

**GOVERNMENT OF MAHARASHTRA****COMMISSIONER****FOOD AND DRUGS ADMINISTRATION, MAHARASHTRA STATE**

Survey No. 341, Bandra–Kurla Complex, Opp. Reserve Bank of India, Bandra (East),

Mumbai 400051

File no. 3443337/Drug/DI11/2026**Date: 29/09/2026****STANDARD OPERATING PROCEDURE**

FOR TESTING OF DRUGS (ALLOPATHIC), AYURVEDIC, SIDDHA & UNANI
DRUGS AND COSMETICS BY APPROVED TESTING LABORATORIES APPROVED
/ LICENSED UNDER THE DRUGS AND COSMETICS ACT, 1940 AND RULES
THEREUNDER

1.0 OBJECTIVE

- 1.1** To lay down a uniform, documented procedure to be followed by every approved testing laboratory approved under Part XV (A) and Part XVI (A) of the Drugs Rules, 1945 and Chapter VIII of the Cosmetics Rules, 2020, by the Food and Drugs Administration, Maharashtra State, while carrying out tests for identity, purity, quality, safety, performance, and strength of drugs, Ayurvedic/Siddha/Unani (ASU) drugs, cosmetics, and raw materials used in manufacture.
- 1.2** To secure compliance with the requirements of Schedule L1 (Good Laboratory Practices and Requirements of Premises and Equipments) of the Drugs Rules, 1945 and the Eleventh Schedule of the Cosmetics Rules, 2020.
- 1.3** To harmonise the practices of approved/registered approved laboratories with the technical competence requirements of ISO/IEC 17025:2017 and the accreditation criteria and policies of the National Accreditation Board for Testing and Calibration Laboratories (NABL).
- 1.4** To define the obligations of approved/registered laboratories towards the Licensing/Approving/Registration Authority, including mandatory intimation of Not of Standard Quality (NSQ) results, submission to inspection, and maintenance of records.

2.0 SCOPE

2.1 This SOP applies to all approved testing laboratories situated in the State of Maharashtra that hold:

Category	Approval Form	Governing Provisions
Drugs (Allopathic) and raw materials thereof	Form 37	Rules 150B to 150K, Drugs Rules, 1945; Schedule L-1
Ayurvedic, Siddha and Unani drugs and raw materials thereof	Form 48	Rules 160A to 160J, Drugs Rules, 1945
Cosmetics and raw materials thereof	Form COS-23	Rules 55 to 62 and the Eleventh Schedule, Cosmetics Rules, 2020

2.2 It applies to testing undertaken: a) on behalf of licensees for manufacture for sale of drugs/ASU drugs/cosmetics; b) on behalf of an individual, organisation or procurement agency (including Government and public procurement bodies); c) on raw materials, in-process materials, intermediates, finished products, packaging materials and stability samples, to the extent covered by the granted scope of approval.

2.3 Exclusions. This SOP does not apply to (a) the Drugs Control Laboratory and other Government analysts' laboratories of the State; (b) testing of samples drawn by Drugs Inspectors under Section 23 of the Act, which shall be tested only by the Government Analyst or the Central Drugs Laboratory as provided in the Act; (c) clinical/medical diagnostic testing; (d) testing of food articles, which is governed by the FSS Act, 2006.

2.4 No laboratory shall test any category of product, or perform any test, outside the scope endorsed on its approval. A separate application is required for approval to test additional categories of drugs (rule 150B (2)).

3.0 RESPONSIBILITY

Role	Responsibility
Management	Overall legal responsibility; providing adequate resources, staff, premises, and equipment; ensuring freedom from commercial or financial pressure.
Quality Manager / Technical Manager	Implementation and maintenance of the quality system; authority to stop nonconforming work; direct reporting to top management.

Approved Analyst / Competent Person (Medical Devices)	Active direction and supervision of all tests; review and signature of every test report (Form 39, 39A, Form MD-41).
Analysts / Testing Staff	Execution of testing as per approved SOPs/methods; contemporaneous recording of raw data.
Sample Custodian	Receipt, verification, coding, storage under controlled conditions, distribution, retention, and disposal of samples.
Instrument / Calibration In charge	Qualification (DQ/IQ/OQ/PQ), calibration, maintenance, and performance verification of equipment.

5.0 REGULATORY AND NORMATIVE REFERENCES

5.1 Statutes and Rules

- 5.1.1. The Drugs and Cosmetics Act, 1940 — in particular Sections 16, 17, 17A, 17B, 18, 20, 21, 22, 23, 25, 33EE and Chapter IVA (ASU drugs).
- 5.1.2. The Drugs Rules, 1945 — Rules 150B to 150K (Part XV (A)); Rules 160A to 160J (Part XVI (A));
- 5.1.3. Schedule L-1, Drugs Rules, 1945 (see rules 74, 78 and 150E) — Good Laboratory Practices and Requirements of Premises and Equipments.
- 5.1.5. The Cosmetics Rules, 2020 — Chapter VIII (Rules 55 to 62), the Ninth Schedule (Standards for cosmetics/BIS), the Tenth Schedule (permitted colorants) and the Eleventh Schedule (requirements of premises, plant and equipment for an approved testing laboratory), as amended.
- 5.1.6. The Prevention of Cruelty to Animals Act, 1960 and CPCSEA requirements, Where animal testing forms part of the approved scope.
- 5.1.7. The Narcotic Drugs and Psychotropic Substances Act, 1985, where Schedule X / Narcotic substances are handled.
- 5.1.8. The Environment (Protection) Act, 1986 and the Bio-Medical Waste Management Rules, 2016, for disposal of laboratory waste, as applicable.

5.2 Pharmacopoeial and standard references

- 5.2.1. Indian Pharmacopoeia (current edition) and IP Addenda; other pharmacopoeias notified in the Second Schedule to the Act (BP, USP-NF, Ph. Eur., International Pharmacopoeia) as applicable.
- 5.2.2. Ayurvedic Pharmacopoeia of India (API), Ayurvedic Formulary of India (AFI), Siddha Pharmacopoeia of India, Unani Pharmacopoeia of India and the authoritative books specified in the First Schedule to the Act.

- 5.2.3.** Relevant BIS Standards for cosmetics referred to in the Ninth Schedule, including IS 4707 (Part 1 and Part 2) and IS 4011:2018 (methods of test for safety evaluation of cosmetics).

5.3 Accreditation and quality references

- 5.3.1.** ISO/IEC 17025:2017 — General requirements for the competence of testing and calibration laboratories.
- 5.3.2.** NABL 100 (General Information Brochure); NABL 103 (Specific Guidelines for Chemical Testing Laboratories); NABL 142 (metrological traceability/calibration policy); NABL 163 (Proficiency Testing policy); NABL 165 (NABL's Policies for Accreditation as per ISO/IEC 17025:2017); NABL 127/154 (Integrated Assessment with regulatory requirements); NABL assessment forms and checklists, all as current.
- 5.3.3.** WHO Good Practices for Pharmaceutical Quality Control Laboratories (WHO TRS, current annex) — for guidance where the Rules are silent.

6.0 PROCEDURE

6.1 Legal Status and Scope of Approval

- 6.1.1** The laboratory, or the organisation of which it forms part, shall be an entity that is legally authorised to function and that can be held legally responsible (Schedule L-1, cl. 1(a)).
- 6.1.2** A copy of the valid approval in Form 37 / Form 48 / Form COS-23, together with the endorsed scope (categories of drugs, ASU drugs or cosmetics and the tests permitted), shall be displayed at a conspicuous place in the laboratory and shall be produced on demand to any Inspector.
- 6.1.3** The laboratory shall monitor the retention fee due dates (rule 150D / rule 59 of the Cosmetics Rules, 2020) and deposit the licence retention fee before the expiry of each successive period of five years. Non-payment, with late fee, beyond the permitted period results in the approval being deemed cancelled.
- 6.1.4** The laboratory shall not undertake, accept, sub-contract, advertise or represent itself as competent to perform any test outside the endorsed scope. Any expansion of scope requires a fresh application and inspection.
- 6.1.5** NABL accreditation, where held, shall be maintained current and its scope shall be cross-mapped against the statutory scope of approval. Accreditation does not

substitute for approval under the Act; conversely, approval under the Act does not exempt the laboratory from accreditation requirements where accreditation has been made a condition of any tender, procurement or notification.

6.2 Organisation, Management and Quality System (*Schedule L-1, cl. 1 and cl. 10; ISO/IEC 17025:2017 cl. 4, 5, 8*)

- 6.2.1** Management shall ensure that testing, calibration, validation and all other technical activities are carried out in a manner that meets GLP requirements (Schedule L-1, cl. 1(b)).
- 6.2.2** A qualified Quality Manager / Technical Manager shall be designated, who shall be responsible for all technical activities and for implementation of the documented quality system, and who shall report to top management (Schedule L-1, cl. 1(c)).
- 6.2.3** The laboratory shall establish and maintain a Quality Manual supported by quality system procedures, work instructions, SOPs, specifications, formats and records. The Quality Manual shall include the quality policy, organisation chart, job descriptions with qualification and experience criteria, statement of scope, and cross-reference to the statutory requirements in Section 5.0.
- 6.2.4 Impartiality and freedom from conflict of interest.** No approved laboratory shall test a sample where the laboratory, its management or the Approved Analyst has a proprietary, financial or managerial interest in the outcome that could influence the result. Remuneration of analysts shall not be linked to the outcome of any test.
- 6.2.5 Confidentiality.** All customer information and results shall be treated as confidential, subject to the overriding statutory duty to report NSQ results to the Authority under Section 6.13 of this SOP. The laboratory shall not withhold, alter or suppress a result at the instance of a customer.

6.3 Personnel (*Schedule L-1, cl. 3; rule 150C (2) (5) & (6)*)

- 6.3.1.** Testing shall be under the active direction of a person whose qualification and experience are adequate in the opinion of the Approving Authority, and who shall be responsible for the reports issued.
- 6.3.2.** Tests shall be performed only by persons of adequate qualification and experience. Indicative minimum qualifications:

Function	Indicative minimum qualification
----------	----------------------------------

Approved Analyst / Head of Testing (drugs)	M. Pharm. / M.Sc. (Chemistry or allied) / B. Pharm. with prescribed experience in testing of drugs, acceptable to the Approving Authority
Analyst — ASU drugs	Degree in Ayurveda/Siddha/Unani, or B. Pharm. (Ayurveda), or M.Sc. with experience in pharmacognosy/photochemistry, acceptable to the Approving Authority
Microbiologist	M.Sc. (Microbiology) with experience in sterility, BET/pyrogen and microbial limit testing
Analyst — cosmetics	M.Sc. (Chemistry) / B. Pharm. with experience in cosmetic and BIS test methods

6.3.3 An up-to-date personnel file shall be maintained for every technical staff member containing qualifications, experience, appointment letter, job description, authorisation matrix, training records, competency assessment, health records and signature/initial specimen.

6.3.4 Training. A documented annual training calendar shall cover GLP/Schedule L-1, ISO/IEC 17025, data integrity, SOPs, instrument handling, pharmacopoeial updates, safety and regulatory requirements. Competency of each analyst shall be assessed and recorded before independent authorisation for a test, and re-assessed at least annually or on change of method/instrument.

