20, AVENUE APPIA – CH-1211 GENEVA 27 – SWITZERLAND – TEL CENTRAL +41 22 791 2111 – FAX CENTRAL +41 22 791 3111 – WWW.WHO.INT

Prequalification Team Inspection services
WHO PUBLIC INSPECTION REPORT
of the Quality Control laboratory

<table>
<tr><th>Part 1</th><th>General information</th></tr>
<tr><td>Laboratory details</td><td></td></tr>
<tr><td>Laboratory information</td><td></td></tr>
<tr><td>Name of the laboratory</td><td>Instituto Nacional de Controle de Qualidade em Saude / National Institute of Health Quality Control (INCQS)/ FIOCRUZ</td></tr>
<tr><td>Address of Laboratory</td><td>Av. Brasil,4365 – Manguinhos – Rio de Janeiro- RJ - Brasil
Zip Code:21040-900</td></tr>
<tr><td colspan="2">Inspected Laboratory</td></tr>
<tr><td>Address of inspected Laboratory if different from that given above</td><td>As above</td></tr>
<tr><td>Summary of activities performed at the laboratory</td><td>
<table>
<tr><th>Type of Analysis</th><th>Finished Products</th></tr>
<tr><td>Physical/Chemical analysis</td><td>pH, disintegration, density, dissolution, uniformity of content, uniformity of weight, specific rotation (polarimetry)</td></tr>
<tr><td>Identification</td><td>FTIR, identification reactions, TLC, HPLC, UV-vis spectrophotometry, basic tests</td></tr>
<tr><td>Assay, impurities and related substances</td><td>HPLC (UV-vis, PDA, refractometer), UV-vis spectrophotometry, FTIR</td></tr>
<tr><td>Microbiological tests</td><td>Microbial limit tests and bacterial endotoxins</td></tr>
</table>
</td></tr>
<tr><td>Inspection details</td><td></td></tr>
<tr><td>Dates of inspection</td><td>19 – 24 April 2018</td></tr>
<tr><td>Type of inspection</td><td>Routine</td></tr>
<tr><td>Introduction</td><td></td></tr>
<tr><td>General information</td><td>INCQS is the National Reference Laboratory that handles the quality control of foods, drugs, biological products, health related and dialysis items, hygiene and disinfectant agents, diagnostic kits, cosmetics, blood and blood derivatives, environment and services. As delegated by the Brazilian National Regulatory Agency (ANVISA), INCQS is responsible for the analysis and approval for release and distribution of blood products and its derivatives that are to be dispensed in Brazil or exported.</td></tr>
</table>

	INCQS is responsible for the analysis and approval for release and distribution of all batches of vaccines and sera produced and consumed in Brazil. Main laboratory activities: • analysis of health products; • to develop, adjust and/or implement new methodologies; • to prepare reports about Health Surveillance issues; • to write Technical Norms and Standardize Operating Procedures regarding health products, environments and services; • to inspect and evaluate international and national industries and laboratories with ANVISA or with other public institutions; • to give technical support to other public laboratories; • to evaluate and report on product registration requested by the Ministry of Health; • to establish and distribute chemical and biological reference materials; • to promote and participate in inter-laboratory experiments, including proficiency tests
History	This was third WHO inspection. In addition the Laboratory was inspected by: • National Institute of Metrology • Quality and Technology-Inmetro (Biological tests)
Scope and limitations	
Areas inspected	See Part 2 below
Restrictions	N/A
Out of scope	N/A

Abbreviations

AHU	air handling unit		
ALCOA	attributable, legible, contemporaneous, original and accurate		
API	active pharmaceutical ingredient		
BDL	below detection limit		
CAPA	corrective actions and preventive actions		
CC	change control		
CFU	colony-forming unit		
CoA	certificate of analysis		
DQ	design qualification		
EM	environmental monitoring		
FAT	factory acceptance test		
FMEA	failure modes and effects analysis		
FPP	finished pharmaceutical product		
FTA	fault tree analysis		
FTIR	Fourier transform infrared spectrometer		
GC	gas chromatograph		

