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

Part 1	**General information**
Laboratory details	
Laboratory information	
Name of the laboratory	Adcock Ingram RD&I
Corporate address of Laboratory	1 New Road, Midrand, Gauteng, South Africa Telephone:+27 11 635 0000 Fax: +27 86 553 0000
Inspected Laboratory	
Address of inspected Laboratory if different from that given above	1 Sabax Road, Aeroton, Gauteng, South Africa GPS: Latitude: -26,256756 Longitude: 27,981500
Licence	Medicines Control Council (MCC) of South Africa No:0000000807, for manufacture and/ or packaging and testing of capsules, tablets, liquids, creams and ointments, excluding penicillin or other sensitizing substances, for research and development of pharmaceutical products
Summary of activities performed at the laboratory	

Type of analysis	**Finished products**	**Active pharmaceutical ingredients**
Physico –Chemical analysis	pH, water content, loss on drying, friability, disintegration, tablet hardness, uniformity of dosage units (mass, content), tablet dimensions, dissolution, AA, viscosity, density/specific gravity, re-dispersibility time, re-suspendability and sedimentation rate.	pH, water content, loss on drying, residual solvents, limit tests. Other tests are per pharmacopoeial monograph or supplier method.
Identification	HPLC (UV-VIS, RI, DAD detection), GC, TLC, UV-VIS spectrophotometry,	HPLC (UV-VIS, RI, DAD detection), GC, TLC, UV-VIS spectrophotometry, IR,

		FTIR, basic tests.	basic tests.
	Assay, impurities and related substances	(U)HPLC (UV-VIS, RI, DAD detection), GC (FID), UV-VIS spectrophotometry, AA spectrophotometry, volumetric titrations, dissolution. Determination of related substances/impurities and degradation products.	HPLC (UV-VIS, RI, DAD detection), GC (FID), UV-VIS spectrophotometry, AA spectrophotometry, volumetric titrations.
	Stability Studies	ICH conditions/ WHO conditions	N/A

Inspection details	
Dates of inspection	8-9 December 2016
Type of inspection	Routine
Introduction	
General information / history	The laboratory was inspected by WHO in July 2011. The site has also been inspected by the following regulatory authorities: • MCC Inspection in 2008, the facility was approved in compliance to Good Manufacturing Practices • USFDA in August 2012 • South African Pharmacy Council (SAPC) September 2016. The site is 16 years old. The facility consists of an administration block, analytical laboratory, formulation laboratory, pilot plant manufacturing area and walk-in stability chambers for sample storage. The site manufactures and/ or packs capsules, tablets, liquids, creams and ointment formulations for pilot trial stability studies only. No bulk toxic, poisonous or hazardous substances are handled at the site except for organic and inorganic solvents being handled in the analytical laboratory during analysis. The laboratory's main activities include: • Method development and validation (for QC release and stability studies, cleaning validation studies, comparative dissolution and specification development), • Analysis and release of products manufactured for local and international markets belonging to Adcock Ingram Limited, as well as other third party contract manufacturers under licence to Adcock Ingram, • Assisting with investigations related to commercial products and analysis of customer complaints (Adcock products) when required, • Analysis of product development studies for pilot batches for new and reformulated products,

	• Storage and management of pilot and commercial stability samples for Adcock Ingram Limited, • Testing and evaluation of raw and packaging materials for pilot trial stability purposes. The laboratory had not conducted any tests on behalf of UN agencies, their partners, and procurement agencies serving national authorities and UN agencies and/or national authorities of WHO Member States in the last three years.
Scope and limitations	
Areas inspected	See Part 2 below
Restrictions	N/A
Out of scope	Microbiological laboratory

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 0000000807, which was valid until 28.07.2020.

Managerial and technical personnel were appointed in the laboratory to perform the relevant duties. Organizational charts, the organization and management structure and the position of the laboratory within the corporate organization were presented to the inspectors. Responsibilities were specified.

The laboratory maintained a registry of received consignments of samples and kept records of all incoming samples and accompanying documents.

2. Quality management system

The Quality Manual was discussed. The QM described, but was not limited to, the following: quality policy, registration and licensing, personnel, management responsibilities, organizational structure, quality management structure, self-inspections, design controls, document controls, non-conformances, data integrity and CAPAs. The QM was valid for one year.