6.3.5 A signature and initials register with specimen signatures of all persons authorised to make entries in, review or approve records shall be maintained and kept current.

6.3.6 Any change in the person-in-charge of testing or in the expert staff responsible for testing shall be reported forthwith to the Approving Authority as required by rule 150E(e).

6.4 Premises (*Schedule L-1, cl. 2; rule 150C(2)(1)–(3); Eleventh Schedule, Cosmetics Rules, 2020*)

6.4.1 Premises shall be well lighted, properly ventilated and, where the nature of the test requires, air-conditioned so as to maintain the accuracy and functioning of instruments and to enable performance of special tests such as sterility and microbiological tests.

6.4.2 Adequate space shall be provided having regard to the nature and number of samples proposed to be tested. The Approving Authority shall determine from time to time whether the space continues to be adequate.

6.4.3 Segregated and clearly identified areas shall be provided for at least the following, with controlled access where appropriate:

- a) Sample receipt and sample storage (including a controlled/cold storage area and a separate secure area for Schedule X/narcotic and habit-forming substances under double lock);
- b) Chemical/wet analysis.
- c) Instrumentation room, with separate provision for sensitive instruments and balances (vibration-free, humidity-controlled).
- d) Microbiology section, physically separated from the chemical section, comprising a sterility testing area of appropriate classification with laminar air flow, a media preparation room, an incubation room, a culture handling room and a decontamination/autoclave area.
- e) Separate area for testing of ASU drugs, including pharmacognosy/microscopy, where such scope is held.
- f) Reference standard and working standard storage, under the custody of the quality control function, with defined storage conditions.
- g) Retention/control sample storage.
- h) Reagent and solvent storage, including a flammables store with fire-rated construction.
- i) Documentation and archival room, secure against fire, water, pests and unauthorised access.
- j) Washing/glassware cleaning area and a separate area for purified water generation and storage.
- k) Waste collection and disposal area.

6.4.4 Where the approved scope includes tests requiring the use of animals, an animal house shall be provided which complies in all respects with rule 150C(2)(3), including adequate area, lighting and ventilation, air-conditioned housing for animals under test, hygienic housing with removal of excreta and foul smell, arrangements for feed preparation, quarantine on receipt, periodic examination of physical fitness, isolation of sick animals and animals under test, compliance with the Prevention of Cruelty to Animals Act, 1960 and CPCSEA registration, and safe disposal of carcasses.

6.4.5 Environmental conditions (temperature, relative humidity, differential pressure, particulate and microbial counts where applicable) shall be monitored, recorded and trended, with defined alert and action limits. Testing shall be suspended when conditions jeopardise the validity of results.

6.4.6 Bio-burden and environmental monitoring shall be routinely carried out in controlled and uncontrolled areas as applicable to the tests performed.

6.5 Equipment — Provision, Qualification, Calibration and Maintenance (*Schedule L-1, cl. 4 and cl. 7; rule 150C(2)(4)*)

6.5.1 Suitable equipment adequate for the nature and number of samples to be tested shall be provided and maintained. An equipment master list shall be maintained showing identification number, make/model, serial number, date of commissioning, location, calibration frequency, last and next due dates, and current status.

6.5.2 Every major instrument shall undergo documented Design/Installation/Operational/Performance Qualification (DQ/IQ/OQ/PQ) before use and shall be prequalified after major repair, relocation or at defined intervals.

6.5.3 Calibration shall be carried out as per a written schedule against standards traceable to national or international standards, using accredited calibration agencies and certified reference materials. Indicative frequencies:

Equipment	Indicative calibration / verification frequency
Analytical balances	Daily verification before use; external calibration at least half-yearly
Weight box / standard weights	Annually, traceable
pH meter	Before each use with buffers; monthly performance check
HPLC / UPLC / GC	Performance verification at least half-yearly; system suitability before each run
UV-Visible / IR spectrophotometer	Wavelength accuracy, resolution, stray light — at least half-yearly
Dissolution apparatus	Calibration/mechanical qualification at least half-yearly
Karl Fischer titrator, potentiometric titrator	Half-yearly
Autoclave, hot air oven, incubators, water bath	Temperature mapping and validation at least annually; load validation for autoclave
Laminar air flow / biosafety cabinet	Half-yearly validation with particle count and filter integrity
Thermometers, thermo-hygrometers, timers	Annually, traceable
Refrigerators, deep freezers, stability chambers	Continuous monitoring; mapping annually
Muffle furnace, melting point apparatus, viscometers, TLC/HPTLC systems	Annually or as per manufacturer's recommendation

6.5.4 Each instrument shall bear a calibration status label stating the date of calibration, next due date and the identity of the person responsible. Instruments that are out of

calibration, defective or of doubtful performance shall be taken out of service, labelled "OUT OF ORDER — DO NOT USE" and segregated until restored and prequalified.

6.5.5 Preventive maintenance shall be carried out as per a documented annual plan; breakdown maintenance, repairs and changes shall be recorded in an instrument logbook/history card maintained for the life of the instrument.

6.5.6 Where an instrument failure is discovered, the laboratory shall carry out an impact assessment on all results generated since the last successful calibration/verification and shall notify affected customers and, where an NSQ/standard-quality conclusion is affected, the Approving Authority.

6.5.7 Utilities. Purified water shall meet Pharmacopoeial requirements and shall be tested for chemical and microbiological attributes at defined frequencies. Compressed gases, nitrogen and air used in analysis shall be of the requisite grade. Power backup adequate for uninterrupted operation of critical instruments and storage facilities shall be provided.

6.6 Chemicals, Reagents, Reference Materials and Microbiological Cultures (*Schedule L-1, cl. 5, 8 and 9*)

6.6.1 Chemicals and reagents shall be of the grade prescribed by the relevant monograph or method (AR/GR/HPLC grade, as applicable) and shall be procured from reliable sources.

6.6.2 Every container shall be labelled with name, grade, manufacturer, lot number, date of receipt, date of opening, date of expiry/re-test and, for prepared solutions, date of preparation, standardisation details, potency/factor, storage condition, validity period and the initials of the preparer and checker.

6.6.3 Volumetric solutions shall be standardised before use and re-standardised at defined intervals; records of standardisation and factors shall be maintained.

6.6.4 Reagents shall be stored under prescribed conditions; expired, deteriorated or unlabelled reagents shall not be used and shall be segregated and discarded with record.

6.6.5 Reference standards. Adequate space with proper storage conditions shall be provided for keeping reference and working standards, maintained by the quality control function, and an SOP for maintenance of reference standards and for

evaluation of working and secondary standards shall be prepared and followed (Schedule L-1, cl. 1(f)).

- a) Pharmacopoeial reference standards (IPRS, and BP/USP/EP RS where applicable) shall be procured from the official source and used within their validity, in accordance with the certificate of the issuing body.
- b) Working standards shall be prepared by comparison against the reference standard and shall be routinely checked for purity (Schedule L-1, cl. 8(b)); the characterisation report, assigned potency, validity period and storage condition shall be documented.
- c) A reference/working standard register with receipt, issue, usage, balance and reconciliation shall be maintained.
- d) For ASU drugs, authentic raw drug/herbarium reference specimens, marker compounds and reference HPTLC fingerprints shall be maintained where the relevant monograph so requires.

6.6.6 Microbiological cultures. Cultures shall be obtained from a recognised national or international culture collection (e.g. ATCC/MTCC/NCTC or equivalent), maintained as master, working and seed lots with documented passage number not exceeding five from the original, subjected to periodic identity and viability checks, stored securely with restricted access and destroyed/disposed of by validated decontamination with record.

6.7 Documentation, Standard Operating Procedures and Data Control (*Schedule L-1, cl. 13, 14, 15 and 16*)

6.7.1 The laboratory shall maintain a documented SOP system covering, at minimum: sample receipt and handling; each analytical technique and instrument; calibration and maintenance; preparation and standardisation of reagents; management of reference standards; media preparation and sterility assurance; environmental monitoring; method validation and verification; OOS/OOT investigation; deviation and change control; internal audit; management review; complaints; training; data integrity and computerised systems; archival and retrieval; safety and waste disposal; and issue of reports.

6.7.2 Every SOP shall carry a unique number, version number, effective date, review date, page numbering in "Page X of Y" format, and signatures of preparer, reviewer and approver. SOPs shall be reviewed at least once in two years or earlier on change of method, equipment or regulation.

6.7.3 A master list of documents with current version status shall be maintained. Issue of controlled copies shall be recorded; superseded copies shall be withdrawn, stamped "OBSOLETE" and destroyed, except one master copy retained for the archival period.

6.7.4 Raw data shall be recorded contemporaneously, in indelible ink, on controlled, pre-numbered, bound or issued formats. Corrections shall be made by a single line strike-through leaving the original entry legible, with the correct entry, reason, initials and date. Overwriting, use of correction fluid, pencil entries, back-dating, recording on loose sheets and transcription from rough notes are strictly prohibited.

6.7.5 Data integrity. All records, paper and electronic, shall satisfy ALCOA+ principles. For computerised systems:

- a) Unique user identities with password protection and role-based access privileges shall be assigned; sharing of passwords is prohibited.
- b) Audit trails shall be enabled at all times, shall not be disabled or edited, and shall be reviewed by a designated person at defined frequency and, in any case, before release of the test report.
- c) No analyst shall have administrator rights over the data acquisition software.
- d) Electronic data shall be backed up at defined frequency, the backups shall be stored securely and restoration shall be periodically verified.
- e) Deletion of a run, aborted injections, trial or unofficial "test" injections and re-integration without documented justification are prohibited.
- f) The system shall be validated and a validation summary retained.

6.7.6 Protocols, specifications, methods and their archives shall be maintained so that the complete testing history of any sample can be reconstructed from the record.

6.8 Receipt, Identification, Storage and Handling of Samples

6.8.1 Samples shall be received only against a written test request (order/requisition) from the customer, accompanied by the sample in a sealed and labelled condition, bearing at least: name of product; batch/lot number; manufacturing and expiry date; quantity; name and address and licence number of the manufacturer/sender; the specification/pharmacopoeial standard to be applied; and the tests required.

6.8.2 On receipt, the sample custodian shall verify the condition of the seal, integrity of the container, quantity, labelling and storage condition during transit, and shall record the date and time of receipt. Any discrepancy, damage, insufficiency or deviation from the required storage condition shall be recorded and referred to the customer in writing

before testing; where the sample is unfit for testing it shall be rejected with recorded reasons.

- 6.8.3** Each sample shall be allotted a unique Analytical Report Number (ARN)/Lab code and entered in the Sample Inward Register. The laboratory shall preserve the chain of custody from receipt to disposal.
- 6.8.4** Proper facilities for storage shall be provided so as to preserve the properties of the samples to be tested, as required by rule 150E (b) and rule 62(b) of the Cosmetics Rules, 2020. Samples requiring cold chain, protection from light, or controlled humidity shall be stored accordingly with monitored and recorded conditions.
- 6.8.5** Samples shall be sub-divided into the portion for analysis and the retention/control portion (Section 6.16). Quantities received, used, retained and returned/destroyed shall be reconciled.
- 6.8.6** Contract/test request review. Before acceptance, the laboratory shall satisfy itself that it holds the requisite scope of approval, competent personnel, validated method, equipment, reference standards and sufficient sample quantity, and shall agree with the customer the specification to be applied and the turnaround time. Any request to test against a specification lower than the statutory standard, or to omit a mandatory test, shall be refused and recorded.

