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

Part 1	**General information**
Laboratory details	
Laboratory information	
Name of the laboratory	**SGS India Pvt Ltd**
Corporate address of Laboratory	SGS India Private Limited 4B, Adishankaracharya Marg, Vikhroli (West), Mumbai - 4000 083, Maharashtra, India. Phone :+91 (0) 22 6640 8888
Inspected Laboratory	
Address of inspected Laboratory if different from that given above	SGS India Pvt Ltd 2nd Floor, TICEL Bio Park Ltd, Tharamani Road, Tharamani, Chennai, Tamil Nadu, 600 113, India Latitude: 12095607 Longitude: 8024900200000002 D-U-N-S: 650463859
License	No TN00002021 valid up to 06.01.2020 Scope of licence for testing: Categories of Drugs, items of Cosmetics a. Drugs other than those specified in Schedule C and C (1) and also Homoeopathic Drugs i. Crude Vegetable drugs ii. Mechanical Contraceptives iii. Surgical dressings iv. Drugs requiring the use of Ultraviolet/Infra Red spectrometer/Chromatography/ Surgical dressings v. Disinfectants vi. Other drugs b. Drugs specified in Schedule C and C (1) i. Antibiotics ii. Vitamins iii. Paranteral preparations excluding test for Pyrogen

<table>
<tr><td></td><td>iv. Sterilized surgical ligature/suture
v. Drugs requiring microbiological tests
vi. Drugs requiring the use of Ultraviolet/Infra Red spectrometer/Chromatography
c. Cosmetics</td></tr>
<tr><td>Summary of activities performed at the laboratory</td><td>
<table>
<tr><th>Type of Analysis</th><th>Finished products</th><th>Active pharmaceutical Ingredients</th></tr>
<tr><td>Physico-Chemical analysis</td><td>pH, refractive index, optical rotation, viscosity, water content, Loss on drying, density, residual solvents, limit tests, tablet hardness, friability, disintegration, dissolution, uniformity of dosage units (mass, content), Particulate matter test, Osmolality test</td><td>pH, density, refractive index, optical rotation, viscosity, melting point, loss on drying, heavy metals, sulphated ash, water content, conductivity, residual solvents, limit tests, particle size</td></tr>
<tr><td>Identification</td><td>HPLC (UV-Vis, PDA, RI,DAD fluorescence detection),GC (FID), TLC, UV-Vis spectrophotometry, FTIR, basic tests</td><td>HPLC (UV-Vis, PDA, RI, DAD fluorescence detection), GC (FID), TLC, UV-Vis spectrophotometry, FTIR, basic tests</td></tr>
<tr><td>Assay, impurities and related substances</td><td>HPLC (UV-Vis, PDA, RI, DAD fluorescence detection), ,UPLC(UV-Vis, PDA,), GC (FID), UV-Vis spectrophotometry, AAS, FTIR, ICP-MS, polarimetry, potentiometry, volumetric titrations</td><td>HPLC (UV-Vis, PDA, RI, DAD fluorescence detection),UPLC(UV-Vis, PDA, detection), GC (FID), UV-Vis spectrophotometry, AAS, FTIR, ICP-MS, polarimetry, potentiometry, volumetric titrations</td></tr>
<tr><td>Microbiological Tests</td><td>Sterility test, microbial limit tests, bacterial endotoxins test (LAL), preservative efficacy test, microbial assay of antibiotics</td><td>Sterility test, microbial limit tests, bacterial endotoxins test (LAL), preservative efficacy test, microbial assay of antibiotics</td></tr>
<tr><td>Stability studies</td><td>ICH conditions</td><td>ICH conditions</td></tr>
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</td></tr>
<tr><td>Inspection details</td><td></td></tr>
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</table>

