GOOD PRACTICES SELF-EVALUATION GUIDE FOR NATIONAL PHARMACEUTICAL CONTROL LABORATORIES

PAN AMERICAN NETWORK FOR DRUG REGULATORY HARMONIZATION

Pan American Health Organization
Washington, D.C.

GOOD PRACTICES SELF-EVALUATION GUIDE FOR NATIONAL PHARMACEUTICAL CONTROL LABORATORIES

ACKNOWLEDGMENT

This document responds to Annex 3, Report 36 of the WHO Technical Report Series No. 902. It was prepared with the collaboration of professionals at the National Center for Quality Control–INS of Lima, Peru, headed by Rosario Vega Huanca of the Executive Office on Laboratories. It was reviewed by the Working Group on Good Laboratory Practices (TAG/GLP) of the Pan American Network for Drug Regulatory Harmonization (PARF Network) it during the Third Meeting, held in Santo Domingo, the Dominican Republic, from 6 to 10 March 2006. It was edited by José M. Parisi (PAHO/WHO Secretariat). The English version was prepared with the collaboration of professionals at the Center of Reference Drug Testing Laboratory (CRDTL) in Jamaica, and the Instituto Especializado de Analisis (IEA) of Panama University in Panama.

5th Meeting of the Working Group on Good Laboratory Practices GLP/WG)
Guatemala City, Guatemala (May 30-31, 2007)

Members

- *María Gloria Olate, ISP/ Chile, Coordinator*
- *Rosario Vega Huanca, INS/ Perú*
- *Nilka G. de Solís, IEA/ Panamá*
- *Lucette Cargill, CRDTL/ Jamaica*
- *Silvânia Vaz de Melo Mattos, GGLAS- ANVISA/ Brasil*
- *Víctor Pribluda, USP*

Secretariat

- *José M. Parisi, PAHO/WHO/ Washington, D.C.*

Observers

- *Carlos Saldarriaga Alzate, Univ. de Antioquia/ Colombia*
- *Catalina Massa, Univ. de Córdoba/ Argentina*
- *Milagros Real Pérez, INS de Lima/Perú*
- *Antonio Hernández-Cardoso, USP*
- *Ismael Mansilla, LNS/Guatemala*

GOOD PRACTICES SELF-EVALUATION GUIDE FOR NATIONAL PHARMACEUTICAL CONTROL LABORATORIES

PART ONE: MANAGEMENT AND INFRASTRUCTURE

#	QUESTIONS	REF	COMPLIES	DOES NOT COMPLY	REMARKS
1. ORGANIZATION AND MANAGEMENT					
1.1	Does the laboratory possess a document legally authorizing it to serve as the National Pharmaceutical Control Laboratory?	1.1			
1.2	Do the laboratory's technical and managerial personnel have sufficient authority and the necessary resources to meet their obligations and identify and prevent deviations from: the quality system?	1.3.(a)			
1.3	- protocols for doing the assays and/or calibrations and validating testing methods?				
1.4	- assessment, verification, and calibration of equipment?				
1.5	Does the laboratory have measures in place to ensure that both Management and staff are not subject to commercial, political, financial, or other pressure or conflicts of interest that could undermine the quality of their work?	1.3.(b)			
1.6	Do laboratory personnel have organizational charts indicating the organization and structure of laboratory management, and do they know where they fit in the organization and the relationships between management, technical operations, support services, and the quality system?	1.3.(c)			
1.7	Does the laboratory's documentation indicate the responsibilities, authority, and relationships of all staff that manages, executes, or verifies the work?	1.3.(d)			
1.8	Does the laboratory have mechanisms to guarantee communication between and coordination of the personnel involved in testing the same sample in the different units?	1.5			
2. QUALITY SYSTEM					
2.1	Is there an up-to-date quality system appropriate to its activities?	2.1			
2.2	Is there a description of the policies, systems, programs, procedures, and instructions to assure the quality of the results it produces?	2.1			
2.3	Is the documentation on the quality system disseminated, available, acted on, and understood by the respective personnel?	2.1			
2.4	Does the laboratory have a quality assurance manual that is maintained and updated by the personnel in charge and that contains the following? :	2.1			
2.5	- the structure (organizational chart) of the laboratory?	2.1.(a)			
2.6	- operational and functional activities, so that each person involved knows the extent and limits of his responsibilities?	2.1.(b)			
2.7	- a list of the assays performed?				
2.8	- a list of the equipment available to carry out these activities?				
2.9	- the corresponding references to the general procedures for internal quality assurance?	2.1.(c)			
2.10	- the corresponding references to the specific quality assurance procedures for each assay?	2.1.(d)			
2.11	- information on the mechanisms for participation in appropriate programs to test improvements, the use of reference materials, etc.?	2.1.(d)			
2.12	- appropriate detailed plans for feedback to take corrective action when there are discrepancies in test results?	2.1.(f)			
2.13	- procedures for responding to complaints?	2.1.(g)			