6.9 Analytical Methods, Specifications and Validation (*Schedule L-1, cl. 14; ISO/IEC 17025:2017 cl. 7.2*)

- 6.9.1** Testing shall be carried out against the standard prescribed under the Act, in the following order of precedence:

Product category	Applicable standard
Allopathic drugs	Indian Pharmacopoeia (current edition with addenda); failing that, the pharmacopoeia/official compendium specified in the Second Schedule to the Act; for patent or proprietary medicines, Schedule V and the manufacturer's approved specification
ASU drugs	Ayurvedic/Siddha/Unani Pharmacopoeia of India, the Ayurvedic Formulary of India and the authoritative books listed in the First Schedule to the Act; for patent or proprietary ASU medicines, the specification approved by the Licensing Authority
Cosmetics	The Ninth Schedule to the Cosmetics Rules, 2020 and the corresponding BIS specifications; IS 4707 Parts I and II for colourants and ingredient restrictions; IS 4011:2018 for safety evaluation

6.9.2 The laboratory shall provide books of standards recognised under the Act and such books of reference as may be required in connection with the testing of the products for which approval is held (rule 150C(2)(7); rule 56(2) of the Cosmetics Rules, 2020). Current editions shall be procured and superseded editions withdrawn from routine use but retained for reference.

6.9.3 Pharmacopoeial (standard) methods shall be used as published, without modification. The laboratory shall verify the suitability of a pharmacopoeial method under its own conditions of use before first use (specificity, precision, accuracy and, for microbiological methods, method suitability/growth promotion and neutralisation studies).

6.9.4 Non-pharmacopoeial and in-house methods shall be fully validated before use. Validation shall address, as applicable: specificity, linearity and range, accuracy, precision (repeatability and intermediate precision), limit of detection, limit of quantitation, robustness, ruggedness, solution stability and system suitability. A signed validation protocol and validation report shall be retained.

6.9.5 Measurement uncertainty shall be estimated for quantitative tests, and the method of estimation documented, in accordance with ISO/IEC 17025:2017 and NABL policy. Where a result is close to a specification limit, the treatment of uncertainty in the conformity statement shall follow a documented decision rule agreed with the customer.

6.9.6 Any change in a validated method shall be handled through documented change control with revalidation to the extent affected.

6.10 Performance of Analysis

6.10.1 Analysis shall commence only after the analyst has verified: the current version of the method/SOP; validity of instrument calibration; validity of reagents, volumetric solutions, media and reference standards; and suitability of environmental conditions.

6.10.2 System suitability criteria prescribed in the monograph shall be met before and, where required, during the analytical run. A run failing system suitability shall be invalidated with recorded reason and repeated; the failed data shall be retained.

6.10.3 All observations, weighings, dilutions, readings, calculations, chromatograms, spectra and printouts shall be recorded on the analytical worksheet at the time of performance and shall be signed and dated by the analyst, and independently checked and countersigned by a second qualified person.

- 6.10.4** Calculations shall be verified independently. Where a validated spreadsheet or software is used for calculation, it shall be validated and protected against unauthorised change.
- 6.10.5** For microbiological testing, negative and positive controls, growth promotion tests of media, and media sterility checks shall be performed and recorded for each batch of media and each test occasion as applicable.
- 6.10.6** For ASU drugs, the analysis shall include, as relevant to the monograph: organoleptic and macroscopic/microscopic identification, foreign matter, ash values, extractive values, moisture/loss on drying, pH, TLC/HPTLC fingerprinting, assay of marker compounds where prescribed, heavy metals (lead, cadmium, arsenic, mercury), microbial load, pesticide residues, aflatoxins, and, for rasa/bhasma preparations, the tests prescribed in the relevant text.
- 6.10.7** For cosmetics, the analysis shall include, as relevant: description, pH, identification and limits of restricted ingredients, heavy metals (lead, arsenic, mercury, cadmium), microbial limits, colorant verification against the Tenth Schedule, and the specific BIS test parameters for the product category.

6.11 Out-of-Specification and Out-of-Trend Results

- 6.11.1** Any result outside the prescribed limit shall be handled under a written OOS/OOT investigation SOP. The result shall not be discarded, averaged out, or replaced by a repeat result without investigation.
- 6.11.2 Phase I** - Laboratory investigation shall be initiated immediately by the analyst and the Approved Analyst to determine whether an assignable laboratory error exists (dilution/calculation error, instrument malfunction, reagent or standard failure, method deviation, analyst error). All original data shall be preserved.
- 6.11.3** Retesting or resampling shall be performed only on documented authorisation of the Approved Analyst, by a second analyst where practicable, under a pre-defined retest plan stating the number of retests and the acceptance criteria. "Testing into compliance" is prohibited.
- 6.11.4 Phase II** - Where no assignable laboratory error is established, the original OOS result shall be confirmed and reported. The investigation record shall state the conclusion, the CAPA, and the signatures of the Approved Analyst and Quality Manager.

6.11.5 An OOS/OOT register shall be maintained and shall be produced to the Inspector on demand.

6.12 Reports of Test or Analysis

6.12.1 A report shall be issued only after review of the complete analytical package (raw data, chromatograms, audit trails, calculations, calibration status, standards used) and shall be signed by the Approved Analyst, who is responsible for the report.

6.12.2 Reports shall be issued in the statutory form:

Category	Form of report
Drugs — sample received from a manufacturer	Form 39 (rule 150E(f))
Drugs — sample received from an individual, organisation or procurement agency	Form 39A (rule 150E(f))
ASU drugs	Form 50
Cosmetics	COS-24

6.12.3 Every report shall contain, at minimum:

- Name and address of the laboratory with approval number and validity.
- Unique report number and date.
- Name and address of the customer.
- Complete sample particulars (name, batch/lot no., manufacturing and expiry date, quantity, label claim, manufacturer's name, address and licence number);
- Date of receipt, date of commencement and date of completion of analysis.
- The specification/standard applied with edition.
- Test-wise results with limits, expressed with correct units and significant figures.
- A clear conclusion as to whether the sample complies with the prescribed standards.
- Reference to the protocol of tests.
- Name, designation and signature of the Approved Analyst with date.
- Page numbering in "Page X of Y" form.

6.12.4 The report shall state the protocols of tests showing readings and calculations or shall refer to them by unique identification, such protocols being retained under rule 150E(c).

6.12.5 A report shall not be issued for tests not actually performed, nor for a scope not held, nor on the basis of results obtained from another laboratory unless sub-contracting is disclosed under Section 6.14.

6.12.6 Amended reports. Where an error is discovered after issue, an amended report bearing a new number, a cross-reference to the original report and the reason for amendment shall be issued; the original report shall be recalled in writing. Amendment of a report to change a conclusion from "Not of Standard Quality" to "Standard Quality" without a fully documented investigation is prohibited and shall be treated as a serious breach.

6.12.7 Reports shall be issued in a secure manner (serially controlled stationery or tamper-evident electronic format with digital signature) so as to prevent forgery. A register of reports issued shall be maintained.

6.13 Mandatory Intimation of Not of Standard Quality Results

6.13.1 Where any sample of a drug is found on test to be Not of Standard Quality, the approved laboratory shall furnish the Licensing Authority of the State in which the manufacturer and/or sender is located, with a copy of the test report together with the protocols of tests applied (rule 150E(g)). The same obligation applies, mutatis mutandis, to ASU drugs and to cosmetics under the corresponding provisions.

6.13.2 Such intimation shall be sent within two working days of issue of the report, in writing, under acknowledgment, to the Joint Commissioner (Drugs) of the concerned Division and to the Commissioner, FDA, Maharashtra State, with a copy endorsed to the customer. An electronic copy shall be sent to the e-mail address notified by the Administration.

6.13.3 An NSQ intimation register shall be maintained showing the report number, product, batch, manufacturer, nature of failure, date of intimation and the acknowledgment reference.

6.13.4 Where the sample indicates a spurious, adulterated or misbranded product, or a result with potential for serious public health consequence, intimation shall be given immediately and in any case within twenty-four hours by the fastest available means, followed by the written report.

6.13.5 The laboratory shall not delay, withhold or negotiate the issue of an NSQ report at the instance of the customer. Any attempt to induce suppression of such a report shall itself be reported to the Licensing Authority.

6.14 Sub-contracting and Referral

6.14.1 Sub-contracting of any test shall be resorted to only with the prior written consent of the customer and only to a laboratory that holds the requisite approval under the Act for that scope, and that is NABL-accredited for the test wherever feasible.

6.14.2 The sub-contracted portion shall be clearly identified in the report, naming the sub-contracting laboratory and its approval number. The issuing laboratory remains responsible to the customer and to the Authority for the entire report, except for results explicitly attributed to the sub-contractor.

6.14.3 A register of sub-contracted tests and an evaluated list of approved sub-contractors shall be maintained.

6.15 Retention of Samples, Protocols and Records

6.15.1 Records of tests for identity, purity, quality and strength carried out on all samples, and the results thereof together with the protocols of tests showing the readings and calculations, shall be maintained in such form as to be available for inspection, and shall be retained (rule 150E(c); rule 62(c) of the Cosmetics Rules, 2020):

Nature of substance	Minimum retention period
Substances to which an expiry date is assigned	Two years from the date of expiry
Other substances	Six years

6.15.2 Where any other law, contract, accreditation requirement or direction of the Authority prescribes a longer period, the longer period shall apply. Records relating to a sample that is the subject of a pending enquiry, prosecution, appeal or litigation shall be retained until final disposal, notwithstanding the above.

6.15.3 Retention (control) samples shall be preserved in the original or equivalent container under the prescribed storage conditions, in a quantity sufficient to permit at least one complete re-analysis, for the period specified in 6.15.1 or, where the quantity received does not permit, the fact shall be recorded and communicated to the customer at the time of acceptance.

6.15.4 Archived records shall be stored in a secure, environmentally suitable area with controlled access and an index enabling retrieval. Electronic records shall remain readable and retrievable throughout the retention period, with migration validated where technology changes.

6.15.5 Destruction of records and retention samples at the end of the retention period shall be carried out only on written authorisation of the Quality Manager, and shall be documented in a destruction register.

6.16 Internal Audit, Management Review and Continual Improvement (*Schedule L-1, cl. 11 and 12*)

6.16.1 Internal quality system audits covering all elements of the quality system and all technical areas shall be conducted at least once every twelve months, by trained auditors independent of the activity audited, against a documented audit plan and checklist.

6.16.2 Non-conformities shall be recorded, classified, subjected to root cause analysis, and closed through documented CAPA with verification of effectiveness. Where a non-conformity casts doubt on the validity of results already reported, the laboratory shall notify affected customers in writing and, where a statutory conclusion is affected, the Approving Authority.

6.16.3 Management review shall be conducted at least once a year and shall consider, at minimum: suitability of policies and procedures; reports of technical and supervisory personnel; outcome of internal and external audits; corrective and preventive actions; results of proficiency testing and inter-laboratory comparisons; complaints; changes in the volume and type of work; resource adequacy; regulatory changes; and recommendations for improvement. Minutes with action points, owners and due dates shall be recorded.