Type of inspection	Routine
Representative from the National Regulatory Authority	None. The local authority was informed by the WHO in advance about the upcoming inspection.
Introduction	
History	SGS, the corporate company, is headquartered in Geneva, Switzerland. SGS operates a network of more than 1,800 offices and laboratories around the world with 85,000 employees. SGS Life science services has over 35 years of experience and has 1.600 full time employees (of which 1.000 within Laboratories) SGC has 25 facilities in 13 countries. SGS Life Science Services (LSS) India has two laboratories, one in Chennai and the other one in Navi Mumbai. SGS Chennai started operations in February 2005 and currently has about 103 full time employees. SGS Mumbai started operations in January 2012 with a total of 130 full time employees. SGS has 25 facilities in 13 countries: • Canada • USA • Belgium • Czech Republic • France • Germany • Italy • Poland • Switzerland • United Kingdom • China • Singapore <u>Main activities:</u> • Method Development and Validation • Raw material & Finished product Testing • Stability Studies • Pharmaceutical/Medical Device • Container Closure/Package Integrity

- Microbial Examination of Non-Sterile Products
- Antimicrobial Preservative Effectiveness
- Endotoxin screening via Gel clot
- Sterility Assurance Services
- Bio burden Testing
- On-site Microbial Monitoring
- Microbial Identification
- Disinfectant Efficacy Testing

The laboratory was first inspected by WHO in December 2009. Follow-up inspection was carried out in July 2010. The site has also been inspected by the following regulatory authorities:

Local FDA-India	June 2016
NABL/National Accreditation Board for Testing and Calibration Laboratories)	May 2014
US FDA inspection	May 2014
WHO	August 2013
US FDA inspection	October 2010
WHO follow-up inspection	July 2010
US FDA inspection	February 2007

Changes

The SGS was ISO 9000 and ISO 17025:2005 certified.

Scope and limitations

Areas inspected	See Part 2 below
Restrictions	N/A
Out of scope	Microbiological laboratory, retained samples, safety, stability, archive

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 (where applicable)

Brief summary of the findings and comments

1. Organization and management

The laboratory was legally authorized to perform the tests under the license No TN00002021 valid up to 06.01.2020

In general the laboratory had managerial and technical personnel to carry out their duties. Organizational charts, the organization and management structure of the laboratory and its place in corporate organization was presented to the inspectors. Responsibilities were specified.

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

2. Quality management system

There was a common Quality Manual for the two Indian sites (Mumbai and Chennai). The Quality Manual (QM) applicable for Chennai and Mumbai labs was briefly discussed. Generally, the QM covered aspects according to good practices for pharmaceutical quality control laboratories. Quality policy and quality statement were discussed. The contents included e.g. complaints, training, internal audits, CAPAs, improvements, management review.

The SOP "Management review meeting" was discussed. The SOP referred to four monthly meetings, and a standard agenda was included. The SOP and meetings covered e.g. trending of OOS, deviations, CAPAs, previous minutes, policy and procedures, objectives, customer feedback, quality plan.

The last MR meeting was held in October 2016. List of attendees and MR minutes from last two MR meetings were discussed.

The list of SOPs was presented to the inspectors.

The SOP "Deviation management" was discussed. Deviations were classified as:

- Unplanned
- Critical
- Major
- Minor

Section XX described trending or tracking of deviations.

The SOP "Customer complaints" and customer complaint log books for 2015 and 2016 were discussed, according to the SOP, complaints should be trended.

The SOP "CAPA" was discussed. Non-conformances for initiation the CAPAs were classified as:
- Critical
- Major
- Minor

The SOP was applicable, but not limited, to internal audits, OOS, deviations, customer surveys, regulatory inspections, customer audits, and complaints, compliance of computer system and outputs of MR meetings.

The SOP "Investigation and root cause analysis" was discussed. The SOP was applicable for:
- CAPA
- Complaints
- Deviations
- OOS
- Or any failure which directly or in-directly is associated with the Process / procedure / method / materials /product / documentation.

The following tools were used:
- 5 Why analysis
- Fish bone diagram
- Six Ps: people, process, place, policies, procedure, products
- Four Ss: surroundings, suppliers, system, skills

The SOP "GMP internal auditing and spot check" was discussed. Audits were carried out by a cross functional team. The audit schedule for 2016 was presented. An audit was carried out according to a check list. Findings were listed in the audit report and classified as:
- Critical
- Major
- Minor

CAPAs were submitted by the inspected department and evaluated by the QA.

The SOP "Method transfer guidelines" was discussed.