#	QUESTIONS	REF	COMPLIES	DOES NOT COMPLY	REMARKS
2.14	- a flow chart for the samples?	2.1.(h)			
2.15	- details of audits and review of the quality system?	2.1.(i)			
2.16	- information on the qualifications that personnel should possess?	2.1.(j)			
2.17	- information on staff training, both initial and in-service?	2.1.(k)			
2.18	Does it include the quality policy, statement of intent, purpose, hiring conditions, and the knowledge required of staff?	2.1.(l)			
2.19	- the expectations of the laboratory's Management regarding the standard of service that will be provided?	2.1.l.(i)			
2.20	- the purpose of the quality system?	2.1.l.(ii)			
2.21	- the commitment of Management to good professional practice?	2.1.l.(iii)			
2.22	- the commitment of Management to compliance with the content of this guide?	2.1.l.(iv)			
2.23	- the requirement that all personnel involved in assays and calibration activities in the laboratory be familiarized with the quality documentation and application of the policies and procedures governing their work?	2.1.l.(v)			
2.24	Is the quality system systematically and periodically reviewed (internal and external audits) and the results recorded, together with the details of the corrective action taken?	2.2			
2.25	Has a person in charge of quality (Quality Manager) been appointed by the laboratory's Management?	2.3 and 6.6.(f)			
2.26	Has the person in charge of quality (Quality Manager) been given the functions and sufficient authority to ensure that the quality system is continuously up and running, regardless of his other obligations and responsibilities?	2.3			
2.27	Does the Quality Manager have direct access to the highest level of Management where the decisions on laboratory policy and resources are made?	2.3			
3. DOCUMENT CONTROL					
3.1	Does the laboratory have procedures to keep track of and review all documents (internally generated and from external sources) that are part of the quality documentation?	3.1			
4. RECORDS					
4.1	Does the laboratory have procedures for the identification, collection, indexing, retrieval, storage, maintenance, delivery, and access to all quality documentation and technical records?	4.1			
4.2	Are records of all the original observations, calculations, and derived data, calibrations, validation and verification records for other related activities, as well as the end results, retained for a appropriate period as stipulated in national regulations?	4.2			
4.3	Do the records for each assay contain sufficient information to allow for its repetition?	4.2			
4.4	Do the records include the identity of the staff involved in the sampling, preparation, and sample analysis?	4.2			
4.5	Do the records of the samples to be used in legal procedures conform to the applicable legal requirements?	4.2			
4.6	Are all records legible, rapidly retrievable, stored, and protected in facilities that provide a suitable environment that prevents alterations, damage, deterioration and/or loss?	4.3			
4.7	Do the quality records include the internal (and external, if applicable) audits and Management reviews, including the records of possible corrective and preventive actions?	4.3			