6.16.4 A self-inspection against the Schedule L-1 checklist at Annexure IV shall be carried out half-yearly and the compliance report retained for production during inspection.

6.17 Proficiency Testing and Quality Control of Results

6.17.1 The laboratory shall participate in proficiency testing programmes or inter-laboratory comparisons for the major disciplines within its scope, at a frequency consistent with NABL policy and, at minimum, once per discipline per accreditation cycle, and additionally whenever a new major test category is added.

6.17.2 Internal quality control measures shall be applied, including use of control samples, replicate testing, retesting of retained samples, blind samples, control charts and trend analysis of standard/system suitability data.

6.17.3 Unsatisfactory PT performance shall trigger a formal investigation, CAPA, review of results issued in the affected period, and, where relevant, notification to customers

and the Approving Authority. Records of PT participation and outcome shall be produced during inspection.

6.18 Complaints, Deviations and Change Control

- 6.18.1** All complaints regarding the laboratory's results or services shall be recorded in a complaint register, acknowledged, investigated by a person not involved in the original work, and closed with a written response within a defined period, normally thirty days.
- 6.18.2** Deviations from SOPs or methods shall be recorded, justified, authorised by the Quality Manager before or, if unavoidable, immediately after occurrence, and assessed for impact on results.
- 6.18.3** Changes to methods, equipment, software, premises, key personnel or the quality system shall be routed through change control, with impact assessment, approval, implementation and, where applicable, intimation to the Approving Authority under rule 150E(e).

6.19 Good Housekeeping, Safety and Waste Disposal (*Schedule L-1, cl. 6*)

- 6.19.1** The laboratory shall be maintained clean, orderly and free of materials not required for the work in hand. Eating, drinking, smoking and storage of food are prohibited in all technical areas.
- 6.19.2** Personal protective equipment appropriate to the hazard (lab coats, safety goggles, gloves, face shields, respirators) shall be provided and used. Fume hoods shall be provided and periodically tested for face velocity.
- 6.19.3** Safety data sheets for all hazardous chemicals shall be readily accessible. Flammables, corrosives, oxidisers and toxic substances shall be stored separately in compatible, vented storage.
- 6.19.4** Fire extinguishers of appropriate class, fire alarm, emergency shower, eye-wash station, first-aid box, spill kits and clearly marked emergency exits shall be provided, inspected periodically and covered in mock drills conducted at least annually.
- 6.19.5** Chemical, solvent, microbiological and, where applicable, animal waste shall be neutralised/decontaminated and disposed of through authorised agencies in compliance with environmental and bio-medical waste legislation, with records of disposal.

6.19.6 Narcotic, psychotropic and Schedule X substances shall be stored under double lock with a register of receipt, usage and balance, and destroyed only in the presence of and with the authorisation of the competent authority.

6.20 Inspection by the Administration and Inspection Book (*rule 150E (d) and (i)*)

6.20.1 The laboratory shall allow an Inspector appointed under the Act to enter, with or without prior notice, the premises where testing is carried on, to inspect the premises, equipment and testing procedures, to inspect all registers and records maintained under the Rules, and shall supply such information as the Inspector may require.

6.20.2 An Inspection Book shall be maintained at the laboratory to enable the Inspector to record impressions and defects noticed. The Inspection Book shall be produced on demand and shall not be removed from the premises.

6.20.3 Observations recorded by the Inspector shall be replied to in writing with a time-bound CAPA plan within 7 days of receipt, or within such shorter period as may be specified, and compliance shall be evidenced.

6.20.4 Refusal of entry, non-production of records, obstruction, or furnishing of false information shall render the laboratory liable to action under Section 22 and Section 23 of the Act and to withdrawal or suspension of approval under rule 150K.

6.21 Prohibited Practices

The following shall constitute serious breaches of the conditions of approval and this SOP, and shall attract action under rule 150K / rule 160J / rule 61 of the Cosmetics Rules, 2020 and, where applicable, prosecution under the Act:

6.21.1 Issue of a report of test or analysis for a test not actually performed, or on a sample not actually received ("paper testing").

6.21.2 Testing or reporting outside the endorsed scope of approval.

6.21.3 Suppression, alteration, back-dating or fabrication of raw data, chromatograms, audit trails or reports.

6.21.4 Failure to intimate an NSQ result to the Authority as required under Section 6.13.

6.21.5 Testing into compliance, unauthorised repeat testing or discarding of unfavourable data.

6.21.6 Disabling, editing or failing to review audit trails; sharing of user credentials.

- 6.21.7** Use of expired, uncalibrated or unqualified equipment, expired reagents or uncharacterised working standards.
- 6.21.8** Signature of reports by a person other than the Approved Analyst endorsed by the Authority, or use of a rubber stamp facsimile signature.
- 6.21.9** Sub-letting of the approval or operation of the laboratory by a person other than the approval holder.
- 6.21.10** Failure to report changes in key personnel, premises or equipment under rule 150E (e).

7.0 CATEGORY-SPECIFIC REQUIREMENTS

7.1 Allopathic Drugs

- 7.1.1** Testing against the Indian Pharmacopoeia and the compendia in the Second Schedule to the Act; for formulations, the label claim and the approved specification.
- 7.1.2** Where the scope covers Schedule C and C (1) drugs (biological and special products), the laboratory shall additionally possess the specialised facilities, cold chain, biological testing and, where applicable, animal facilities required for such tests, and shall hold specific endorsement for the same.
- 7.1.3** Sterility testing, bacterial endotoxin testing, abnormal toxicity and pyrogen testing shall be performed only where specifically endorsed, in facilities of the requisite classification, with validated methods and documented method suitability.
- 7.1.4** Dissolution, uniformity of dosage units, related substances and residual solvents shall be performed as prescribed by the monograph; the laboratory shall maintain impurity reference standards where the monograph requires identification of specified impurities.

7.2 Ayurvedic, Siddha and Unani Drugs

- 7.2.1** Approval under Part XVI (A) (Form 48) is required; testing shall be under the direction of a person with ASU qualifications acceptable to the Approving Authority.
- 7.2.2** Authentication of raw drugs by macroscopic and microscopic examination, and maintenance of authentic reference specimens and a herbarium, where the scope includes raw material identification.
- 7.2.3** Testing shall cover the parameters prescribed in the API/SPI/UPI monograph and, for formulations covered by Schedule T, the quality control parameters prescribed therein.

7.2.4 Heavy metal limits (lead, cadmium, mercury, arsenic), microbial load, aflatoxins and pesticide residues shall be determined where prescribed, particularly for products intended for export or for metallic/mineral preparations, and results shall be reported against the applicable limits.

7.2.5 Where a patent or proprietary ASU medicine is tested, the specification approved by the Licensing Authority shall be obtained from the customer in writing before testing.

7.3 Cosmetics

7.3.1 Approval in Form COS-23 under Chapter VIII of the Cosmetics Rules, 2020 is required; the premises and equipment shall comply with the Eleventh Schedule to those Rules.

7.3.2 Testing shall be against the standards specified in the Ninth Schedule (BIS specifications for the relevant product category), and colorants shall be verified against the Tenth Schedule and IS 4707 (Parts I and II).

7.3.3 Heavy metal content (lead, arsenic, mercury, cadmium) shall be determined and reported against the limits prescribed in the Rules for every cosmetic tested for compliance, unless the specific product standard provides otherwise.

7.3.4 Where safety evaluation of a new cosmetic is undertaken within the endorsed scope, methods shall be as specified in IS 4011:2018.

7.3.5 The general conditions in rule 62 of the Cosmetics Rules, 2020, including maintenance of records and retention periods, shall be complied with in the same manner as set out in Sections 6.15 and 6.20.

8.0 INDICATIVE TIMELINES

Activity	Timeline
Acknowledgement of sample receipt to customer	1 working day
Communication of sample deficiency/rejection	2 working days from receipt
Completion of routine chemical analysis and issue of report	10 to 15 working days, unless otherwise agreed in writing
Completion of sterility testing	As per pharmacopoeial incubation period plus report time
Intimation of NSQ result to the Authority	Within 2 working days of issue of report; within 24 hours where spurious/adulterated or of serious public health consequence
Reply to inspection observations	30 days
Response to a complaint	30 days

Internal audit	At least once in 12 months
Management review	At least once in 12 months
Self-inspection against Schedule L-1 checklist	Half-yearly
Review of SOPs	At least once in 2 years
Submission of quarterly return of samples tested to the Authority	By the 15th of the month following each Quarter. (Annexure I)

9.0 RETURNS AND PERIODIC SUBMISSIONS TO THE ADMINISTRATION

- 9.1** Every approved laboratory shall submit to the Joint Commissioner (Drugs) of the concerned Division, with a copy to the Commissioner, FDA, Maharashtra State, a quarterly return in the format at Annexure I showing the number and category of samples received and tested.
- 9.2** The laboratory shall also intimate the result of any sample reported as Not of Standard Quality (NSQ) within 2 working days from the date of issue of the test report. In cases where the sample is found to be spurious, adulterated, or otherwise poses a serious public health risk, the laboratory shall intimate the result within 24 hours of issue of the test report.
- 9.3** The laboratory shall furnish, within the period specified, any additional information, record or clarification called for by the Approving Authority.
- 9.4** Any change in the constitution of the firm, ownership, name, address or premises shall be intimated within thirty days, and a fresh approval obtained where the Rules so require.
- 9.5** Periodic reviews at every quarter of the year of all approved testing laboratories shall be conducted by the Licensing Authority, i.e., the Joint Commissioner of the respective Division. Commissioner, Food and Drug Administration, Maharashtra State, may take review based on the reports of the Licensing Authority as per the schedule fixed time to time to assess compliance with the applicable statutory and regulatory requirements.

10.0 Roles and Responsibilities of FDA Officers for Implementation of this SOP

10.1 Joint Commissioner (Drugs) — Licensing Authority, Approved Testing Laboratories:

The Joint Commissioner (Drugs), being the Licensing Authority for Approved Testing Laboratories under the Drugs and Cosmetics Act 1940 & rules thereunder, shall be responsible for:

- I. Overall supervision and enforcement of this SOP within the jurisdiction, including ensuring that all Approved testing laboratories holding licence comply with the requirements of Rules 150B to 150K, 160A to 160J, 55 to 62 of Drugs Rules, 1945;

Schedule L-1, the Eleventh Schedule, Cosmetics Rules, 2020 & other applicable guidelines.

- II. Reviewing and approving inspection reports and compliance recommendations submitted by the Assistant Commissioner (Drugs) & drugs Inspectors and directing further action, including re-inspection, wherever necessary;
- III. Ensuring that inspections of all licensed Approved Testing Laboratories within the jurisdiction are conducted as per prescribed periodicity.
- IV. Initiating the administrative action in case of non-compliance of mandatory requirements arising out of inspection.
- V. Periodically reporting the status of compliance, enforcement action taken, and pendency, if any, to the office of the Commissioner, Food and Drug Administration, Maharashtra State.

