Agent, Broker, Trader, Distributor, Repacker and Relabeller**
    Agent, Broker, Trader, Distributor, Repacker and Relabeller shall maintain
    (1) complete traceability of APIs and intermediates that they distribute; implement an effective system of managing quality and ensure adherence to GMP and GDP standards in all activities carried out.
    (2) records of complaints and recalls.

20. **Non-Compliance with GMP Requirements**
    The Agency may, as part of control measures withdraw, cancel or suspend the manufacturing or marketing authorization of any person or company who contravenes the provisions of these Regulations.

21. Regulatory reliance
    The Agency shall adopt regulatory reliance mechanisms in making regulatory decisions on APIs.

22. **Prohibition**
    (1) A person shall not manufacture, process, package, hold, handle imported, exported, advertise, sell, distribute, or use an API or starting materials except as provided in these Regulation.
    (2) Non-conformance to these Regulations shall render such API or starting materials substandard or adulterated.

Part VII
Offences and Penalties, Forfeiture after Conviction

23. **Offences and Penalties**

(1) Any person who contravenes any of the provisions of these Regulations commits an offence and shall be liable on conviction, in case of;

(a) an individual, to imprisonment for a term not exceeding 1 year or to a fine not exceeding ₦800,000.00 or to both; and

(b) a body corporate, to a fine not exceeding ₦5,000,000.00.

(2) Where an offence under these regulations is committed by a body corporate, firm, or other association of individuals, every --

(a) director, manager, secretary, or other similar officer of the body corporate;

(b) partner or officer of the firm;

(c) trustee of the body concerned;

(d) person concerned in the management of the affairs of the association; or

(e) person who purports to act in a capacity referred to in the paragraphs (a) to (d) of this sub-regulation,

It is liable to be proceeded against and punished for that offence in the same manner as if the person committed the offence, unless the person proves that the act or omission constituting the offence took place without his knowledge, consent, or connivance.

24. **Forfeiture after Conviction**

A person convicted of an offence under these Regulations shall forfeit to the Federal Government-

(i) asset or property constituting proceeds derived from or obtained, directly or indirectly, as a result of the offence; and

(ii) the person's property or instrumentalities used in any manner to commit or to facilitate the commission of the offence.

25. **Enforcement of these Regulations**

The Agency shall be responsible for the enforcement of these Regulations.

Part VII
Miscellaneous

26. **Interpretations**

In these Regulations, unless the context otherwise requires:

'Agency' means National Agency for Food and Drug Administration and Control

'Acceptance Criteria' means Numerical limits, ranges, or other suitable measures for acceptance of test results.

'Active Pharmaceutical Ingredient (API) (or Drug Substance)' means any substance or mixture of substances intended to be used in the manufacture of a drug (medicinal) product and that, when used in the production of a drug, becomes an active ingredient of the drug product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure and function of the body.

'API Starting Material' means A raw material, intermediate, or an API that is used in the production of an API and that is incorporated as a significant structural fragment into the structure of the API.

An API Starting Material can be an article of commerce, a material purchased from one or more suppliers under contract or commercial agreement or produced in-house. API Starting Materials are normally of defined chemical properties and structure.

'Batch (or Lot)' means a specific quantity of material produced in a process or series of processes so that it is expected to be homogeneous within specified limits. In the case of continuous production, a batch may correspond to a defined fraction of the production. The batch size can be defined either by a fixed quantity or by the amount produced in a fixed time interval.

'Contamination' means the undesired introduction of impurities of a chemical or microbiological nature, or of foreign matter, into or onto a raw material, intermediate, or API during production, sampling, packaging or repackaging, storage or transport.

'Critical' means a process step, process condition, test requirement, or other relevant parameter or item that must be controlled within predetermined criteria to ensure that the API meets its specification.

'Cross-Contamination' means contamination of a material or product with another material or product.

'Deviation' means departure from an approved instruction or established standard.

'Drug (Medicinal) Product' means the dosage form in the final immediate packaging intended for marketing.

'Drug Substance' See Active Pharmaceutical Ingredient

'Expiry Date (or Expiration Date)' means the date placed on the container/labels of an API designating the time during which the API is expected to remain within established shelf-life specifications if stored under defined conditions, and after which it should not be used.