GOOD PRACTICES SELF-EVALUATION GUIDE FOR NATIONAL PHARMACEUTICAL CONTROL LABORATORIES

#	QUESTIONS	REF	COMPLIES	DOES NOT COMPLY	REMARKS
4.8	Does the laboratory have written, authorized Standard Operating Procedures (SOPs) to carry out basic functions and following:	4.4			
4.9	- the purchase and receipt of shipments of materials (e.g., samples, reference materials, reagents)?	4.4.(a)			
4.10	- internal labeling, quarantine, and storage of materials?	4.4.(b)			
4.11	- proper installation of each instrument and piece of Equipment?	4.4.(c)			
4.12	- sampling and inspection?	4.4.(d)			
4.13	- analysis of material, with a description of the methods and equipment used?	4.4.(e)			
4.14	- the assessment of equipment?	4.4.(f)			
4.15	- the calibration of instruments for analysis?	4.4.(g)			
4.16	- maintenance, cleaning, and sanitization?	4.4.(h)			
4.17	- safety precautions?	4.4.(i)			
4.18	- activities related to personnel, including qualifications, training, dress code, and hygiene?	4.4.(j)			
4.19	- environmental monitoring?	4.4.(k)			
4.20	- the preparation and control of reference materials?	4.4.(l)			
5. EQUIPMENT WITH DATA PROCESSORS					
5.1	Does the laboratory have a mechanism that ensures that calculations and data transfers are systematically and properly verified?	5.1.(a)			
5.2	Is the software developed by the user documented, appropriately validated, and verified for use?	5.1.(b)			
5.3	Does the laboratory have procedures in place to protect the integrity of the data in equipment with data processors? And does it have:	5.1.(c)			
5.4	- a maintenance program for computers and automated equipment?	5.1.(d)			
5.5	- the necessary environmental and operating conditions to ensure the integrity of the assay and calibration data?	5.1.(d)			
5.6	- procedures in place to document and monitor changes in the information protected in computer systems?	5.1.(e)			
5.7	- procedures to protect and maintain the back-ups of the data in equipment with data processors?	5.1.(f)			
6. PERSONNEL					
6.1	Does the laboratory have sufficient personnel with adequate training and know-how and the experience necessary for properly carrying out the functions assigned?	6.1			
6.2	Does it have mechanisms to ensure the technical competency of the personnel that operate specific equipment, instruments, or other devices and that perform assays and/or calibrations, validations or verifications?	6.2			
6.3	Are personnel in training supervised and evaluated?	6.3			
6.4	Do the laboratory personnel who perform specific tasks have the skills to do so?	6.3			
6.5	Are laboratory personnel permanently employed or under a fixed-term contract (temporary)?	6.4			
6.6	Does the laboratory have a manual containing descriptions or profiles of posts for the staff that performs the assays and/or calibrations, validations or verifications?	6.5			
6.7	Does it have rosters of technical personnel, including those under contract, that describes their areas of competence, educational and professional qualifications,	6.5			

#	QUESTIONS	REF	COMPLIES	DOES NOT COMPLY	REMARKS
	training, skills, and experience?				
6.8	Is there a Laboratory Chief with experience in the analysis of pharmaceutical products and the management of pharmaceutical control laboratories in the regulatory or industrial sector?	6.6.(a)			
6.9	Is verifying of the competence and level of key personnel based on their responsibilities one of the duties of the Laboratory Chief?	6.6.(a). (i)			
6.10	- verifying the periodic analysis of standard samples?	6.6.(a). (ii)			
6.11	- ensuring that the existing staff are trained and that management and training protocols are periodically reviewed?	6.6.(a). (iii)			
6.12	- verifying the development of self-evaluation protocols for the staff that operates instruments?	6.6.(a). (iv)			
6.13	- preparing regular in-service training programs to upgrade the skills of professional staff and technicians?	6.6.(a). (v)			
6.14	- secure storage of any narcotic kept in the workplace, under the supervision of a duly authorized individual?	6.6 (a) (vi)			
6.15	Does the laboratory have a Chief of Central Records with experience in the analysis of pharmaceutical products?	6.6.(b)			
6.16	Do the responsibilities of the Chief of Central Records include receiving and preserving the records on incoming samples and the documents attached?	6.6.(b). (i)			
6.17	- supervision of the shipment of the samples to specific units?	6.6.(b). (ii)			
6.18	- monitoring of the course of the analyses and the dispatch of test reports?	6.6.(b). (iii)			
6.19	- evaluation of test results, if necessary ?	6.6.(b). (iv)			
6.20	Does the laboratory have professional staff with a degree in pharmacy, analytical chemistry, microbiology, or other pertinent disciplines?	6.6.(c)			
6.21	Does the laboratory have technicians with degrees from technical schools?	6.6.(d)			
6.22	Does the laboratory have warehouse staff responsible for storing materials in the central warehouse?	6.6.(e)			
6.23	Is there a mechanism to ensure the competence of warehouse staff in the correct and safe handling of reagents?	6.6.(e)			
6.24	If it has subunits, does the laboratory have Chiefs of the different subunits?	6.7.(a)			
6.25	If it has subunits, does the laboratory have a reference materials coordinator?	6.7.(b)			
6.26	Is the ratio of technicians to professional staff adequate?	6.8			
7. INSTALLATIONS					
7.1	Are the size, structure, location, and security of the laboratory adequate?	7.1			
7.2	Does the laboratory's design permit an adequate degree of separation for the activities carried out?	7.2			
7.3	Does it have enough areas to ensure that analysis systems are isolated from each other?	7.3			
7.4	Is the laboratory's safety equipment in working order (enough fire extinguishers, specific substances to eliminate spills, etc.)?	7.4			
7.5	Is the state of the facility periodically reviewed?				
7.6	Are the necessary energy sources available and, for variable voltage lines, have the proper stabilizers been	7.4			