10.2 Assistant Commissioner (Drugs) & Drugs Inspector

- I. Conducting periodic and, surprise inspections of Approved Testing Laboratories within the assigned jurisdiction, to verify compliance with the requirements set out in this SOP, including premises and accommodation, personnel, records, and testing procedures.
- II. Verifying compliance with the conditions of licence, including staffing, equipment, cold-chain arrangements, and biomedical waste management.
- III. Preparing and submitting a detailed inspection report to the Licencing Authority clearly recording deficiencies observed and recommending appropriate action;
- IV. Bringing instances of serious or repeated non-compliance — including operation without a valid licence, absence of documented SOPs for sample storage, testing & reporting of results, use of non-validated methods for the analysis of patent & proprietary drugs, failure to report NSQ test reports to the Licensing Authority — to the immediate notice of the Licensing Authority for necessary action under the Act;
- V. Maintaining jurisdiction-wise inspection records and ensuring timely follow-up inspection to confirm rectification of deficiencies previously pointed out.

11.0 NON-COMPLIANCE AND ENFORCEMENT

11.1 Non-compliance with this SOP, being a non-compliance with the conditions of approval and with Schedule L-1, may result in:

11.1.1 Withdrawal or suspension of the approval, wholly or in respect of some categories of drugs, under rule 150K (1) / the corresponding provisions for ASU drugs and cosmetics, after affording an opportunity to show cause.

11.1.2 Prosecution under the relevant provisions of the Act, where the non-compliance discloses an offence.

11.1.3 Intimation to NABL and to procurement agencies, where the non-compliance bears on technical competence.

11.2 Classification of deficiencies for inspection purposes shall be as Critical, Major and other, as set out in Annexure II, and the enforcement response shall be proportionate to the classification.

12.0 ANNEXURES

Annexure	Title
Annexure I	Format — Half-Yearly Return of Samples Tested and NSQ Intimations
Annexure II	Schedule L-1 Self-Inspection and Inspection Checklist with classification of deficiencies

***NB:** This SOP is issued as a guidance and compliance document under the administrative authority of the Commissioner, Food and Drugs Administration, Maharashtra State. It supplements — and does not override or dilute — the Drugs and Cosmetics Act, 1940, the Drugs Rules, 1945, the Cosmetics Rules, 2020, and the Rules made thereunder, as amended from time to time. In the event of any inconsistency, the statutory provision shall prevail.*

Digitally signed by
TUKARAM H MUNDHE
Date: 01-10-2026
15:50:40

Tukaram Mundhe, I.A.S.
Commissioner

Food and Drug Administration,
Maharashtra State, Mumbai.

To,

All Licensees of approved testing laboratory approved under Part XV(A) and Part XVI(A) of the Drugs Rules, 1945 and under Chapter VIII of the Cosmetics Rules, 2020 by the Food and Drugs Administration, Maharashtra State

Copy for kind information:

The Additional Chief Secretary, Food and Drug Administration, Government of Maharashtra, Mantralaya, Mumbai.

Copy forwarded for implementation and necessary action:

1. All Joint Commissioners (Drug), FDA Maharashtra.
 2. All Assistant Commissioners (Drug), FDA Maharashtra.
 3. All Drugs Inspectors, FDA Maharashtra.
-

Annexure I

(Format – Quarterly Return of Samples Tested and NSQ Intimations)

Name and address of laboratory:

Recognition/licence/approval reference:

Reporting period:

Scope of testing: _____

Name of authorised signatory:

Sr. No.	Category	Samples Received	Samples Tested	Complying	NSQ/OOS	Pending	NSQ Intimations Sent	Remarks
1	Drugs							
2	ASU Drugs							
3	Medical Devices							
4	Cosmetics							
5	Microbiological tests							
Total								

Certification: I certify that the information furnished above is complete and accurate to the best of my knowledge and is supported by the laboratory records.

Annexure II

(Schedule L-1 Self-Inspection and Inspection Checklist with Classification of Deficiencies)

Note: The checklist shall be aligned with the applicable statutory requirements, approved laboratory scope, quality system and any prescribed Schedule L-1 provisions or successor requirements, as applicable.

Area / Requirement	Compliant	Partially Compliant	Non-Compliant	Critical/Major/Minor	Evidence / Observation	CAPA Ref.
Organisation and personnel						
Premises and environmental controls						
Sample receipt and storage						
Equipment qualification and calibration						
Reference standards and reagents						
Test methods and method validation/verification						
Analytical records and data integrity						
Microbiological controls, where applicable						
Reporting and NSQ communication						
Internal audit and CAPA						
Safety, waste and contamination control						
Record retention and document control						

Classification guidance: Critical – deficiency with actual or potential serious impact on result reliability, public health or regulatory compliance; Major – significant system failure or repeated non-compliance; Minor – isolated deficiency not immediately affecting result reliability. The final classification shall be determined by the competent inspecting authority based on evidence and applicable rules.

CHECK LIST FOR INSPECTION OF DRUG TESTING LABORATORIES
(Based on Schedule L1, Rule 74, 78, and 150 E)

A	GENERAL		
1	Date of Inspection		
2	Name & address of the Laboratory		
3	Telephone Number		
	<u>E mail</u>		
5	Constitution of the Firm		
6	(i) Approval Number and Date		
	Certification Held (NABL and Others)		
7	Name and designation of the Responsible Persons of Laboratory present during Inspection:	Head Quality	
		Quality Manager	
		Executive	
		Executive	
8	Organization Chart of the Laboratory (Please attach annexure, if required)		

9	List of Approved Staff <i>(Provide a copy as per Annexure-I)</i>		
10	List of equipment/Instruments (Provide a copy as per Annexure-II)		
11	List of Reference standards available in the laboratory. (Provide a copy as per Annexure-III)		
12	List of working standards available in the laboratory (Provide a copy as per Annexure-IV)		
13	List of Reference Microbial cultures available in the laboratory (Provide a copy as per Annexure-V)		
14	Total Number of Samples Analysed during last three years		
	Total Number of Samples declared as (i) Not of Standard quality (NSQ) (ii) Spurious		
B	Categories		
1	Whether approval has been granted for carrying out testing on the following Categories of Drugs Items and Cosmetics		
1.1	Drugs other than those specified in Schedule C & C (1) including/excluding Homeopathic Medicine.		
1.2	Crude, Vegetable Drugs		
1.3	Mechanical contraceptives (Schedule R)		
1.4	Surgical Dressings (Schedule F-II)		
1.5	Drugs requiring to use U.V./I.R. or Chromatography.		

1.6	Disinfectants		
1.7	Other Drugs (Indicate Category)		
1.7.1	Medicinal Gases		
1.7.2	Diagnostics		
1.7.3	Devices		
1.2	Drugs other than those specified in Schedule C & C (1)		
1.2.1	Sera, Vaccines, Antigens, Toxins, Antitoxins, Toxoids, Bacteriophages & similar Immunological products		
1.2.2	Antibiotics		
1.2.3	Vitamins		
1.2.4	Parenteral Preparations		
1.2.5	Sterilised Surgical Ligature/Suture		
1.2.6	Drug requiring the use of animals for their test		
1.2.7	Drugs requiring microbiological tests		
1.2.8	Drugs requiring to use U.V./I.R. or Chromatography		
1.2.9	Other Drugs (Indicate Category)		
1.2.9.1	Diagnostics		
1.3	Homeopathic Drugs		
1.4	Cosmetics		
C	General Requirements	Details of the Compliance (Mention the details that what system in place to comply the requirements)	Remark/Comments
1.1	Whether the laboratory or the organization of which it is a part must be an entity that is legally authorized to function and can be held legally responsible.		

1.2	Whether management is responsible to ensure that the laboratory carries out its testing, calibration, validation, and all other technical activities in such a way as to meet Good Laboratory Practices (GLP) requirements.		
1.3	Whether a qualified individual to be known as quality manager or technical manager for carrying out all technical activities and for the implementation of documented quality system and which shall report to the top management directly, is available in the Laboratory?		
1.4	Whether a quality manager prepares a schedule for technical audit of the laboratory for GLP compliance by an expert or experts appointed by the top-management other than the in-charge of the laboratory and ensures the maintenance of documented quality system as per quality manual?		
2	Premises:		
2.1.1	Whether there are any sources of pollution in the neighborhood of the building.		
2.1.2	Whether there is any open drain, blocked sewer or public lavatory nearby		
2.1.3	Whether the laboratories is designed, constructed and maintained so as to prevent entry of insects and rodents besides cross contamination;		
2.1.4	Site plan showing area allotted for each section		

2.1.5	Is plan lay out already approved by the Licensing Authority? Indicate any change in the approved premises. Whether these changes are approved by the Licensing Authority?		
2.1.6	Whether interior surface (walls, floor, and ceilings) are smooth and free from cracks, and permit easy cleaning and disinfection;		
2.1.7	Whether adequate provisions are made not only for space and equipment for carrying out necessary test but also for utilities like water, power and gas;		
2.1.8	Whether air ventilation system is provided to ensure dust free environment.		
2.1.9	Is lighting and ventilation adequate to work?		
2.1.10	Whether the laboratory is provided with adequate lighting and ventilation and if necessary, air-conditioning to maintain satisfactory temperature and relative humidity that will not adversely affect the testing and storage of drugs or the accuracy of the functioning of the laboratory equipment or instruments.		
2.1.11	Whether the drainage system facility facilitates proper maintenance and prevents water logging in the laboratory.		
2.1.12	Whether Table tops are constructed with acid, alkali and solvent resistant material and are smooth and free from crevices as far as possible		

2.1.13	Whether all bio-medical laboratory waste is destroyed as per the provisions of the Bio-Medical Waste Management Rules, 2016.		
2.1.14	Whether adequate space with proper storage conditions in the laboratory is provided for keeping reference and working standards and how it is maintained by the quality control department		
2.1.15	Whether Standard Operating Procedure (SOP) for the maintenance of reference standards and evaluation of Working and Secondary standards is available with the laboratory.		
2.1.16	Whether air circulation is maintained in the area where sterility test is carried out as per" Schedule 'M'.		
2.1.17	Whether Bio-burden levels are routinely monitored in the controlled and uncontrolled area, (e.g. Air locks)		
2.2	Animal house		
2.2.1	Whether Animal House has the approval of the Committee for the Purpose of Control and Supervision on Experiments on Animals (CPCSEA).		
2.2.2	Whether it is designed in such a way that there is an arrangement to quarantine the new animals procured or purchased and have a provision for clean corridor and dirty corridor.		
2.2.3	In case of a diseased animal, whether proper diagnosis is done and proper record of treatment are maintained.		