'Impurity' means any component present in the intermediate or API that is not the desired entity
.
'Impurity Profile' means a description of the identified and unidentified impurities present in an API.

'In-Process Control (or Process Control)' means checks performed during production in order to monitor and, if appropriate, to adjust the process and/or to ensure that the intermediate or API conforms to its specifications.

'Intermediate' means a material produced during steps of the processing of an API that undergoes further molecular change or purification before it becomes an API. Intermediates may or may not be isolated. (Note: this Regulation only addresses those intermediates produced after the point that the company has defined as the point at which the production of the API begins.)

'Lot' See Batch

'Manufacture' means all operations of receipt of materials, production, packaging, repackaging, labelling, relabelling, quality control, release, storage, and distribution of APIs and related controls.

'Material' means a general term used to denote raw materials (starting materials, reagents, solvents), process aids, intermediates, APIs and packaging and labelling materials.

'Mother Liquor' means the residual liquid which remains after the crystallization or isolation processes. A mother liquor may contain unreacted materials, intermediates, levels of the API and/or impurities. It may be used for further processing.

'Packaging Material' means any material intended to protect an intermediate or API during storage and transport.

'Procedure' means documented description of the operations to be performed, the precautions to be taken and measures to be applied directly or indirectly related to the manufacture of an intermediate or API.

'Process Aids' means materials, excluding solvents, used as an aid in the manufacture of an intermediate or API that do not themselves participate in a chemical or biological reaction (e.g. filter aid, activated carbon, etc).

'Process Control' See In-Process Control.

'Production' means all operations involved in the preparation of an API from receipt of materials through processing and packaging of the API.

'Qualification' means the action of proving and documenting that equipment or ancillary systems are properly installed, work correctly, and actually lead to the expected results. Qualification is part of validation, but the individual qualification steps alone do not constitute process validation.

'Quality Assurance (QA)' means the sum total of the organised arrangements made with the object of ensuring that all APIs are of the quality required for their intended use and that quality systems are maintained.

'Quality Control (QC)' means checking or testing that specifications are met.

'Quality Unit(s)' means an organizational unit independent of production which fulfils both Quality Assurance and Quality Control responsibilities. This can be in the form of separate QA and QC units or a single individual or group, depending upon the size and structure of the organization.

'Quarantine' means the status of materials isolated physically or by other effective means pending a decision on their subsequent approval or rejection.

'Raw Material' is a general term used to denote starting materials, reagents, and solvents intended for use in the production of intermediates or APIs.

'Reprocess' means introducing an intermediate or API, including one that does not conform to standards or specifications, back into the process and repeating a crystallization step or other appropriate chemical or physical manipulation steps (e.g., distillation, filtration, chromatography, milling) that are part of the established manufacturing process. Continuation of a process step after an in-process control test has shown that the step is incomplete is considered to be part of the normal process and not reprocessing.

'Retest Date' means the date when a material should be re-examined to ensure that it is still suitable for use.

'Rework' means subjecting an intermediate or API that does not conform to standards or specifications to one or more processing steps that are different from the established manufacturing process to obtain acceptable quality intermediate or API (e.g., recrystallizing with a different solvent).

'Solvent' means an inorganic or organic liquid used as a vehicle for the preparation of solutions or suspensions in the manufacture of an intermediate or API.

'Specification' means a list of tests, references to analytical procedures, and appropriate acceptance criteria that are numerical limits, ranges, or other criteria for the test described. It establishes the set of criteria to which a material should conform to be considered acceptable for its intended use. "Conformance to specification" means that the material, when tested according to the listed analytical procedures, will meet the listed acceptance criteria.

'Validation' means a documented program that provides a high degree of assurance that a specific process, method, or system will consistently produce a result meeting pre-determined acceptance criteria.

27. **Citation**

These Regulations may be cited as the NAFDAC Active Pharmaceutical Ingredient (API) Regulations 2026

MADE at Abuja this ……day of..... 2026.

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Dr. Mansur Kabir

Chairman of the Governing Council

National Agency for Food and Drug Administration and Control (NAFDAC)