#	QUESTIONS	REF	COMPLIES	DOES NOT COMPLY	REMARKS
	installed?				
7.7	Are the storage areas for materials and supplies conveniently located?	7.5			
7.8	Are storage areas separate from the testing areas, and is there adequate protection from infestation, contamination, and/or deterioration?	7.5			
7.9	Does the laboratory have separate areas for the receipt and storage of testing and reference materials?	7.6			
7.10	Are the storage areas built in such a way as to preserve the identity, concentration, purity, and stability of the testing materials?	7.7			
7.11	Does the laboratory have installations that ensure the proper storage of hazardous substances?	7.7			
7.12	Do the storage areas have fire protection equipment compliant with the applicable regulations?	7.7			
7.13	Does the laboratory have adequate installations to protect against and reduce environmental contamination from flammable reagents, fumes, concentrated acids and bases, volatile amines, etc.?	7.7			
CENTRAL STOREROOM (WAREHOUSE)					
7.14	Does the laboratory have a central storeroom (warehouse)?	7.8			
7.15	Does the central storeroom have separate facilities for storing samples, retained samples, reagents, laboratory accessories, and reference materials?	7.8			
7.16	Does the central storeroom have the necessary equipment and conditions for samples requiring special storage conditions?	7.8			
7.17	Is access to the central storeroom restricted to authorized personnel?	7.8			
7.18	Is the central storeroom organized to accommodate incoming and outgoing samples, reagents, equipment, instruments, and other devices?	7.9			
7.19	Is there a written safety protocol for the storage and use of toxic and flammable reagents?	7.10			
7.20	Are poisonous or controlled narcotics and psychotropic substances stored separately in locked cabinets?	7.11			
7.21	Are records kept on substances subject to additional regulations and on the people responsible maintaining them?	7.12			
7.22	Is proper management of these substances in the workplace assured?				
7.23	Are there installations for files where reliable storage of documents (generated by internal or external sources), samples of testing materials, and specimens is assured?	7.13			
7.24	Do the design and conditions of these installations assure preservation of the documents and samples?	7.13			
7.25	Is access to the files restricted to authorized personnel?	7.13			
7.26	Does the laboratory have protocols and installations for the collection, management, classification, transport, and disposal of waste?	7.14			
7.27	Are the laboratory's facilities protected from heat, cold, dust, humidity, steam, noise, vibration, electromagnetic disturbances or interference, as required?	7.15			
7.28	If the nature of the tests so indicates, are environmental monitors present?	7.15			
7.29	Is the access of staff to the laboratory and its various areas monitored and restricted?	7.15			
7.30	Is the entry of nonlaboratory staff controlled?	7.15			

8. EQUIPMENT, INSTRUMENTS, AND OTHER DEVICES					
8.1	Does the protocol for procuring laboratory equipment include the requirements for the operations to be carried out?	8.1			
8.2	Do the laboratory's equipment suppliers have representatives who provide complete technical support and maintenance when necessary?	8.1			
8.3	Do the equipment, instruments, and devices have manuals written in the language of the laboratory staff?	8.1			
8.4	Does the laboratory have enough equipment and instruments to ensure proper performance of the tests and/or calibrations, validations and verifications and to do the sampling?	8.2			
8.5	Do the equipment, instruments, and other devices meet the laboratory's requirements and the pertinent standard specifications, and are they calibrated and/or verified?	8.3			

PART TWO: MATERIALS AND MAINTENANCE OF EQUIPMENT, INSTRUMENTS, AND OTHER DEVICES

#	QUESTIONS	REF	COMPLIES	DOES NOT COMPLY	REMARKS
9. SPECIFICATIONS RECORDS					
9.1	Does the laboratory have specifications records containing up-to-date data on all quality specifications and related documents?	1.4.(d) and 9.1			
9.2	Is there a written protocol for updating the specifications records?	9.1			
9.3	Is there a list of all the available pharmacopeias?	9.2 (a)			
9.4	Are there records on nonpharmacopeia quality specifications?	9.2 (b)			
9.5	Is there a protocol for document control in specifications records?	9.2 (b) and 9.3			
9.6	Are there policies or standards that guarantee the confidentiality of manufacturers' specifications?	9.4			
9.7	Does the laboratory have staff responsible for the documentation service?	9.5			
9.8	Do the responsible staff have a mechanism for updating the pharmacopeias, supplements, etc.?	9.5.(a)			
9.9	Do the staff personnel have a mechanism to ensure compliance with the specifications of the drugs authorized for sale in the country?	9.5.(b)			
10. REAGENTS					
10.1	Are there mechanisms that assure the quality of the reagents and materials used in the laboratory?	10.1			
10.2	Does the laboratory have prequalified suppliers for the procurement of reagents?	10.2			
10.3	Are the reagents procured for use in the laboratory accompanied by a certificate of analysis?	10.2			
10.4	Is someone in charge of the preparation of reagents?	10.3			
10.5	Does the person in charge of preparing the reagents have written protocols for this activity?	10.3			
10.6	Does the person in charge of preparing the reagents keep records of the preparation and standardization of volumetric solutions?	10.3			
10.7	Do the labels of all reagents used in the laboratory list the contents, manufacturer, date of receipt, and, when appropriate: the concentration, standardization factor, expiration date, and conditions for storage?	10.4.(a)			
10.8	Do the labels of the reagents prepared in the laboratory	10.4.(a)			