2.2.4	Are different types of animals housed separately with proper identification		
2.2.5	Whether SOP for breeding and care of animals, maintenance, cleaning or sanitation with suitable schedule for cleaning of animal cages, racks, floor and other equipment is available with the Laboratory		
2.2.6	Whether animal house has proper air-conditioning (temperature and humidity) facility with proper lighting and is monitored regularly and documented periodically.		
2.2.7	Is the animal house separate from other activities		
2.2.8	Are the animals kept in hygienic surroundings		
2.2.9	Is there proper arrangements for cleaning of animal house		
2.2.10	Is there suitable arrangements for preparation of animal feed		
2.2.11	Is there suitable arrangements for quarantining of animals		
2.2.12	Is there separate arrangement for housing the animals under test?		
2.2.13	Are the sick animals isolated?		
2.2.14	Whether proper arrangements for disposal of carcasses of animals in a manner as not to cause hazard to public health being followed		
2.2.15	Are the animals being periodically examined for their physical fitness by a veterinary doctor, are the records available?		
2.2.16	Is the firm complying with the requirements of the Prevention of Cruelty to animal act 1960(59/of 1960) as amended		

	from time to time.		
3	Personal:		
3.1	Whether staff in the laboratory possesses necessary qualification, proper training and has adequate, experience for the assigned duties.		
3.2	Whether training records of all the personnel maintained.		
3.3	Whether Medical examination of Staff is conducted at least once a year and records maintained. (Check randomly)		
3.4	Whether Head of the laboratory is of high professional standing with experience in drug analysis and laboratory management		
3.4.1	Whether he is responsible for ensuring the control and maintenance of documents including the quality system as per the requirements of regulatory authorities which involves all raw data, SOPs, documentation exhibits, protocols, training charts, etc;		
3.4.2	Whether he is responsible for planning and organizing the audit of the quality system and initiation as well as follow up action of the corrective actions, if any;		
3.4.3	Whether he is responsible for investigation of technical complaints;		

3.4.5	Whether he is responsible for taking final responsibilities for recommending any regulatory action in the event of noncompliance of tested samples.		
3.4.6	Indicate any change in the approved technical Staff. Whether these new staffs is approved by the concerned Licensing Authority.		
4	Equipment :		
4.1	Whether the laboratory is furnished with all types of equipments as may be necessary for carrying out the different activities within the laboratory.		
4.2	Whether the analytical instruments are housed in dust-free environment and whenever required,' conditions of temperature and humidity are maintained and periodic checks on temperature and humidity are made and recorded.		
4.3	Whether the instruments, instrument bench and surrounding areas are clean and tidy		
4.4	Whether Instruments requiring calibration calibrated at regular intervals and records of such calibration or maintenance is maintained and are there any written instructions in the form of Standard Operating Procedures for the operation, maintenance and calibration of instruments.		
4.5	Whether Equipment records are maintained and such records contain the following:-		

4.5.1	name of equipment or machine or apparatus;		
4.5.2	manufacturer's name, model number and type of identification;		
4.5.3	serial number;		
4.5.4	date on which equipment was received in laboratory;		
4.5.5	current location;		
4.5.6	condition when received (e.g. new, used, re-conditioned);		
4.5.7	copy of the manufacturer's operating instructions;		
4.5.8	frequency of calibration (check on label too)		
4.5.9	frequency of maintenance		
4.5.10	log Book (day to day entry including status of the equipment)		
4.5.11	staff responsible for monitoring the calibration and maintenance status of the equipment;		
4.5.12	calibrating records (with validity)		
4.5.13	list of authorized users or operators, if any;		
4.5.14	history of any damage, malfunction, modification or up gradation, repair and calibration;		
4.5.15	List of spares and accessories, if any.		
4.6	Whether a progress register for non-functional equipments and action for procurement of spares and accessories, monitoring thereof, is available and maintained properly.		
4.7	Whether SOP for preventive maintenance of machine or equipment or apparatus is available with the laboratory.		

4.8	operators carrying out sterility tests wear sterilized garments including headgear, face masks and shoes;		
4.9	Specify whether separate washing and drying area is provided for glassware		
4.10	Specify which grade of glassware is used in assay procedures and whether they are certified/calibrated. Verify the certificates and calibration records.		
4.11	Whether Maintenance procedure in the form of SOP is available and regular servicing is performed by the maintenance engineer or specialist		
4.12	Whether Equipment, instruments giving anomalous results or defective are labelled as 'out-of order' till they are repaired and after instrument is repaired is it calibrated before use		
4.13	Whether the maintenance of equipment for services like electricity, gas, water, steam, and compressed gas is handled by competent person.		
4.14	Whether Autoclaves meet the requirements described for operations, safety and validation procedures, and are the validation carried out by the laboratory recorded.		

	Fume Cupboards.-		
4.15	Is work involving the evolution of harmful and obnoxious vapors carried out in a fume cupboard. Whether the exhaust system of the fume cupboard is checked frequently to ensure that it is in order. Is there a water drainage system inside the fume cupboard and checked frequently to ensure that there is no water logging and it is in order.		
5	Chemicals and Reagents:		
5.1	Whether the storage and handling of chemicals and reagents are done in a manner considering the physicochemical properties of these substances and the hazards involved in their use.		
5.2	Whether all reagents and solutions in the laboratory properly labeled along with concentration/titer and expiration date		
5.3	Whether period for reuse and scientific basis for this period is available		
5.4	Whether authenticity of weights are available		
5.5	Whether standardization is within permissible limit (10% of stated value)		
5.6	Is a standardization register maintained by the laboratory along 'with its raw data and SOP for preparation and standardisation on stock solutions, standard solutions, volumetric solutions are available for the guidance of staff?		

5.7	Whether Containers of stock solutions and of standard solutions bear the following details:-		
5.7.1	name of analytical chemist who prepared the solution;		
5.7.2	date of preparation and acceptance criteria of normality and precision.		
5.7.3	Each volumetric solution shall have "use before date" depending upon the stability of the solution;		
5.7.4	Whether Standardization records maintained.		
5.8	Whether the transfer of hazardous chemicals and reagents from one container to another container carried out with suitable equipment by taking the care of safety and no make-shift or hazardous methods resorted to.		
5.9	Specify the procedure followed for preparation, consumption & destruction of volumetric solution. Verify the SOP and records.		
5.10	Specify whether there is a log book for the preparations of the reagent including name of the analyst, name of the reagent, Calculations, Date of preparation & expiration.		
5.11	Specify the procedure followed for using GR, LR and AR grade of chemicals / solvents used for calibration & sample testing.		

6	Good housekeeping and safety:		
6.1	Is General and specific written down instructions for safety circulated to each staff member and the instructions revised periodically as appropriate (e.g., poster displays, audio-visual material and by seminars/conferences)		
6.2	Whether SOP for safety, house-keeping and loss prevention is prepared in accordance with the various rules, and regulations of the Government of India and include the following requirements, namely:-		
6.3	Safety data sheets available to staff before testing is carried out;		
6.4	Drinking, eating and smoking is not permitted in the laboratories; food for human consumption is not kept in working or storage areas; food meant for test animals is handled by the workers under the guidance of a veterinary doctor or qualified person. In the animal house, the facilities for collection and disposal of animal waste or safe sanitary storage of waste before removal from testing is provided;		
6.5	Staff wear laboratory coats or other protective clothing including gloves and face masks and eye protection wherever required;		
6.6	The laboratories have adequate first aid kit and-firefighting equipment located at the right places and the staff is familiar and trained with the use of		

	firefighting equipment including fire extinguishers, fire blankets and gas masks,		
6.7	Operators carrying out sterility tests wear sterilized garments including headgear, face masks and shoes;		
6.8	The staff is educated in the first aid techniques, emergency care and use of antidotes; and		
6.9	Safety rules in handling cylinders of compressed gases are observed and staff is familiar with relevant color identification codes;		
6.10	Protective Precautions to be taken in Laboratories		
6.11	Is water showers installed at appropriate places in the laboratory		
6.12	Is there washing shower provision for eye wash		
6.13	Is rubber suction bulbs used on manual pipettes and siphons		
6.14	Is warnings, precautions, and written instructions given for work with violent, uncontrollable or dangerous reactions (e,g, mixing water and acids, biological such as infectious agents, etc.);		
6.15	Are appropriate facilities for the collection, storage, and disposal of waste available?		
6.16	Is staff aware of methods for safe disposal of corrosive or dangerous products by neutralization or deactivation and of the need for complete disposal of mercury and its salts.		

6.17	Is staff also aware about the safety precautions to be adopted while handling potassium cyanide and cyanogen bromide?		
6.18	Is SOP for handling, collection, disposal of chemical and biological wastes available.		
6.19	Specify the safety measures taken to avoid any accidental hazards in the QC department.		
7	Maintenance, calibration, and validation of equipments		
7.1	Whether all equipments, instruments and other devices used in the laboratory have appropriate methods and procedures for all tests or calibrations and are regularly calibrated and validated.		
7.2	Whether original equipment manufacturer's recommendations along with the experience of the laboratory staff and the use of equipment per day also considered while fixing the frequency of calibration.		
7.3	Whether SOP for calibration and calibration schedule of equipments and instruments prepared by the laboratory and whether logbook is also available and maintained for proper documentation of calibration results.		

7.4	Dissolution: Verify the records of calibration of following parameters: —Checking of RPM —Checking of Temperature —Checking of distance between inside bottom of the vessel & paddle —Checking of distance between inside bottom of the vessel & Basket —Checking Wobbling of paddle —Checking of Wobbling of Basket —Checking of Timer: Calibrate against standard stop watch —Performance verification test <i>Verify whether dissolution is calibrated against standard prednisolone tablets.</i>		
7.5	UV Spectrophotometer: Verify the records of calibration of following parameters: —Control of wavelengths (Wavelength accuracy) —Control of absorbance (Photometric accuracy) —Limit Of Stray Light —Resolution Power —Resolution (second order derivative spectrum) —CELLS Verification —I0 flatness —Calibration of Visible Wavelength —Calibration of absorbance reproducibility for visible wavelength —Photometric linearity at 430nm		
7.6	FTIR: Verify the records of calibration of following parameters: —Verification of the wave number scale		

	—Control of resolution performance		
7.7	TOC: Verify the records of calibration of following parameters: —System suitability: —Calibration (Four point calibration)		
7.8	HPLC: Verify the records of calibration of following parameters: — Calibration of pump. — Calibration of Gradient proportionate valve (GPV). — Calibration of Auto injector. — Calibration of Detector. — Temperature calibration for Column oven and — Sample Trays compartment. — Auto Sampler Carry over. — Manual injector calibration — System suitability		
8	Reference Materials:		
8.1	Whether Reference materials used for testing and, or Calibration, validation or verification of sample or of equipment, instruments or other devices and all such materials are traceable to agency authorized by Government of India or any other International body. <i>Specify the source of procurement of various reference standards</i>		
8.2	Whether list of available reference standards being maintained		

8.3	Whether the laboratory prepares working standard by comparing with the reference standards and is routinely checked for their purity by selecting parameters such as identity, loss on drying or on water, impurity and assay, etc. <i>Verify the SOP and records for preparation of working standard from the reference standard.</i>		
8.4	Whenever, any new reference material is received by the laboratory, whether a code number is assigned and this code number is quoted on the laboratory note book and analytical work sheet. Is working standard also provided with identification code.		
8.5	Whether lab has adequate arrangements for proper storage (according to requisite storage conditions), security and labelling of reference standard and working standard. <i>How the reference standards are stored, evaluated and maintained.</i>		
8.6	Whether lab maintains record of preparation of working standard for daily use.		
8.7	Whether the lab has written procedure for handling and storage of reference standards		
8.8	Are SOP's for testing of working standards available if so, records thereof		
8.9	Whether a register pertaining to reference and working materials maintained by the laboratory and the following details mentioned in the register:		

