World Health Organization

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Prequalification Unit Inspection services
WHO PUBLIC INSPECTION REPORT

Desk Assessment of Active Pharmaceutical Ingredient (API) Manufacturer

Part 1	**General information**
Company information	
Name of Manufacturer	Ipca Laboratories Ltd
Corporate address of manufacturer	Plot No. 125, Government Industrial Estate Charkop, Kandivali (West) Mumbai, 400 067 India
Inspected site	
Name & address of manufacturing site	Ipca Laboratories Ltd. Sejavta, Ratlam, Madhya Pradesh, 457001, India DUNS: 862179827
Synthetic Unit/Block/Workshop	N/A
Desk assessment details	
Review Date	30 November 2022
APIs covered by this desk assessment	PQT Number, API and Prequalification Status MA160 - Artemether API in Artemether/Lumefantrine Tablet 80mg/480mg - Prequalified MA160 - Lumefantrine API in Artemether/Lumefantrine Tablet 80mg/480mg - Prequalified MA167 - Artemether API in Artemether/Lumefantrine Tablet 20mg/120 mg - Prequalified MA167 - Lumefantrine API in Artemether/Lumefantrine Tablet 20mg/120mg - Prequalified MA185 - Lumefantrine API in Artemether/Lumefantrine Tablet, Dispersible 20mg/120mg – Under Assessment MA185 - Artemether API in Artemether/Lumefantrine Tablet, Dispersible 20mg/120mg – Under Assessment

	MA186 - Artesunate (sterile) API in FPP - Under Assessment (only the non-sterile part of the process is covered by this desk assessment) APIMF042 - Lumefantrine - Acceptable APIMF030 - Amodiaquine (hydrochloride) - Acceptable APIMF081 - Artesunate - Acceptable APIMF163 - Artemether - Acceptable APIMF233 - Dihydroartemisinin - Acceptable APIMF240 - Artesunate (sterile) – Acceptable (only the non-sterile part of the process is covered by this desk assessment) WHOAPI-042 - Lumefantrine - Prequalified WHOAPI-030 - Amodiaquine dihydrochloride dihydrate - Prequalified WHOAPI-081 - Artesunate - Prequalified WHOAPI-163 - Artemether - Prequalified WHOAPI-233 - Dihydroartemisinin - Prequalified WHOAPI-240 - Artesunate (sterile) – Prequalified (only the non-sterile part of the process is covered by this desk assessment) MA056 - Amodiaquine dihydrochloride dihydrate API in Amodiaquine (hydrochloride)/Artesunate Tablet 67.5mg/25mg - Prequalified MA057 - Amodiaquine dihydrochloride dihydrate API in Amodiaquine (hydrochloride)/Artesunate Tablet 135mg/50mg - Prequalified MA058 - Amodiaquine dihydrochloride dihydrate API in Amodiaquine (hydrochloride)/Artesunate Tablet 270mg/100mg - Prequalified MA062 - Lumefantrine API in Artemether/Lumefantrine Tablet 20mg/120mg - Prequalified MA062 - Artemether API in Artemether/Lumefantrine Tablet 20mg/120mg - Prequalified MA062 - Artemether API in Artemether/Lumefantrine Tablet 20mg/120mg - Prequalified

	MA080 - Amodiaquine dihydrochloride dihydrate API in Amodiaquine (hydrochloride)/Artesunate Tablet 67.5mg/25mg - Prequalified MA080 - Artesunate API in Amodiaquine (hydrochloride)/Artesunate Tablet 67.5mg/25mg - Prequalified MA081 - Artesunate API in Amodiaquine (hydrochloride)/Artesunate Tablet 135mg/50mg - Prequalified MA081 - Amodiaquine dihydrochloride dihydrate API in Amodiaquine (hydrochloride)/Artesunate Tablet 135mg/50mg - Prequalified MA082 - Amodiaquine dihydrochloride dihydrate API in Amodiaquine (hydrochloride)/Artesunate Tablet 270mg/100mg - Prequalified MA082 - Artesunate API in Amodiaquine (hydrochloride)/Artesunate Tablet 270mg/100mg - Prequalified HA736 - Trimethoprim API in Sulfamethoxazole/Trimethoprim Tablet 800mg/160mg - Prequalified MA092 - Lumefantrine API in Artemether/Lumefantrine Tablet, Dispersible 20mg/120mg - Prequalified MA092 - Artemether API in Artemether/Lumefantrine Tablet, Dispersible 20mg/120mg - Prequalified HA735 - Trimethoprim API in Sulfamethoxazole/Trimethoprim Tablet 400mg/80mg - Prequalified HA745 - Trimethoprim API in Sulfamethoxazole/Trimethoprim Tablet 800mg/160mg - Prequalified MA135 - Artesunate (sterile) API in Artesunate Powder, solvent and diluent for solution for injection + Sodium Bicarbonate Solution for injection + Sodium Chloride Solution for injection 5%w/v + 0.9%w/v+60mg - Prequalified MA132 - Artesunate API in Amodiaquine (hydrochloride)/Artesunate Tablet 67.5mg/25mg - Prequalified MA132 - Amodiaquine dihydrochloride dihydrate API in Amodiaquine (hydrochloride)/Artesunate Tablet 67.5mg/25mg - Prequalified MA133 - Artesunate API in Amodiaquine (hydrochloride)/Artesunate Tablet 135mg/50mg - Prequalified