The SOP "Quality Management Review" was discussed. The SOP referred to six monthly meetings, a standard agenda was included in the SOP.

The SOP defined meeting's agenda, but was not limited to the following: OOS and OOT, deviations, CAPAs, follow up of previous management review, customer complaints, outcome of internal and external audits.

The last management review meeting was held on July 2016. The list of attendees and MR minutes were discussed.

The SOP "Deviation Management" and the deviation register for 2016 were discussed. Deviations were classified by the QA Manager/designee as:

- Critical
- Major
- Minor

Deviation due dates were determined on a case-by-case basis. In the event that the due date was extended, the "Motivation for Extension of Deviation Due Date" form would be completed and submitted to the QA department.

It was noted that the "Deviation Management", Deviation Form, Section C, indicated remedial actions/action plans and the Section for "Additional QMS Actions" specified CAPA implementation.

The SOP "Analysis of Customer Complaint Samples Requested by Group Quality Assurance" and the Customer Complaint Log Book for 2016 were discussed. The laboratory was responsible for managing complaints received from the corporate QA unit. The role of the laboratory, in the complaint procedure, was limited to the investigation of complaints, pertaining to the analysis of related samples.

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

- Critical
- Major
- Minor

The SOP was applicable to all equipment, batch manufacturing, processes, protocols and procedures, as well as, non-conformances raised within all departments at RD&I.

The SOP "Root Cause and Failure Investigation" was discussed.

The SOP "Self-Inspection" was discussed. Self-inspection was carried out by the relevant members of the QA department. The inspection schedule was drawn up annually by the QA department and the schedule for 2016 was presented. The following departments were included in the self-inspection schedule:

- Analytical (twice per year)
- Formulations
- Stability
- QA

Self-inspection was carried out according to the aide memoire. Findings were listed in the audit report, but were not classified. CAPAs were submitted by the inspected department, and evaluated by the QA department.

To date, the laboratory had not participated in proficiency testing schemes and collaborative trials to evaluate laboratory performance.

3. Control of documentation

Documented procedures were in place to control documents. The authorized SOP "Master List", identifying the current version, status and distribution of documents, was available and was 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.

The SOP "Control of Documents" was discussed. Document review was performed every two 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 notebooks.

5. Data processing equipment

The Validation Master Plan (VMP) briefly explained the approach to computer system validation (CSV). The VMP specified that CSV should follow the following guidelines: USP Chapter 1058 "Analytical Instrument Qualification" and the GAMP GPG "A Risk-Based Approach to GxP Compliant Laboratory Computerized Systems".

The document "Qualification Protocol for UPLC Optimus Prime Based Empower Software" was discussed. Qualification was performed by an external company.

The document "Qualification Protocol for Empower Server" was discussed.

The qualification protocol "Equipment: Ultra Performance Liquid Chromatography" was discussed. Excel sheets, used for calculations, were validated.

The "Management of Empower Data" and the back-ups register were discussed. Various types of back-ups were specified:

- Daily
- Weekly
- Monthly
- Annually

The same back-up procedure was applied for stand-alone instruments such as the IR, UV and AAS.

Procedure for data restoration and disaster recovery was defined. A disaster recovery simulation was carried out by the contracted service provider every year.

Empower management privileges were defined.

The "Data Integrity" was discussed. QA was responsible for reviewing relevant audit trails, raw data and metadata, as part of the self-inspection procedure.

The "Review, Approval and Authorisation of Documents" was discussed.

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

The job description of QA Supervisor was discussed. QA Supervisor was responsible for scheduling and performing internal quality audits, as well as additional QA activities, including, but not limited to: QMS, pilot batch documentation, process validation documents, performance verification of analytical equipment, reference and WS, empower. An alternate responsible person, in case of absence, had also been nominated.

The "Training Programme" was discussed. Several types of training were specified. These included:

- Induction training
- SOP training
- On-the-job training
- Unplanned training
- Annual training

Training effectiveness was evaluated through written assessment: open questions and multiple choice questions.

The "Training and Qualification of Laboratory Analysts" was discussed. Analyst's performance was evaluated through theoretical testing, practical evaluation and/or comparative testing.

An Analyst's Competency Matrix was presented to the inspectors.