8.9.1	source of supply		
8.9.2	code number of the reference material		
8.9.3	date of receipt		
8.9.4	batch number or identification number of the supplying agency		
8.9.5	details like assay value, water content or any other information provided		
8.9.6	storage condition of the material; and		
8.9.7	Date of expiry, if any and date of manufacturing if possible		
8.10	Whether all working standards are checked at appropriate intervals or before use to ensure that it has not deteriorated or decomposed during storage. Are these observations be recorded in a register. <i>Verify the SOP and records for destruction of unused working standard.</i>		
8.11	Specify whether authorized access system is followed for reference standards.		
9	Microbiological Section		
9.1	Whether microbiological section separate from other activities (with proper air-lock)		
9.2	Whether separate AHU's are provided for microbiological testing areas.		
9.3	Whether support areas are under same AHU which is used for sterile area.		
9.4	Briefly describe layout of the microbiology lab (attach copy of the layout if available)		
9.5	Whether entry to the sterile area is through three air lock systems with separate exit		

9.6	Specify whether access in sterile area is controlled, and if so the system followed in this regard		
9.7	Verify the list of equipment used in the microbiological lab and also specify whether these are placed logically and function accurately		
9.8	Specify whether operators are trained in gowning procedures. Verify the training records.		
9.9	Specify the gowning procedure to enter the sterile area. Verify the entry and exit records.		
9.10	Specify the air class of sterile areas and whether pressure difference is maintained. Verify the records.		
9.11	Specify whether an environmental monitoring programme is followed with alert and action limit.		
9.12	Specify whether a documented cleaning and disinfection programme is in place.		
9.13	Specify whether a procedure for dealing with spillages in sterile area is in place.		
9.14	Whether separate areas provided for sterility testing, assay of antibiotics & vitamins and MLT in sterile area.		
9.15	Specify the type of workstations (LAF) provided in the sterile area.		
9.16	Whether double door autoclave is provided for transferring of materials from unclassified area to sterile area.		

9.17	Verify the area qualification document for sterile area.		
9.18	Verify the procedure for selection of sampling location and interpretation of results for environmental monitoring of sterile area along with the SOP and documents. (Specify whether the method is in compliance with ISO 14644-1).		
9.19	Specify whether qualification of all equipment and instruments used in this department is covered under VMP.		
9.2	Verify the qualification document of major equipment like autoclave/incubator, hot air oven, refrigerator, LAF etc.		
9.21	Specify the Calibration procedure of temperature measurement devices used in autoclave and incubator. Verify whether it is traceable to standard temperature.		
9.22	Verify the procedure for the handling and disposal of chemical and microbial waste.		
9.23	Specify the procedure followed to verify the validity of the test in case of antibiotic potency testing.		
9.24	Specify whether there is separate autoclave for decontamination.		
9.25	Specify whether the Vendors for dehydrated media is approved and qualified.		
9.26	Specify whether GPT is carried out for dehydrated media.		
9.27	Specify whether performance of culture media (recovery or survival maintenance) is carried out and the results meet acceptance criteria.		

9.28	Specify the source of procurement of reference culture and its maintenance.		
9.29	Verify how the concentration of the inoculums is determined.		
9.30	Whether firm has provided microbiology lab for MLT test for nonsterile dosage form. If no how this test is complied.		
9.31	Specify the Air Grades for following areas:		
	I. Sterility testing room		
	II. Microbiological Assay room		
	III. MLT room		
	IV. Airlocks (entry and exit both)		
9.32	Whether sterile area properly designed to keep it free from outside contaminations?		
9.33	Are LAF tables properly validated to class 100 requirements		
9.34	Verify the following records:		
	—Log book for the entry/exit in the sterile area		
	—Media preparation record		
	—Records for water testing (micro)		
	—Records for MLT		
9.35	If the cultures have become non-viable or mutant, whether proper procedure is followed to destroy these cultures by autoclaving under an authorised personnel for biological testing(Preferably not more than five passages may be prepared).		
9.36	Whether all activities are carried out in a aseptic area by authorized person		

9.37	Does the laboratory perform standard biochemical tests on the sub-culture as given in literature to ensure their viability.		
9.38	Specify whether performance of culture media (recovery or survival maintenance) is carried out and the results meet acceptance criteria.		
9.39	Specify the source of procurement of reference culture and its maintenance.		
10	Quality system :		
	Whether the quality system is designed to ensure the following objectives:-		
10.1	Do the measurements and calibrations fully conform to the compendial requirements and the methods demonstrably based on validation protocols are followed.		
10.2	Whether the quality system is effective in providing necessary assurance that the activities or processes or techniques or practices comply with planned arrangements.		
10.3	Whether the quality system helps in early detection and correction of non-conformities.		
10.4	Whether remedial action on the observations by internal and external audits are taken appropriately.		
10.5			
10.6	Whether it has a documented quality policy for the organization		
10.7	Specify whether any particular test is outsourced. If so mention the name of laboratory and verify the contract made in this regard.		

10.8	Is there any SOP for handling of OOS product (out of specification)?		
11	Internal quality system audits:		
11.1	Whether Internal audits are done to assure the integrity of the analysis and whether such audits are conducted periodically with a predetermined schedule and procedure with appropriate checklist, to verify that the operations continue to comply with the requirements of quality system and requirements of regulatory authorities. Whether Internal quality audits is carried out by trained and qualified personnel who are independent of the activity to be audited.		
11.2	Whether the periodicity of quality audit is fixed by the Head of the laboratory so that each activity is audited at least once in a year. Please specify the periodicity and date of last quality audit.		
11.3	Whether Head of the laboratory is responsible for initiation of the corrective action arising from audits and verification of corrective action.		
11.4	Whenever any non-compliance or any diversion is noticed by the team in implementing quality policy or quality system, protocols, the same will be attended by the Quality Manager. The problem will be analysed and necessary actions will be taken with proper documentation.		

11.5	Whether the Quality Manager maintains all the records of the analysis being conducted which includes test system, the type of analysis, date on which analysis is done, etc and also maintains copies of all protocols pertaining to different activities being checked by the audit team.		
11.6	Are the outcomes of internal and external audits, PT, customer feedback and all other information derived from the tracking of quality indicators used to improve lab performance?		
12	Management review:		
	Whether Quality system reviews are conducted by the top management at least once in every twelve months and the agenda of review generally cover the following:-		
12.1	report or input of internal audits;		
12.2	matter arising from previous reviews		
12.3	report of external audits, if any;		
12.4	surveillance report, if any;		
12.5	result of proficiency testing		
12.6	complaints or feedback received from users of laboratory services;		
12.7	details of in-house quality control checks;		
12.8	need of amendment of the quality system and documentation		
12.9	induction training of new staff; and		
12.1	any other requirements of the laboratory		

13	Standard Operating Procedures:		
13a	Whether SOPs is written in a chronological order listing different steps leading to an analysis of drugs or calibration of an instrument and include designation of the person responsible for intended activity.		
13b	Whether Standard Operating Procedures in addition to those recommended under various activities are available to the minimum in respect of the following:		
13.1	sample handling and accountability;		
13.2	receipt identification, storage, mixing and method sampling of the test and control articles;		
13.3	record keeping, reporting, storage and retrieval of data;		
13.4	coding of different studies, handling of data including use of computerized data system;		
13.5	operation of technical audit personnel in performing and reporting audits, inspections and final report reviews;		
13.6	routine inspection of cleaning, maintenance, testing, calibration and standardization of instruments;		
13.7	action to be taken in respect of equipment failure		
13.8	analytical data methods		
13.9	the raw data		
13.10	data handling and storage retrieval		
13.11	health and safety protection		
13.12	animal room preparations		
13.13	animal care		
13.14	storage and maintenance of		

	microbial cultures		
13.15	maintenance of sterility room (Le. constant maintenance and monitoring of Aseptic condition of sterility room);		
13.16	use and storage of reference standards		
13.17	procurement of stores and equipment		
13.18	monitoring of testing of samples;		
13.19	method of retention of unexpended samples their maintenance and disposal;		
13.20	document control		
13.21	redressal of technical complaints		
13.22	housing-keeping		
13.23	corrective and preventing action;		
13.24	working procedure (test methods);		
13.25	calibration Manual; and		
13.26	training manual		
13.27	Verify the sampling SOPs and records for: —starting materials —primary packaging materials —secondary packaging materials —in process materials —finished products —water analysis —wash water analysis —swab analysis —wash water analysis of cleaned garments		

14	Protocols and specifications archive:		
14.1	Whether the laboratory has a specification archive and whether current versions of all necessary specifications are kept as per the requirements of the Act and the rules made there under and the National Pharmacopoeia (Indian Pharmacopoeia).		
14.2	Are all updates and corrections noted in the master volumes of Pharmacopoeias to prevent the use of obsolete sections; whether supplement and addendum are also available in the laboratory.		
14.3	Whether specification/standards are authentic and original		
14.4	Whether details of Drugs/Cosmetics reported not of standard quality forwarded to the respective Drug Controller and the Licensing Authority. Whether records maintained in this regard		
14.5	Whether the comparison is available that the in-house method is equivalent or superior, in case in-house method is used instead of compendial method		
14.6	Whether the record of study that non interference of placebo has been confirmed, is available		
14.7	For how long the sample declared of Standard Quality preserved.		
14.8	For how long the sample declared Not of Standard Quality preserved and what is the policy of the laboratory in		

	Disposal of samples once expired		
14.9	Verify whether all approved specifications are based on validation.		
14.10	Whether the specification archive contain the following		
14.10. 1	List of all the pharmacopoeias		
14.10. 2	a file on patent and proprietary medicines (non-pharmacopoeial) test methods to specifications prepared and validated the manufacturer or the laboratory itself. Whether the validated test methods developed by the manufacturer or the laboratory also stand to the requirements of compendia parameters in regard to its precision, accuracy, reproducibility, specificity, linearity, and ruggedness etc.		

14.11	Analytical Method Validation: Specify whether following Characteristics are considered during validation of analytical methods: — Specificity — Linearity — Range — Accuracy — Precision — Detection Limit — Quantification Limit — Robustness. —Solution Stability/Filter Study		
14.12	Specify whether approved specifications are available for all: —starting materials —primary packaging materials —secondary packaging materials —in process materials —finished products —water analysis —wash water analysis —swab analysis —wash water analysis of cleaned garments		
15	Raw data:		

15.1	Check randomly if raw data is available? (Raw data refers to the laboratory work sheet, note books or analysis sheet, records, memorandum, notes or extract copies thereof that may be the results of general observations and other activities and such raw data shall include hand written notes, photographs, software, drawings, computer printouts, spectral charts, dictated observations or recorded data from automated equipments. The raw data also includes record on receipt of animals, result of environmental monitoring, calibration, records of equipments, integrator output from analytical equipment, including work-sheet used to read a note, information from Light Emitting Diode (LED) display of any equipment.)		
15.2	Pl. Specify how changes in data is made, if required. (A single line shall strike through the data being changed; the correct information shall be recorded along with the old data and the reason of change. The analyst making the change shall be identified by his signature with date. In case of automated data collection system, the person responsible shall be identified at the time of data output. The original entry must be saved and the system have audit trail for all the data)		
15.3	Whether Data integrity and security is maintained.		