	GMP	good manufacturing practice		
	HACCP	hazard analysis and critical control points		
	HPLC	high-performance liquid chromatograph		
	HVAC	heating, ventilation and air conditioning		
	IR	infrared spectrophotometer		
	IQ	installation qualification		
	KF	Karl Fisher		
	LAF	laminar air flow		
	LIMS	laboratory information management system		
	LoD	limit of detection		
	LOD	loss on drying		
	MB	Microbiology		
	MBL	microbiology laboratory		
	MR	management review		
	NMR	nuclear magnetic resonance spectroscopy		
	NRA	national regulatory agency		
	OQ	operational qualification		
	PHA	process hazard analysis		
	PM	preventive maintenance		
	PQ	performance qualification		
	QA	quality assurance		
	QC	quality control		
	QCL	quality control laboratory		
	QRM	quality risk management		
	RA	risk assessment		
	RCA	root cause analysis		
	SOP	standard operating procedure		
	TAMC	total aerobic microbial count		
	TFC	total fungi count		
	TLC	thin layer chromatography		
	URS	user requirements specifications		
	UV	ultraviolet-visible spectrophotometer		

Part 2	Brief summary of the findings and recommendations

Brief summary of the findings and comments

1. Organization and management

The laboratory was legally authorized with managerial and technical personnel to oversee the quality management system and oversee the procedures for performing tests and/or calibrations, validation and verification, and to initiate corrective actions when required. Management and personnel were civil servants and had to comply with State Civil Servant law.

The laboratory maintained a registry for receiving, distributing and supervising the consignment of the samples to the specific testing units; and keeping records on all incoming samples, analytical worksheets, certificates of analysis and accompanying documents.

2. Quality management system

Generally, the Quality Management System covered aspects according to good practices for pharmaceutical quality control laboratories. The contents included e.g. contracts, purchasing services, non-conforming testing, corrective actions, complaints, personnel, protection of confidential information.

The Quality Management System (QMS) covered all activities of the laboratory. It was based on ABN NBR ISO/IEC 17025:2017 with reference to WHO guidelines on good practice for pharmaceutical quality control laboratories and good practice for pharmaceutical microbiology laboratories.

Quality manual was briefly discussed. Revision incorporated the principles of risk management.

All SOPs were signed and approved by the Director General except the work instructions.

The SOP “Computer and equipment data integrity policy in the laboratory” was briefly discussed. This SOP was general SOP and did not give detailed guidelines on data integrity, for example: access levels to the software’s and privileges.

The SOP “Instrumental data control” was briefly discussed. According to the SOP back-ups were performed by IT department once per month. Backs-up were taken on external magnetic tapes and transferred to the server stored in data canter.

The SOP “Critical analysis” was briefly discussed. Critical analysis was defined as systematic review of key performance indicators. According to the SOP critical analysis review meeting should be carried out annually. General standard agenda was specified in the SOP. Critical analysis report was presented to the inspectors. Critical analysis reports were prepared by individual departments.

The SOP “Internal audits” was briefly discussed. According to the SOP internal audits should be performed at least every two years. Internal audit program for 2018 was presented to the inspectors. Audits according to the WHO guidelines should be performed by qualified internal auditors from the Quality Management

Department. List of internal auditors was presented to the inspectors. Internal audits plan for microbiological department and chemical department as well as internal audit reports were presented to the inspectors. Internal audits were carried out using laboratories specific check list. Non-conformities were listed, corrective actions were proposed together by auditors and technical personnel from audited department. Implementation of corrective actions was controlled monthly by person from Quality Management Department. Audit reports discussed were very detailed and addressed all sections of WHO guidelines.

The SOP "Control of CAPAs and non-conformities, opportunities for improvement" and form Annex XX "Non conformity record" were briefly discussed.