	MA133 - Amodiaquine dihydrochloride dihydrate API in Amodiaquine (hydrochloride)/Artesunate Tablet 135mg/50mg - Prequalified HA744 - Trimethoprim API in Sulfamethoxazole/Trimethoprim Tablet 400mg/80mg - Prequalified HA747 - Trimethoprim API in Sulfamethoxazole/Trimethoprim Tablet 400mg/80mg - Prequalified HA748 - Trimethoprim API in Sulfamethoxazole/Trimethoprim Tablet 800mg/160mg - Prequalified MA136 - Artemether API in Artemether/Lumefantrine Tablet, Dispersible 20mg/120mg - Prequalified MA136 - Lumefantrine API in Artemether/Lumefantrine Tablet, Dispersible 20mg/120mg - prequalified MA134 - Amodiaquine dihydrochloride dihydrate API in Amodiaquine (hydrochloride)/Artesunate Tablet 270mg/100mg Prequalified MA134 - Artesunate API in Amodiaquine (hydrochloride)/Artesunate Tablet 270mg/100mg - Prequalified
List of documents requested	a) A list of all regulatory inspections performed in the last 3 years and their outcomes, including any inspections with “non-compliant” outcomes; An update was submitted to this list on 5th September, which included the 2022 GMP compliance certificates from TGA & ANVISA. b) Current full inspection report(s), including deficiency letters, for inspections performed by a competent stringent regulatory authority in the past three years with a certified translated copy where this is not in English; c) Proof of CAPA implementation and final decision by the competent stringent regulatory authority related to observations or deficiencies noted in the latest inspection report or to any warning letter or equivalent regulatory action (production-line specific); d) A copy of the manufacturing authorization and GMP certificate granted by the local national authority together with a certified translation, where this is not in English; e) A site master file whose approval date was not more than one year ago, and any forecast modifications, together with legible colour printouts of water treatment and air-handling systems, including pipeline and instrumentation drawings in A3 or A2 format;

	f) The list of all the products and dosage forms manufactured on-site. g) The most recent product quality review(s) (PQR)(s) of the concerned product(s); PQR(s) or equivalent documentation covering all required subsections and trend results, including statistical evaluation; h) The completed batch manufacturing and packaging record(s), including the analytical part, for the most recently released batch of the relevant product(s); i) The list of any recalls in the past three years related to any product manufactured on-site with quality defects; j) A confirmation by the senior quality assurance representative that a full self-inspection or external audit dedicated to the product(s) has been performed and all matters dealt with; k) Master batch manufacturing and packaging record(s) of the WHO product(s) of interest; l) Copy of any warning letter, or equivalent regulatory action, issued by any authority to which the site provides or has applied to provide the product; m) Description of any recent or foreseen out-of-stock situations; n) A list of notifications of upcoming inspections by competent national regulatory authorities in the next 6 months; o) The following information regarding waste management practices (As per WHO Points to consider for manufacturers and inspectors: environmental aspects of manufacturing for the prevention of antimicrobial resistance", Technical report series 1025, Annex 6): a. How does your facility dispose of the liquid and solid waste, that contains residues of trimethoprim and sulfamethoxazole APIs and of their intermediates, generated during their manufacturing process? b. If decontamination methods are used for waste management of liquid waste, before releasing the liquid waste to sewers/streams or into the municipality water treatment plant, are any tests performed on wastewater to verify compliance to discharge targets? Please describe. c. For trimethoprim and sulfamethoxazole APIs and their intermediates, which limits/discharge targets do you use?