15.4	Whether the data is accessible to any unauthorized person.		
16	Storage and archival:		
16.1	Whether the residual sample is retained in proper storage condition for a period of one year after the final report.(Check randomly)		
16.2	Does the laboratory maintain procedures for the identification collection, indexing retrieval, storage, maintenance, and disposal of all documents?		
16.3	Whether all the raw data, documentation, Standard Operative Procedures, protocols, and final reports are retained and its archives available for orderly storage and expeditious retrieval. Does the archive provide a suitable environment that will prevent modification, damage, or deterioration and/or loss?		
16.4	Whether the condition under which the original documents are stored, ensures their security and confidentiality		
16.5	Whether the paper documents kept for long periods under high humidity and whether raw data in the form of tape and discs preserved with care.		
16.6	Whether in case of storage of only optical disc, the life of disc is longer than the storage time.		
16.7	Whether a photocopy of the thermal paper is retained in the archive, as Raw data on thermal paper might fade away with time.		
16.8	Whether any time is prescribed in the documents for which records are to be retained.		

17	HANDLING & RETENTION		
17.1	Sample		
17.1.1	Whether samples are right from receiving till disposal, are being handled properly		
17.1.2	Specify whether a designated person is responsible for receipt of samples for testing.		
17.1.3	Specify the procedure followed for receiving and recording (logging in). Verify the SOP and records		
17.1.4	Specify the procedure for storage and distribution of received samples to different analyst.		
17.1.5	Is there a maximum time limit for retention of sample in the laboratory prior to testing?		
17.1.6	Specify the procedure followed for storage of samples after testing.		
17.1.7	Specify the procedure for retention of samples after testing is completed.		
17.1.8	Whether after completion of test samples declared as standard quality and not of standard quality, samples are being kept up to declared time period in proper condition		
17.1.9	The retrieval of control sample is effective or not		
17.1.10	Average work load of testing during the year		
17.1.11	No. of samples received(during last financial year)		

17.1.1 2	Whether the details of sample booking are available		
17.1.9	Whether records in case of substance for which an expiry date is assigned are being retained for a period of two years from the expiry of such date. Whether in case of other substances such records are being maintained for six years.		
17.1.1 0	Whether disposal of records is being done in proper manner and with proper authorization		
17.1.1 1	Specify whether raw materials, intermediates and finished product testing is carried out as per approved STP and specifications and raw data is maintained.		
17.1.1 2	Specify the procedure of reporting the result of analysis by the analyst to QC Head.		
17.1.1 3	Specify the procedure for review of test data & calculations.		
17.2	Records		
17.2.1	Whether the details of Certificate & Reports are maintained		
17.2.2	Whether the documents list with retention period is available		
18	Instruments required for testing of Drugs other than those specified in Schedule C & C1		
18.1	Crude Vegetable Drugs		
18.1.1	General glassware		
18.1.2	Balance (Analytical)		
18.1.3	Microscope		
18.1.4	Soxhlet Extractor		

18.1.5	Water Bath		
18.1.6	Refractometer		
18.1.7	Oven		
18.1.8	Hot Plate		
18.1.9	TLC Kit		
18.1.10	U.V. Chamber		
18.1.11	Any Other Specialized equipment		
18.2	Mechanical Contraceptives (Schedule R)		
18.2.1	Leakage tester		
18.2.2	Bursting col., Pressure tester		
18.2.3	Vernier Caliper		
18.2.4	Micrometer		
18.2.5	Balance (Analytical)		
18.2.6	Aging Oven		
18.2.7	Equipment's for Package integrity test.		
18.3	Surgical Dressing (Schedule F11)		
18.3.1	U.V. Cabinet		
18.3.2	Soxhlet extractor		
18.3.3	Oven		
18.3.4	Scale		
18.3.5	Absorbency Tester		
18.3.6	Balance (Analytical)		
18.3.7	All equipment required for Sterility testing		
18.4	Drug requiring Instrumental Analysis		
18.4.1	UV/VIS Spectrophotometer		
18.4.2	I.R. Spectrophotometer		
a	Pallet maker and holder		
b	KBR discs(for nuzole mull)		
c	Liquid Cell Holder		
18.4.3	HPLC (Isocratic & Quarternary)		
a	Type of detector		
b	Required Columns		
18.4.4	Gas Chromatograph		
a	Type of detector		
b	Required Columns		

18.4.5	AAS (Flame/Graphite furnace/Hydride generator)		
18.4.6	HPTLC		
18.4.7	TLC		
18.4.8	Fluorometer		
18.4.9	Potenimetric Titrator		
18.4.1 0	Flame Photometer		
18.4.1 1	Balance (Ultra Micro Analytical)		
18.4.1 2	Microscope		
18.4.1 3	KF Titrator		
18.4.1 4	Oven		
18.4.1 5	Muffle Furnace		
18.4.1 6	Water Bath		
18.4.1 7	Fridge		
18.4.1 8	Dissolution Test Apparatus		
a	Basket Type		
b	Paddle Type		
18.4.1 9	Disintegration Test Apparatus		
18.4.2 0	Melting Point Apparatus		
18.4.2 1	Refractometer		
18.4.2 2	Polarimeter		
18.4.2 3	General Glassware		
18.4.2 4	Chemicals		
18.4.2 5	Stop watch		
18.4.2 6	Water Distillation Plant		
18.4.2 7	Particle Counter (Specially for LVP's)		

18.4.2 8	710 microne Sieve for Uniformity of dispersion test		
18.4.2 9	Platinum crucible		
18.4.3 0	Any other instrument required for Specialized testing		
18.4.3 1	Vacuum Pump		
18.4.3 2	Filtration unit		
18.4.3 3	pH Meter		
18.4.3 4	Stop Watch		
18.4.3 5	Vernier Caliper		
18.4.3 6	Vortex Mixer		
18.4.3 7	Viscometer		
18.4.3 8	Centrifuge		
18.4.3 9	Orbital Shaker		
18.4.4 0	Griffin Flasks Shaker		
18.4.4 1	Magnetic Stirrer		
18.4.4 2	Heating Mantle		
19	Drugs requiring use of Microbiological Testing		
19.1	General		
19.1.1	Clean room.		
19.1.2	Laminar Flow		
19.1.3	Biosafety Cabinet		
19.1.4	Autoclave for sterility		
19.1.5	pH Meter		
19.1.6	Gas Burner		
19.1.7	Water Bath		
19.1.8	Incubator		
19.1.9	Filtration unit		

19.1.1 0	Vacuum Pump		
19.1.1 1	BOD Incubator		
19.1.1 2	Refrigerator		
19.1.1 3	Balance (Analytical)		
19.1.1 4	Glass wares		
19.1.1 5	Centrifuge		
19.1.1 6	Microscope		
19.1.1 7	Other general equipment required for general day to day activity		
19.1.1 8	Cultures		
20	Special requirements other than General for:		
20.1	Disinfectants		
20.1.1	Platinum loop		
20.1.2	Proper Culture		
20.1.3	Stop Watch		
20.1.4	Oven up to 35°C		
20.2	Antibiotics		
20.2.1	Spectrophotometer		
20.2.2	Vernier Caliper/Zone Reader		
20.2.3	Proper Culture		
20.2.4	Borer		
20.2.5	Media		
20.3	Vitamins (excluding electrophoresis)		
20.3.1	Spectrophotometer		
20.3.2	Vernier Caliper/Zone Reader		
20.3.3	Vortex Mixer		
20.3.4	Culture		
20.3.5	Media		
20.3.6	Borer		
20.4	Sterility		
20.4.1	Filtration Unit		
20.4.2	Vacuum Pump		

20.4.3	Media		
20.4.4	0.45m Pore Filter Paper Sterile		
20.4.5	Sterile forceps, Scissors & Bone cutter, Surgical blade, Ampoule Cutter		
20.4.6	Sterile Gloves		
20.4.7	Face Masks		
20.4.8	Caps		
20.4.9	Sterile garments		
20.5	Endotoxins		
20.5.1	LAL Reagents		
20.5.2	Heating block		
20.5.3	Sterile test tubes		
20.5.4	Vortex mixer		
20.5.5	Sterile tips		
20.5.6	Pipettes tips (Pyrogen free)		
20.5.7	Stop watch		
20.5.8	LAL Water/Pyrogen free Sterile distilled water		
20.6	Pyrogen		
20.6.1	Animal House		
20.6.2	Pyrothermometer/Rectal thermometer		
20.6.3	Sterile syringes, needles		
20.6.4	Pyrogen free glassware		
20.6.5	Pyrogen free Sodium Chloride Solution/Water		
20.6.6	Animal Holding Stands		
20.7	Sterilized surgical Sutures and Ligatures		
20.7.1	Sterility testing facilities		
20.7.2	Tensile Strength Tester		
20.8	Sera Vaccines		
20.8.1	Sterility testing facilities and Other specialized testing facilities required for Testing Sera vaccines		
20.9	Pharmacological Testing:		
20.9.1	Operation Table		
20.9.2	Kymograph		
20.9.3	Water Bath		
20.9.4	Manometer		

20.9.5	Cannula		
20.9.6	Oxygen Cylinder		
20.9.7	Other equipments required for Pharmacological testing		
21	Cosmetic Testing:		
21.1	Pay-off test apparatus		
21.2	Break load apparatus		
21.3	Foam height apparatus		
21.4	Scratch test apparatus		
21.5	Drying time apparatus		
21.6	Penetrometer for consistency		
21.7	Rotating Viscometer		
22	CERTIFICATES & REPORTS		
22.1	Whether Test Reports are issued on prescribed Form 39 containing the required information as prescribed.		
22.2	Whether description of sample received for testing are available including receipt identification		
22.3	Whether statement of method used for each test is maintained and available		
22.4	Whether complete records of all raw data including graphs, charts etc. are available		
22.5	Whether records of all calculations performed are available. Check calculation on random basis.		
22.6	Whether statement of test results and how they compare with specification are available		
22.7	Whether initials or signature along with date of person performing each tests are available in the records.		

22.8	Whether initials or signature along with date of second person showing that the records have been reviewed for accuracy, completeness and compliance with the specifications are available in the records.		
22.9	Whether records of preparation of laboratory reference standards, reagents and standard solution are available.		
22.10	Specify the procedure followed for issuance of COA.		
23	Data Integrity		
23.1	Whether the records are completed at the time of the operation and are legible maintained with raw data if applicable.		
23.2	Whether the firm has software based testing equipment		
23.3	Whether the individuals are provided log in IDs for access. All login and logout information should be available.		
23.4	Whether rights to work, amend, modify, delete are specified in written document.		
23.5	Whether right to access and modify are with two different individuals. If yes how QA is involved in modification of data.		
23.6	Whether audit trails related to project creation (study creation), project (study) modification, deletion etc. are available.		
23.7	Whether the data is backed up at regular intervals. If yes what is the written back up policy. The data backup must be server based.		

23.8	How Excel sheets are validated if calculation are done in Excel sheet.		
23.9	Whether the firm has QA SOP for review of data integrity or audit trail. If yes how the modification and deletions are reviewed.		

This is Only Guidance document. Necessary Changes can be done as per Type and scope of Inspection. Discrepancies and Observations noted may be noted on separate sheets. If Any discrepancy is observed Act and Rules will prevail.