Root cause analysis related to the non-conformities was carried out by Quality Management Department personnel together with technical staff. It was explained that "brain storming" was applied for RCA. If required Fish bone diagram could be used. Till date of inspection Fish bone diagram was used only for uncertainty analysis. Example how to use Fish bone diagram was explained in the SOP "Uncertainty of analytical measurements"

The SOP "Change control and risk management" was briefly discussed. SOP was applicable to the following changes:

- Quality Management System
- Policies
- Process and activities
- Equipment
- Personnel
- Methodology
- Information systems
- Materials specifications
- Facilities
- Reference documents (manuals, SOPs and procedures)
- Unforeseen events and possible risks

CCs were specified in critical analysis reports.

The SOP "Internal and external customers complaints" was briefly discussed. Complaints about the Quality system were received by Quality Management Department. Investigation of complaints was performed by Quality Management Department and the applicable department. Complaints were discussed also in critical analysis review.

3. Control of documentation

Documented procedures were in place. Authorized SOP Master List identifying current version, status and distribution of documents was available and presented to the inspectors. However the document presented was not a controlled document and not identified as uncontrolled.

The following documents were briefly discussed:

- SOP "Protection and validation of the calculation worksheet"
- SOP "Model of logbooks spreadsheets, forms and labels"
- SOP "Flow and control of documents and registers of quality management"
- SOP "Distribution and archiving of manuals SOP and working procedures"
- SOP "Elaboration of manuals, operational procedures and working instructions"
- SOP "General orientation for sample analysis in the sector of medicaments in the chemical department"
- SOP "Time table of archiving of documents". The analytical raw data and other related documents were kept in the product files which were archived for 7 years. Documents related to Risk assessment, external and internal audit, reports and certificates of analysis were required to be kept ad infinite according to the Brazilian law.

An electronic copy of all the master documents controlled by the quality management system was stored in an electronic file with restricted access to authorized persons. One master copy of each document was printed, signed and kept at the quality manager's office.

One controlled copy of SOPs and working instructions (WI) were issued with a hand written date of issue to the department were it was used.

It was noted that blank spreadsheets for records could be printed and used as working documents without being controlled.

Revision of SOPs was done every 2 years and working instruction were revised every 3 years

4. Records

Original observations, calculations and derived data, calibration, validation and verification records and final results, were retained. The records included the data recorded in analytical worksheets. The records included the identity of the personnel involved in the sampling, preparation and testing of the samples.

The SOP "Data records and the spreadsheet XX and control of the spreadsheets used in the sector of medicines in the chemical department" were briefly discussed. Excel calculation sheets were validated.

5. Data processing equipment

HPLCs, UV and IR instruments were linked to computers operated by their respective software. All raw data generated by these instruments were stored as hard copies and electronically on a server. Hard copies of raw data were kept; the system was in place to back-up the raw data from the server.

6. Personnel

Generally the laboratory had sufficient personnel with the necessary education, training, technical knowledge and experience for their assigned functions. Staff members undergoing training were supervised and were assessed on completion of the training.
The SOP "Internal training", the list of training given in 2017 and the training plan for 2018/2019 were briefly discussed.

The SOP "Elaboration of manuals, operational procedures and working instruction" was briefly discussed. Training on SOP was done by the person who wrote the SOP. The training was assessed by means of oral or written test or supervision of daily job.

A number of personnel files including training records were briefly discussed.

7. Premises

Generally Drug pharmaceutical testing laboratory facilities were of a suitable size, construction and location, with the exception of the Drug microbiology laboratory. Rest and refreshment rooms were separate from laboratory areas. Laboratory had storage facilities for storage of samples, reagents and glassware. Temperature and relative humidity in sample storage was checked three times per day.

Generally the laboratory had test equipment, instruments and other devices for the performance of the tests and/or calibrations, validations and verifications. Calibration status labels were attached to instruments. All laboratory instruments had "instrument log books"

Laboratory used only class "A" glassware, which was calibrated every 10 years by external agency.

Microbiological testing was performed in a separate laboratory unit. Two biosafety cabinets were used: one for work with master strains and one for microbial limit test.