3. Control of documentation

Documented procedures were in place to control the documents. Authorized SOP Master List identifying the current version, status and distribution of documents was available and presented to the inspectors. Documents had a unique identifier, version number and date of implementation. A system of change control was in place to inform staff of new and revised procedures.

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.

5. Data processing equipment

The "Validation master plan LSS Chennai", the document "Computerized system validation", "List of instrument computers (GxP systems)" and "Computer system validation schedule" were discussed. The document was applicable to computerized systems that must comply with GxP regulations.

The SOP "Data backup & restore procedures, user ID creation & password policy, software management and security policy" was discussed. Daily, weekly and monthly back-ups were carried out. Back-up log book and back up selection matrix were presented to the inspectors.

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. Personnel performing specific tasks were appropriately qualified in terms of their education, training and experience, as required. Current job descriptions were maintained.

According to the explanation the company had in place "Code of integrity" that should be signed by all employees at the time of joining. Annual training on the topic "Data integrity and code of integrity" was mandatory for all laboratory employees. List of employees from January 2016 for "Data integrity and code of integrity" topic was presented to the inspectors. Annual integrity training 2016 "Code of integrity" India cases was discussed.

The training files for assistant manager QC and analyst QC chemistry were reviewed by the inspectors.

There was a procedure for training of personnel. Records for training and training assessments were available. The SOP "Orientation and training" was discussed. There were several types of trainings specified, such as:

- Orientation training for new employees,
- SOPs training
- Ongoing training
- Technical training
- Retraining
- Refresher training

Training effectiveness was evaluated by written assessment: open questions and pre-given multiple choice answers.

Analysts were qualified by analyzing an already analyzed sample.

7. Premises

Generally laboratory facilities were of a suitable size, construction and location. Rest and refreshment rooms were separate from laboratory areas. Access to the laboratory premises was controlled by biometric system. Laboratory had storage facilities for storage of samples, reagents and glassware. Reference substances and reference materials were stored in locked cabinets (room T) and locked fridge. T and RH in sample storage room, reference substances and reference materials storage units and stability chambers were monitored online at 30 minute intervals.

Microbiological testing was performed in a separate laboratory unit. Due to the time constraints, the microbiological laboratory, retain samples storage room, stability chambers and archive were not inspected.

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.

9. Contracts

Laboratory had a procedure for the selection and purchasing of services and supplies.
The SOP "Supplier evaluation" was discussed. Suppliers were divided in 4 groups. Suppliers of reagents, chemicals and reference standards were evaluated by questionnaire every 3 years. Approved suppliers list was presented to the inspectors.

The representatives of the laboratory explained that subcontracting of tests was done within in the SGS network. The document "Multilateral Intercompany Quality Agreement" was discussed. Responsibilities of "ordering party" and "executing party" were specified. It was also specified that the contracted organization should not pass to a third party any work entrusted to it under contract without the laboratory's and or customer prior evaluation and approval of the arrangements.

10. Reagents

Generally reagents and chemicals were purchased from approved suppliers and were accompanied by the certificate of analysis, and the material safety data sheets as appropriate. Approved suppliers/vendors list was presented to the inspectors. Expiry dates for purchased reagents were specified:

- Based on CoA
- If CoA did not specify expiry date – date of manufacture + 3 years or date of receipt + 3 years.

After opening, expiry date for solid reagents was specified 2 years and for liquid reagents 1 year. Date of opening was recorded. There was an assigned person in charge of reagents.

Reagents prepared in the laboratory were appropriately labelled.

11. Reference substances and reference materials

Reference substances and reference materials were stored in locked cabinets (room T) and locked fridge under controlled conditions. Reference substances and reference materials usage registers were maintained and presented for inspectors. ID numbers of used standards were specified in analytical raw data sheets. There was an assigned person in charge for reference substances and reference materials.

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

Due to the time constraint -attention was paid only to analytical balances and dissolution apparatus calibration.

Balance calibration was performed daily for minimum, middle and maximum weights and monthly for:

- Repeatability,
- Eccentricity
- Linearity and
- Accuracy

The SOP "Operation, calibration and preventive maintenance of dissolution apparatus" and the SOP "Calibration of dissolution apparatus" was discussed.

Mechanical and chemical calibration was used for dissolution apparatus.