#	QUESTIONS	REF	COMPLIES	DOES NOT COMPLY	REMARKS
	contain the date of preparation and the name and initials of the technician who prepared them?				
10.9	Does the labeling of the volumetric solutions prepared in the laboratory include the name of the manufacturer of the original reagent, the date of preparation, the date of standardization, the dilution factor, and the name of the technician who prepared them?	10.4.(b)			
10.10	For the transportation and fractioning of reagents for use in the laboratory, are safety measures applied when the reagents are transferred from the central storeroom to the various units?	10.5.(a), (b) and (c)			
10.11	Are visual inspections of the containers with the reagents recorded on the label, with the date, name, and initials of the person who made the inspection?	10.6 and 10.7			
10.12	Are measures in place for dealing with reagents for use in the laboratory whose seal has been broken (probably adulterated)?	10.8			
Distilled and Deionized water					
10.13	Is the water used in assays and the preparation of reagents regularly checked?	10.11			
10.14	Does the laboratory have written protocols to ensure compliance with pharmacopeia or other official requirements?	10.11			
Storage					
10.15	Does the central storeroom (warehouse) have enough clean containers, spoons, funnels, and labels of the right type to dispense reagents?	10.12			
10.16	Does the person in charge of the central storeroom have an up-to-date inventory of chemicals and reagents, with expiration dates?	10.13			
10.17	Has the person in charge of the central storeroom been trained in the safe handling of chemicals?	10.13			
10.18	Does the laboratory have separate areas for storing flammable substances, fume-producing substances, concentrated acids and bases, volatile amines. and other reagents such as hydrochloric acid, nitric acid, ammonia, and bromide?	10.14			
10.19	Does the laboratory have separate areas for storing autoflammable materials such as: metallic sodium and potassium?	10.14			
11. REFERENCE MATERIALS					
11.1	Does the laboratory have an up-to-date list of reference materials (e.g. official reference substances and reference preparations, secondary reference materials and unofficial preparations in the laboratory as standards for its work)?	11.1			
Records and Labeling					
11.2	Does the laboratory have a written protocol that assigns an identification number to every reference material, where each vial of material is marked and the number indicated on an analysis worksheet each time the material is used?	11.2, 11.3, 11.4, and 11.5			
Central Records					
11.3	Is the up-to-date list of reference materials kept in a central records system containing the details of each reference material?	11.6			
11.4	Do the central records provide:	11.7.(a)			

#	QUESTIONS	REF	COMPLIES	DOES NOT COMPLY	REMARKS
	the identification number of the material?				
11.5	- a precise description of the material?	11.7.(b)			
11.6	- information on the origin of the material?	11.7.(c)			
11.7	- the date of receipt?	11.7.(d)			
11.8	- the lot number or another identification code?	11.7.(e)			
11.9	- the purpose of the material (e.g. as an infrared reference materials, as impurity for thin-layer chromatography, etc.)?	11.7.(f)			
11.10	- information on where it is stored in the laboratory or any special storage conditions?	11.7.(g)			
11.11	- any additional information (e.g. the results of inspections)?	11.7.(h)			
11.12	Is someone been appointed to oversee the central records on reference materials, with assigned functions?	11.8			
11.13	If the official laboratory has reference materials for use by other institutions or pharmaceutical manufacturers, does it have a separate unit to handle this function?	11.9			
Information Records					
11.14	Does the laboratory have records with information on the properties of each reference material, in addition to the central records?	11.10			
11.15	Do the information records have lists of standard reference materials prepared in the laboratory that include the results of all tests and verifications, as well as the initials of the analyst who performed them?	11.11			
Inspection					
11.16	Are reference materials regularly inspected to ensure that have they not deteriorated and that the storage conditions are adequate?	11.12			
11.17	Are the results of the inspections of reference materials kept in the central and/or information records with the initials of the analyst who performed them?	11.13			
12. CALIBRATION, VALIDATION, AND VERIFICATION OF EQUIPMENT, INSTRUMENTS, AND OTHER DEVICES					
12.1	Does the laboratory have programs for calibration, validation, and verification of the equipment, instruments, and other devices?	12.1 and 8.1			
12.2	Does the laboratory have SOPs for the use, calibration, validation, and verification of equipment, instruments, and other devices, specifying how often it should be done?	12.2			
12.3	Is there a list of personnel authorized to operate the equipment, instruments, and other devices?	12.3			
12.4	Are up-to-date operating manuals for the equipment, instruments, and other devices kept with them and are they available for use by the appropriate personnel?	12.3			
12.5	Does the laboratory have cards or records of past and scheduled verifications/calibrations in view?	12.3			
12.6	Does each piece of equipment, instrument, or other device used in the laboratory for assays, verification, and calibration have a unique identification number?	12.4			
12.7	Does the laboratory have records on use of the equipment, instruments, or other devices used in assays, verification, and/or calibration?	12.5 12.5.(a)			
12.8	Do the records on the use of the equipment, instruments, and other devices contain the name of the manufacturer, the serial number, or some other unique identification number?	12.5.(b)			
12.9	Do the records of use for the equipment, instruments, and other devices indicate the verification and/or calibration	12.5.(c)			