Documents were stored in central document archive in good order. The procedure was in place to microfilm all documents. One copy of microfilm was stored in archive in metal drawers and another in outsourced storage facility. Inspectors were told that only some part of documents had been microfilmed as this job was contracted out and contractor had problems.

8. Equipment, instrument and other devices

Generally the laboratory had test equipment, instruments and other devices for the performance of the tests and/or calibrations, validations and verifications. Calibration status labels were attached to instruments. All laboratory instruments had "instrument log books".

The SOP "Use Monitoring and disinfection of the safety cabinet"; was briefly discussed. Once per month settle plates with specific media for fungi and bacteria were exposed for 30 minutes. Decontamination of safety cabinet with formaldehyde fumigation was used when positive plate count results exceeding the limits were observed.

9. Contracts

Contracts with service providers were available. As an example contract with RMS group performing qualification of biosafety cabinets was briefly discussed.

Laboratory tests were not subcontracted or outsourced to another laboratory.

10. Reagents

Laboratory reagents were purchased centrally via tenders or single orders. System LICITA WEB was used to purchase materials.

The SOP "Materials and reagents acquisition" was briefly discussed.

The SOP "Materials registration and storage" was briefly discussed. Reagents were delivered together with invoices, certificates of analysis and MSDS. Upon receipt technician from warehouse verified order against received reagents. All reagent containers were visually inspected. Reagents arrived to the central storage, and afterwards were distributed to the laboratories. All reagents had expiry dates. Inventory of the stocks were regularly monitored.

Solutions prepared in the laboratory were labeled and stored appropriately, preparation records were available and traceable to the reagent batch/lot numbers and expiry dates.

Separate room in materials receipt department was provided for storage of flammables, alcohols and acids. Only limited quantities of these materials were kept in the laboratory.

The SOP "Preparation and standardization of laboratory solutions" was briefly discussed.

Water supplied by a Purelab Ultra system was used to prepare HPLC buffer solutions. Conductivity and TOC were monitored on-line. In addition, conductivity was checked off-line monthly. Microbial tests of water was carried out once per month. Ultra-purified water was used for solution preparations.

Dry Medias were visually checked upon receipt. Medias were supplied together with manufacturers CoA.

Medias used in the Microbiology Laboratory was prepared within the INCQS by the Media preparation department, located at Block 8. Department was inspected during the inspection. Positive control using one strain was performed on every batch and on every shipment of dry Media. Growth Promotion (GP) tests were not performed in Media preparation department. GP test for liquid media used in Microbiological Section of Drug department was performed in laboratory using all strains specified in pharmacopeias. Liquid Medias were prepared upon the request.

Medias were sterilized according to the manufacturer's specifications e.g. 121 °C for 15 minutes. Autoclave qualification was carried out annually by external agency. Autoclave qualification report was briefly discussed, load patterns were clearly specified.

11. Reference substances and reference materials

A reference substances register and usage log books were available and traceable to the analysis these were used for. The Laboratory used Pharmacopoeia reference substances or in case reference standards were not available manufacturers working standards. Before usage, related Brazilian Pharmacopeia, USP or EDQM web pages were checked for validity of the reference substances.

The SOP "Identification, storage and usage of reference chemical substances" was briefly discussed. SOP was applicable to reference substances, standard weights and buffer solutions.

Reference standards were stored in the chemical laboratory in a lockable cabinet (room T) or lockable fridge. Temperature was controlled twice per day. Temperature mapping of the fridge was done annually.

In the Microbiology Laboratory reference cultures were obtained from the National Institute of Health Quality Control (INCQS). The strains were originally derived from ATCC strains. No more than 5 subcultures were used from the original source strain.

12. Calibration, verification of performance and qualification of equipment, instruments and other devices

Generally the laboratory had test equipment, instruments and other devices for the performance of the tests and/or calibrations, validations and verifications. Calibration status labels were attached to instruments. All laboratory instruments inspected had "instrument log books".