The SOP "Chromatographic data accusation, process reporting and user account administration for Empower 3 software was discussed.

13. Traceability

The results of an analysis were traceable to reference substances, equipment and instruments used for analysis.

14. Incoming samples

Incoming samples were checked against "Sample receipt check list" and were stored in sample storage room. Samples were registered in the LIMS. In LIMS "Assignment No" was assigned for the lot of samples (for example received form the same company, the same date), afterwards unique sample identification number was assigned to all samples.

15. Analytical worksheet

The analytical worksheets were used by analysts for recording information about the sample, the test procedure, calculations and the results of testing. It was complemented by the raw data obtained in the

analysis. Analytical work sheets contained sample registration ID No, the date on which the analysis was started and completed, the name and signature of the analyst and other relevant information. Analytical worksheets were signed by the responsible analysts, verified and approved and signed by the supervisor/reviewer.

The analytical raw data sheet XX tablets was discussed. Injection sequence and audit trail was part of the raw data sheet.

16. Validation of analytical procedures

According to the laboratory policy, compendial methods were to be verified and customer / in-house methods were to be validated according to the method validation/verification protocols. The SOP "Verification of compendia methods" and a number of method verification protocols/reports were discussed.

According to the SOP for method verification the following tests should be carried out:

- Specificity
- System suitability
- System precision
- Method precision
- Accuracy
- Linearity
- LOD & LOQ (only for impurities)

17. Testing

Samples were tested in accordance with the work plan of the laboratory and agreements with customers. Test results were reviewed and evaluated. OOS results were investigated.

The SOP "Chromatographic techniques" was discussed.

18. Evaluation of test results

Test results were reviewed and evaluated. Tests results were entered to the LIMS by analysts who performed the tests, after which the test results in LIMS were checked by the reviewer.

The SOP "Handling of out of specification and out of trend tests results", flow chart and register for 2015 and 2016 were discussed.

A number of OOS investigation reports were discussed**.** Monthly trending of OOS results was presented to the inspectors.

19. Certificate of analysis

Certificate of analysis was generated automatically by LIMS, reviewed and electronically signed by QA.

20. Retained samples

The laboratory representatives explained that retained samples were stored for 30 days after the CoA release or as per customer's requirements.

21. Safety

Not inspected due to the time constrains.

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 SGS India Private Limited, located at 2nd Floor, TICEL Bio Park Ltd, Tharamani Road, Tharamani, Chennai, Tamil Nadu, 600 113, India 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	Active pharmaceutical Ingredients
Physico-Chemical analysis	pH, refractive index, optical rotation, viscosity, water content, Loss on drying, density, residual solvents, limit tests, tablet hardness, friability, disintegration, dissolution, uniformity of dosage units (mass, content), Particulate matter test, Osmolality test	pH, density, refractive index, optical rotation, viscosity, melting point, loss on drying, heavy metals, sulphated ash, water content, conductivity, residual solvents, limit tests, particle size
Identification	HPLC (UV-Vis, PDA, RI,DAD fluorescence detection),GC (FID), TLC, UV-Vis spectrophotometry, FTIR, basic tests	HPLC (UV-Vis, PDA, RI, DAD fluorescence detection), GC (FID), TLC, UV-Vis spectrophotometry, FTIR, basic tests
Assay, impurities and related substances	HPLC (UV-Vis, PDA, RI, DAD fluorescence detection), ,UPLC(UV-Vis, PDA,), GC (FID), UV-Vis spectrophotometry, AAS, FTIR, ICP-MS, polarimetry, potentiometry, volumetric titrations	HPLC (UV-Vis, PDA, RI, DAD fluorescence detection),UPLC(UV-Vis, PDA, detection), GC (FID), UV-Vis spectrophotometry, AAS, FTIR, ICP-MS, polarimetry, potentiometry, volumetric titrations
Microbiological Tests	Sterility test, microbial limit tests, bacterial endotoxins test (LAL), preservative efficacy test, microbial assay of antibiotics	Sterility test, microbial limit tests, bacterial endotoxins test (LAL), preservative efficacy test, microbial assay of antibiotics
Stability studies	ICH conditions	ICH conditions

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-eight 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-six 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. Fifties 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