#	QUESTIONS	REF	COMPLIES	DOES NOT COMPLY	REMARKS
	requirements to meet their specifications?				
12.10	Do the records of use indicate the present location of the equipment, instrument, or device?	12.5.(d)			
12.11	Do the records of use for the equipment, instruments, and other devices contain the manufacturer's instructions (if available) or a reference to where they can be found?	12.5.(e)			
12.12	Do the records of use for the equipment, instruments, and other devices contain dates, results, and copies of reports, verifications, certificates of calibration, adjustments, acceptability criteria, and date of the next calibration and/or verification?	12.5.(f)			
12.13	Do the records of use for the equipment, instruments, and other devices contain information on the maintenance done to date and the maintenance plan?	12.5.(g)			
12.14	Do the records of use for the equipment, instruments, and other devices contain a history of any damage, malfunction, modification, or repair?	12.5.(h)			
12.15	Does the laboratory have a plan for the safe handling, transport, storage, use, and maintenance of measurement equipment to ensure its proper operation?	12.6			
12.16	Is there a routine maintenance plan for the measurement equipment (with the maintenance performed by a specialized external or internal service)?	12.7			
12.17	Are defective equipment, instruments, and other devices or those that produce results outside the specifications identified and/or separated?	12.8			
12.18	Does the laboratory have records on their repair and calibration/testing before they are put into use?	12.8			
12.19	For each piece of equipment, instrument, and other device in the laboratory, is the calibration or recalibration status indicated?	12.9			
12.20	Are the good operation and calibration of the equipment and instruments guaranteed once they are returned to the direct control of the laboratory?	12.10			
12.21	Are the testing equipment, instruments and other devices located in appropriate environments and duly protected from external agents?	12.11			
13. TRACEABILITY					
13.1	Does the laboratory have procedures in place to ensure the traceability of the analytical measurements that it performs?	13.1			
13.2	Does the laboratory determine the uncertainty of the analytical measurements that it performs?	13.2			
13.3	Are the analytical methods used in the laboratory validated or confirmed under the conditions of use?	13.5			

PART THREE: WORK PROCEDURES

#	QUESTIONS	REF	COMPLIES	DOES NOT COMPLY	REMARKS
14. SAMPLE INCOME					
14.1	Does the laboratory have written sampling protocols?	14.1			
14.2	Does the sampling protocol indicate the obligation to collect a sample large enough to repeat the tests and retain a portion?	14.2			
14.3	Does the sampling protocol call for taking at least three samples, sealed and documented?	14.3			
14.4	Does the laboratory have a sampling plan and an internal sampling protocol that are available to all professionals	14.4			