The SOP Qualification/ calibration of HPLC system and records of the last qualification done in house on XX were briefly discussed.

13. Traceability

Test results were traceable to analyst, analytical instruments, equipment, reagents, reference substances and test procedures.

14. Incoming samples

The SOP "Incoming sample flow" was briefly discussed. Samples were received by responsible persons at sample reception section. The following was checked upon sample receipt:

- Quantity
- Storage conditions
- Package integrity
- Test request

Samples were received in sealed bags. Three sets of samples were collected by supervisory bodies. One set of samples was stored at the place of collection of the sample and two sets were received in the laboratory. One set was sent for analysis and one was kept as retention sample.

Records of incoming samples were properly kept for all incoming samples according to the SOP by logging in a register and HARPYA software. During inspection Influenza vaccine registration into HARPYA system was demonstrated.

Bags containing samples had label indicating HARPYA number. Labelling of bags containing samples was done in sample receiving department.

Sample identification number was recorded on all documents; forms, test reports, CoA, etc.

15. Analytical worksheet

The SOP "General orientation for the analysis of samples" was briefly discussed. Analysts recorded tests performed, raw data, calculations and results in analytical work sheets. Calculations were checked by second analyst. Sufficient details were recorded in analytical work sheets to establish traceability. This was confirmed by verifying Ibuprofen oral suspension 50 mg/ml sample file.

16. Validation of analytical procedures

Microbial enumeration tests were verified for each product to be analyzed. All microorganisms according to the pharmacopoeia were used.

The general policy on validation and verification of analytical procedures was described in the quality manual.

The SOP "Verification of the capacity of inhibition of a product in the department of microbiology and the SOP "Orientation for the validation of analytical methods" were briefly discussed.

Pharmacopeia methods, mainly from the Brazilian pharmacopeia were verified.

The SOP "System suitability of the chromatographic method" was briefly discussed.

17. Testing

Test results were reviewed and evaluated after completion of all the tests. The evaluation took into consideration the results of all tests. When doubtful (atypical results obtained) they were investigated. Tests were performed following pharmacopeia methods or manufacturer's methods. Test results were checked by Head of laboratory.

LAL test was performed in Pharmacological and Toxicology laboratory.

Proficiency testing scheme

Laboratory participated in PAHO, PAHO/WHO, EQAAS proficiency testing schemes.

18. Certificate of analysis

Certificate of analysis was issued by the HARYA system. Data to the HARPYA system was entered by analysts. The SOPs "Process flow relate to the Technical groups "Laboratory samples management system (HARPYA)" and "Issuance of certificate of analysis" were briefly discussed. Raw data was reviewed by the Head of laboratory and afterwards data by analysts were entered to the system. Test results in HARPYA system were checked by Technical Coordinator of Medicines. CoA was signed by Technical Coordinator of Medicines and Vice Director Sanitary surveillance.

19. Retained samples

The SOP "Incoming sample flow" described storage of retains samples. Retention samples were stored in sample reception section in movable racks. Samples were retained till the end of expiry date.

20. Safety

Safety data sheets were available to staff before testing was carried out; smoking, eating and drinking in the laboratory was prohibited. Staff wore laboratory coats and used eye protection. Safety showers were installed.

PART 3 CONCLUSION

Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection, including the observations listed in the Inspection Report, as well as the corrective actions taken **Instituto Nacional de Controle de Qualidade em Saude / National Institute of Health Quality Control (INCQS), located at Av. Brasil,4365 – Manguinhos – Rio de Janeiro- RJ – Brasil**,was considered to be operating at an acceptable level of compliance with WHO Good Practices for Pharmaceutical Quality Control Laboratories for the following expertise:

Type of Analysis	Finished Products
Physical/Chemical analysis	pH, disintegration, density, dissolution, uniformity of content, uniformity of weight, specific rotation (polarimetry)
Identification	FTIR, indentification réactions, TLC, HPLC, UV-vis spectrophotometry, basic tests
Assay, impurities and related substances	HPLC (UV-vis, PDA, refractometer), UV-vis spectrophotometry, FTIR
Microbiological tests	Microbial limit tests and bacterial endotoxins