Job descriptions, training records and records of competency evaluation were kept together in each employee file.

Adcock Ingram's Limited Conflict of Interest Policy was presented to the inspectors. The policy was applicable to all directors, members of the executive committee of Adcock Ingram and its subsidiaries. The document stated that the policy was to be read and applied in conjunction with the Adcock Ingram Board Charter and the Adcock Ingram Code of Ethics.

The Adcock Ingram Code of Ethics was presented to the inspectors.

7. Premises

Access to the laboratory premises was controlled through a biometric control system.

Stability samples were stored in walk-in stability chambers. Temperature and relative humidity (RH) were recorded by the BMS every five minutes. Temperature mapping of the stability chambers was performed annually. The document "Temperature and RH Distribution and Probe Verification Test Protocol" was discussed. Data loggers were used and temperature and RH were recorded every five minutes for three continuous days. Provision for the water tank and back-up generators were made to ensure continuous stability conditions. Stability chambers were equipped with visual alarms and text messaging, to the relevant personnel, in the event of an excursion.

The archive room provided for secure storage and retrieval of documents. The archive was designed to protect the documents from deterioration. Access to the archive was restricted to designated personnel. Documents were stored in movable metal cabinets. Back-up tapes were stored in a different archive room in locked movable metal cabinets.

Generally, the 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. The laboratory had storage facilities for storage of samples, reagents and glassware. WS for daily use were stored in the balance room. Reference substances and bulk WS were stored in cabinets (controlled room temperature) and locked refrigerator / deep freezer. The temperature in the fridge/deep freezer was

monitored continuously and was recorded on temperature charts. Additionally, temperature was checked twice daily. The fridge/deep freezer was equipped with an alarm which was challenged on a weekly basis.

8. Equipment, instrument and other devices

Validation master plan (VMP) was discussed. VMP was effective for one year and was applicable to the analytical laboratory:

- Instrument/equipment qualification
- Computer system validation
- Analytical method validation

Generally the laboratory was equipped with test equipment, instruments and other devices for the performance of tests and/or calibrations, validations and verifications. It was noted that the calibration/verification and maintenance of the main instruments (e.g. HPLC, GC, UV etc.), in the laboratory, was contracted to the third parties. Calibration status labels were attached to instruments.

Individual equipment operating SOPs contained the sections: preventive maintenance and calibration/verification.

The equipment calibration/verification and PM schedule for 2016 was presented to the inspectors.

All laboratory instruments had usage log books.

HPLC and UPLC columns were stored in the original packages in the laboratory cupboards. Column performance was verified upon receipt. Column CoA`s were available.

Class A volumetric glassware was used for analysis.

9. Contracts

Third party laboratories were contracted to perform a limited number of tests on behalf of RD&I. Technical agreements (TA) with two contract laboratories were discussed. Contract laboratories were audited by the corporate QA unit. The TAs allowed the contract giver to audit the contract acceptor and the contract acceptor was not permitted to subcontract any work to a third party without written permission from the contract giver.

The list of approved service providers was presented to the inspectors. As an example, the service agreement between RD&I and Waters Chromatography Instrumentation was reviewed.

10. Reagents

SOP “Reagent Solutions” and SOP RD-QC-072-3 “Volumetric Solutions” were discussed. The standardisation frequency for solutions was specified.

The SOP "Control of Chemicals in the Analytical Laboratory" was discussed. A designated person was responsible for the maintenance of reagents. Generally reagents and chemicals were purchased from reputable and approved suppliers and were accompanied by the certificate of analysis, and the material safety data sheet, as appropriate. An Approved Suppliers List was presented to the inspectors.

Reagents and volumetric solutions prepared in the laboratory were appropriately labelled.

HPLC grade water was used for analysis.

11. Reference substances and reference materials

The "Reference and Working Standards" was discussed. A designated person was nominated to be responsible for the Reference Standards (RS) and Working Standards (WS). WS were standardized against the primary RS.

Reference substances and reference materials were stored in locked cabinets (at room temperature) and in a locked fridge, under controlled conditions. Reference substance and reference material usage registers were maintained and presented during the inspection. 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

Balance calibration was performed daily. Internal balance calibration was performed weekly, monthly and biannually. Additionally, balance verification was performed every six months, by an external contractor.