#	QUESTIONS	REF	COMPLIES	DOES NOT COMPLY	REMARKS
	and technicians in the laboratory?				
Analysis Request Form					
14.5	Does the laboratory have a form for requesting the analysis of a sample?	14.5			
14.6	Does the request form have: space for the name of the institution or the inspector who provided the sample?	14.6.(a)			
14.7	- space for the information on the origin of the material?	14.6.(b)			
14.8	- space for a description of the product, including its composition, international nonproprietary name (INN) (if available), brand name(s), dosage form and concentration or potency, manufacturer, lot number (if available) and sales permit number?	14.6.(c)			
14.9	- space to indicate the size of the sample?	14.6.(d)			
14.10	- space for the reason or purpose of the request?	14.6.(e)			
14.11	- space for the date the sample was taken?	14.6.(f)			
14.12	- when appropriate, space to indicate the size of the batch from which it was taken?	14.6.(g)			
14.13	- space for the expiration date (for pharmaceutical products) or the date of re-analysis (for batch materials or pharmaceutical excipients)?	14.6.(h)			
14.14	- space for the pharmacopeia's or other official specifications to be used in the analysis?	14.6.(i)			
14.15	- space to record any additional comments (e.g. discrepancies found)?	14.6.(j)			
14.16	- space to indicate the storage conditions required?	14.6.(k)			
14.17	For each sample received, is the standard analysis request form, duly completed, attached?	14.5			
Registry and Labeling					
14.18	Is a unique registration number assigned to each sample received in the laboratory?	14.7			
14.19	Are different registration numbers assigned to the samples when the request includes two or more drugs, different lots, or different dosages of the same product?	14.7			
14.20	Is each container of the sample labeled with the registration number, taking care not to damage the marks or writing on the containers?	14.8			
Central Records					
14.21	Does the laboratory have a central records system containing the information on the assigned registration numbers?	14.9			
14.22	Does the central records system have each sample's registration number?	14.9.(a)			
14.23	Does the central records system have each sample's date of receipt?	14.9.(b)			
14.24	Does the central records system have information on the specific unit to which each sample was sent?	14.9.(c)			
14.25	Do laboratory personnel inspect every sample received to ensure that the label conforms to the information contained in the analysis request form?	14.10			
14.26	Do laboratory personnel date and initial the request form, indicating their findings?	14.10			
14.27	If laboratory personnel consult with the supplier of the sample, is information on these consultations recorded?	14.10			

Storage					
14.28	Are the pre-analysis sample, the retained sample, and any part of the sample remaining after all the required tests stored under the conditions indicated for the sample?	14.11			
Resubmission for Analysis					
14.29	Is it the Chief of the central records system who decides whether samples are sent to a specific unit?	14.12			
14.30	Do staff require that all pertinent documentation be provided before analyzing the sample?	14.13 and 14.14			
14.31	If staff orally accept an analysis request (emergencies), are the details immediately recorded in advance of the written request?	14.15			
14.32	When staff send the sample to the specific unit, do they attach copies or duplicates of all the documentation that accompanied the sample?	14.17			
15. ANALYSIS WORKSHEET					
15.1	Do staff have analysis worksheets for recording the information on each sample?	15.1			
Use					
15.2	Do staff use an analysis worksheet for each numbered sample?	15.3			
Contents					
15.3	Does the analytical worksheet contain the registration number of the sample?	15.5.(a)			
15.4	- the number of each page, including the total number of pages (including Annexes)?	15.5.(b)			
15.5	- the date of the analysis request?	15.5.(c)			
15.6	- space for the date the analysis was performed?	15.5.(d)			
15.7	- space for the name and signature of the analyst?	15.5.(e)			
15.8	- space for a description of the sample received?	15.5.(f)			
15.9	- space to indicate the references to the specifications used in analyzing the sample, including limits?	15.5.(g)			
15.10	- space for the results obtained?	15.5.(h)			
15.11	- space for interpretation of the results and final conclusions, signed by each analyst involved and initialed by the supervisor?	15.5.(i)			
15.12	- space for indicating the equipment used?	15.5.(j)			
15.13	- space for additional comments?	15.5.(k)			
15.14	Does the analysis worksheet contain all the complete data and the signature of both the analysts involved and the supervisor?	15.6			
Selection of the Specifications to be Used					
15.15	Does the laboratory have a written protocol for determining the specifications to be used?	15.7			
Records					
15.16	Does it have central records for the analysis worksheets that include the accompanying information, the calculations, and the results of the instrumental analyses?	15.9			
15.17	Does the unit that performed the analysis have a copy of the analysis worksheets?	15.10			