PART 4

List of GMP guidelines referenced in the inspection

1. WHO Good Practices for Pharmaceutical Quality Control Laboratories. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fourth Report. Geneva, World Health Organization, 2010 (WHO Technical Report Series, No. 957, Annex 1
   Short name: WHO TRS No. 961, 957), Annex 1
   http://www.who.int/medicines/publications/44threport/en/

2. WHO good manufacturing practices for pharmaceutical products: main principles. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-eighth Report Geneva, World Health Organization, 2014 (WHO Technical Report Series, No. 986), Annex 2.
   Short name: WHO TRS No. 986, Annex 2
   http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_986/en/

3. WHO good practices for pharmaceutical microbiology laboratories. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 2
Short name: WHO TRS No. 961, Annex 2
http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

4. WHO Good Manufacturing Practices: water for pharmaceutical use. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fourth-sixth Report. Geneva, World Health Organization, 2012 (WHO Technical Report Series, No. 970), Annex 2
Short name: WHO TRS No. 970, Annex 2
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_970/en/

5. WHO guidelines for sampling of pharmaceutical products and related materials. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Thirty-ninth Report. Geneva, World Health Organization, 2005 (WHO Technical Report Series, No. 929), Annex 4
Short name: WHO TRS No. 929, Annex 4
http://whqlibdoc.who.int/trs/WHO_TRS_929_eng.pdf?ua=1

6. WHO guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 5
Short name: WHO TRS No. 961, Annex 5
http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

7. Supplementary guidelines on good manufacturing practices: validation. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fortieth Report. Geneva, World Health Organization, 2006 (WHO Technical Report Series, No. 937), Annex 4
Short name: WHO TRS No. 937, Annex 4
http://whqlibdoc.who.int/trs/WHO_TRS_937_eng.pdf?ua=1

8. WHO Good Practices for Pharmaceutical Products Containing Hazardous Substances. WHO Expert on Specifications for Pharmaceutical Preparations. Forty-fourth Report. Geneva, World Health Organization, 2010 (WHO Technical Report Series, No. 957), Annex 2
Short name: WHO TRS No. 957, Annex 2
http://www.who.int/medicines/publications/44threport/en/

9. WHO good manufacturing practices for sterile pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 6
Short name: WHO TRS No. 961, Annex 6
http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

10. WHO guidelines on transfer of technology in pharmaceutical manufacturing WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 7
Short name: WHO TRS No. 961, Annex 7
http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

11. Model guidance for the storage and transport of time-and temperature-sensitive pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 9
***Short name: WHO TRS No. 961, Annex* 9**
http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

12. General guidelines for the establishment maintenance and distribution of chemical reference substances. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-first Report Geneva, World Health Organization 2007 (WHO Technical Report Series, No.943) Annex 3
Short name: WHO TRS No. 943, Annex 3
http://whqlibdoc.who.int/trs/WHO_TRS_943_eng.pdf?ua=1

13. WHO guidelines on quality risk management. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-seventh Report Geneva, World Health Organization, 2013 (WHO Technical Report Series, No. 981), Annex 2
Short name: WHO TRS No. 981, Annex 2
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_981/en/

14. WHO Technical supplements to Model Guidance for storage and transport of time – and temperature – sensitive pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-ninth Report Geneva, World Health Organization, 2015 (WHO Technical Report Series, No. 992), Annex 5
Short name: WHO TRS No. 992, Annex 5
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/WHO_TRS_992_web.pdf

15. Guidance on good data and record management practices. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fiftieth Report Geneva, World Health Organization, 2016 (WHO Technical Report Series, No. 996), Annex 5
Short name: WHO TRS No. 996, Annex 5
http://www.who.int/medicines/publications/pharmprep/WHO_TRS_996_annex05.pdf