Mechanical and chemical calibration was used for dissolution apparatus. Mechanical calibration was carried out every six months by an external contractor. Chemical calibration using prednisone tablets was carried out every six months by the laboratory.

13. Traceability

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

14. Incoming samples

The SOP "Sample Receipt" was discussed. The SOP described the procedure for sample receipt from Adcock Ingram sites in South Africa.

The SOP "Post Importation Release of Products Intended for Sale" was discussed. This procedure was applicable only for imported products. Samples were received against the "Post Importation Release of Products Intended for Sale" check sheet. Samples were received together with the CoA. Upon receipt,

samples were checked for physical appearance, as well as packaging. Traceability of the samples was ensured through batch number and product name. Samples waiting for testing were stored in a cupboard in the laboratory. A refrigerator in the laboratory was used for the storage of received samples, requiring cold storage conditions. To date, only samples, to be stored below 25 °C, had been received.

15. Analytical worksheet

The analytical laboratory notebooks were used by analysts, each page of the analytical laboratory notebooks was signed: "performed by" and "reviewed by". The date, when the analysis was performed and the date of review were also recorded. Analytical laboratory notebooks were issued by QA and each page, in the notebooks, was numbered. During the inspection, it was indicated that analysts were not required to use electronic analytical laboratory notebooks.

The analytical laboratory notebook for XXXX tablets, batch no. YYYY was reviewed and discussed.

16. Validation of analytical procedures

SOPs "Validation of Analytical Methods" and "Development and Validation of Verification of Dissolution Methods" were discussed. Majority of analytical methods were developed in-house and were validated.

17. Testing

Test results were reviewed and evaluated. OOS results were investigated.

18. Evaluation of test results

Test results were reviewed and evaluated.

SOP "Investigation of Out of Specification Results", the corresponding flow chart and the OOS register for 2016 were discussed. The SOP was written in accordance with the MHRA "Out of Specification Investigation" guideline. The SOP explained Phase 1a, Phase 1b and Phase 2 investigations as well as hypothesis testing.

Six monthly trending of OOS results was presented to the inspectors.

The SOP "Handling of OOT Results" and the OOT register were discussed. This SOP was applicable to the OOT results obtained during testing of stability samples. OOT results, related to the stability studies of commercial products, were not trended in the laboratory. Pilot trial stability batch trends were evaluated by Adcock Ingram RD&I laboratory.

19. Certificate of analysis

The SOP "Certificate of Analysis for Finished Products" was discussed. The CoA was compiled by the analyst and reviewed by the Laboratory Manager. The CoA was authorized by the QA department.

20. Retained samples

Retained samples were stored, in a temperature-controlled room (23 °C – 27 °C), for one year after the expiry date of the product.

21. Safety

Emergency showers and eye wash equipment were provided.

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 Adcock Ingram RD&I, located at 1 Sabax Road, Aeroton, Gauteng, South Africa 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, water content, loss on drying, friability, disintegration, tablet hardness, uniformity of dosage units (mass, content), tablet dimensions, dissolution, AA, viscosity, density/specific gravity, re-dispersibility time, re-suspendability and sedimentation rate.	pH, water content, loss on drying, residual solvents, limit tests. Other tests are per pharmacopoeial monograph or supplier method.
Identification	HPLC (UV-VIS, RI, DAD detection), GC, TLC, UV-VIS spectrophotometry, FTIR, basic tests.	HPLC (UV-VIS, RI, DAD detection), GC, TLC, UV-VIS spectrophotometry, IR, basic tests.
Assay, impurities and related substances	(U)HPLC (UV-VIS, RI, DAD detection), GC (FID), UV-VIS spectrophotometry, AA spectrophotometry, volumetric titrations, dissolution. Determination of related substances/impurities and degradation products.	HPLC (UV-VIS, RI, DAD detection), GC (FID), UV-VIS spectrophotometry, AA spectrophotometry, volumetric titrations.
Stability Studies	ICH conditions/ WHO conditions	N/A

All the non-compliances observed during the inspection that were listed in the full report were addressed by the laboratory, to a satisfactory level, prior to the publication of the WHOPIR.

This WHOPIR will remain valid for 3 years, provided that the outcome of any inspection conducted during this period is positive.

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