15.18	Is there a written protocol for amending or modifying the analysis worksheet?	15.12			
15.19	Do staff record the reasons for changes in the analysis worksheets?	15.12			
16. ANALYSIS					
16.1	If a sample is not analyzed according to plan, do staff indicate the reasons why (for example, on the analysis worksheet) and keep the sample securely under lock and key?	16.1			
16.2	Does the laboratory have a protocol for sending the sample to another division for special testing or for subcontracting tests to an outside laboratory?	16.2			
Guidelines for assay methods					
16.3	Do personnel verify compliance with the criteria for adapting the system, established in the assay methods?	16.3			
16.4	Do personnel immediately note the values obtained for each assay on the analytical worksheet?	16.4			
16.5	Do personnel annex the graphic, manual or automatic data obtained from the equipment to the analytical worksheet?	16.4			
17. TEST PERFORMANCE AUDIT					
17.1	Does the laboratory have protocols for reviewing the results recorded by the analysts?	17.1			
17.2	When appropriate, does it have protocols for statistically evaluating the results?	17.1			
17.3	Is there a written protocol for investigating questionable results?	17.1			
17.4	Do staff record all conclusions on the analysis worksheets and are the worksheets signed by the analyst and supervisor?	17.2			
Analysis Report					
17.5	Does the laboratory issue an analysis report based on the information on the analysis worksheet?	17.3			
17.6	Does the analysis report contain the registration number of the sample?	17.4.(a)			
17.7	- the name and address of the laboratory that analyzed the sample?	17.4.(b)			
17.8	- the name and address of originator of the request for analysis?	17.4(c)			
17.9	- the name and description of the sample's lot number (when appropriate)?	17.4.(d)			
17.10	- references to the specifications used to analyze the samples, including the limits?	17.4.(e)			
17.11	- the results of all the assays performed?	17.4.(f)			
17.12	- conclusions about whether the sample is within the limits of the specification used?	17.4.(g)			
17.13	- the date of the analysis?	17.4.(h)			
17.14	- the signature of the laboratory chief or authorized individual?	17.4.(i)			
17.15	- the name or address of the re-packaging plant and/or distributor?	17.4.(j)			
17.16	- the name and address of the original manufacturer?	17.4.(k)			
17.17	- reports on whether the sample complies with the requirements?	17.4.(l)			
17.18	- the date the sample was received?	17.4.(m)			
17.19	- the expiration date?	17.4.(n)			

18. RETAINED SAMPLES					
18.1	Does the laboratory have a written protocol indicating how long samples should be retained?	18.1			

PART FOUR: SAFETY

#	QUESTIONS	REF	COMPLIES	DOES NOT COMPLY	REMARKS
19. GENERAL REGULATIONS					
19.1	Does the laboratory have written safety protocols?	1.3.(g)			
19.2	Are the safety protocols available to staff and complemented with posters, audiovisual materials, and occasional seminars (when appropriate)?	19.1			
19.3	Are there general safety regulations for staff with the following requirements?:	19.2.(a)			
19.4	- sheets with safety information provided before analyses are done?	19.2.(b)			
19.5	- prohibition of smoking, eating, and drinking in the laboratory?	19.2.(c)			
19.6	- staff training in the use of fire equipment, including extinguishers, fire blankets, and gas masks?	19.2.(d)			
19.7	- use of lab coats or other protective clothing, including eye protection?	19.2.(e)			
19.8	- special handling of highly potent, infectious, or volatile substances	19.2.(f)			
19.9	- chemical labeling with warnings highlighted (when appropriate)?	19.2.(g)			
19.10	- adequate isolation from sparks from electric cables and equipment, including refrigerators?	19.2.(h)			
19.11	- proper handling of compressed gas cylinders, as well as a description of the color coding?	19.2.(i)			
19.12	- avoidance of people working solo?	19.2.(j)			
19.13	- access to first aid materials; training for staff in first aid, emergency care, and the use of antidotes?	19.3			
19.14	Do laboratory personnel have protective clothing, including eye protection, masks, and gloves, and gas extractor hoods?	19.3			
19.15	Does the laboratory have showers?	19.3			
19.16	Are rubber suction bulbs for manual pipettes and dispensers available?	19.3			
19.17	Are personnel trained in the safe handling of glass, corrosive reagents, and solvents?	19.3			
19.18	Does the laboratory have safety containers or baskets to prevent leaks?	19.3			
19.19	Are there instructions for handling uncontrollable or dangerous violent reactions, when working with specific reagents, flammable products, and oxidizing, radioactive, or biological agents such as infectious agents?	19.3			
19.20	Are there procedures for the safe elimination of undesirable corrosives or hazardous substances by neutralization or deactivation and the complete and safe elimination of mercury and its salts?	19.4			
19.21	Are poisonous or hazardous substances kept separately and labeled properly, without considering that the other reagents are therefore safe?				
19.22	Is the use of known carcinogens and mutagens limited or barred pursuant to local regulations?	19.4			

GOOD PRACTICES SELF-EVALUATION GUIDE FOR NATIONAL PHARMACEUTICAL CONTROL LABORATORIES