	p) A table to specify which parts of the manufacturing process for the concerned product(s) were covered by the inspection of the competent SRA authorities performed in the last 3 years.	
Any documents missing?	N/A	
Part 2	**Summary of SRA/NRA inspection evidence considered (from most recent to last) and comments**	
Therapeutic Goods Administration (TGA, Australia)	Dates of inspection:	24 to 27 May 2022
	Type of inspection:	Remote inspection during Covid
	Block/Unit/Workshop:	Not mentioned
	APIs covered:	Not mentioned
	Physical areas inspected:	As above
	Any sections of GMP not covered?	N/A
	Final conclusion of the inspection report:	GMP compliant
ANVISA	Dates of inspection:	18 to 22 July 2022
	Type of inspection:	GMP
	Block/Unit/Workshop:	Not mentioned
	APIs covered:	Not mentioned
	Physical areas inspected:	Not mentioned
	Sections of GMP not covered:	N/A
	Final conclusion of the inspection report:	GMP compliant
Part 3	**Summary of the last WHO inspection**	
Date and conclusion of most recent WHO inspection	23 to 26 February 2016	
Brief summary of manufacturing activities	The site has 22 manufacturing blocks, 2 pilot blocks and a product development laboratory. Production block 12 produces Artesunate, Artemether, DHA (DHA is a key starting material/KSM for the other two APIs), and production block 9 produces Amodiaquine Hydrochloride (which is kept as a risk mitigation plan but Indore site is the key producer) and production block 10 produces Lumefantrine. Ipca Ratlam has withdrawn Artemether (APIMF041) just before the start of the inspection.	
General information about the company and manufacturing	See above Other activities conducted on the site out of the inspection scope include, – Manufacturing of sterile API's, – Manufacturing of non-sterile and sterile dosage forms,	

site	– Research and development.
Focus of the last WHO inspection	Personnel - Organization chart - Staff training programme & records Quality Assurance and Quality Management System - Product Quality Reviews (PQR) - Change Control - Deviations - Complaints - Recalls - Review of batch documents Inspection of Production Operations & Facilities - Warehousing and storage - Production operations - Packaging and labelling operations Quality Control - QC Labs (physico-chemical and microbiology) - Testing of APIs, RM's and intermediates (IPC) - Out of Specification investigations - Reference substance and working standards - Stability program Validation Process validation Validation Master plan, protocols Production facility & equipment management - Purified Water - Cleaning and cleaning validation - Qualification and calibration program - Maintenance program Material Management
Areas inspected	IBD-IX, X, XII
Out of scope and restrictions (last WHO inspection)	N/A

WHO APIs covered by the last WHO inspection	Amodiaquine Hydrochloride (APIMF030) Artemether (APIMF163) Artesunate (APIMF081) Lumefantrine (APIMF042) Dihydroartemisinin (APIMF233)
Additional products to be covered by this desk assessment:	See above
Abbreviations	**Meaning**
BMR	Batch manufacturing record
BPR	Batch production record
CAPA	Corrective and preventive action
CC	Change control
GMP	Good manufacturing practices
NC	Non conformity
NRA	National regulatory agency
PQR	Product quality review
PQS	Pharmaceutical quality system
QA	Quality assurance
QC	Quality control
QCL	Quality control laboratory
QMS	Quality management system
QRM	Quality risk management
RA	Risk assessment
RCA	Root cause analysis
SOP	Standard operating procedure

Part 4	**Summary of the assessment of supporting documentation**

a) Manufacturing authorization and GMP certificate granted by the local authority:
Submitted, valid until 2026

b) Site master file (SMF):
SMF (R05, dated April 2022) submitted, generally acceptable

c) List of all the APIs or other products (intermediates, dosage forms) manufactured on-site:
A list of 938 products over 102 pages, dated December 2021, was submitted.

d) List of all regulatory inspections performed in the last 3 years and their outcomes:

ipca

STATUS OF REGULATORY INSPECTION AT IPCA LABORATORIES LIMITED RATLAM IN LAST 3 YEARS (JULY 2019 to JULY 2022)

Sr. No.	Regulatory Authority	Country	Month of Inspection	Purpose of Inspection	Outcome
01.	The Central Drug Standard Control Organization	India	July 2019	Revalidation of WHO-GMP Certificate	Facility & System is Acceptable, Certificate received
02.	Ministry of Industry and Trade of the Russian Federation	Russia	February 2021	GMP Inspection for registered 20 API's	Facility & System is Acceptable, Certificate received
03.	The Central Drug Standard Control Organization	India	April 2022	Revalidation of WHO-GMP Certificate	Facility & System is Acceptable, Certificate received
04.	The Central Drug Standard Control Organization	India	May 2022	Revalidation of WC Certificate	Facility & System is Acceptable, Certificate received
05.	Therapeutic Goods Administration (TGA)	Australia	May 2022	GMP Inspection for registered 17 API's	Facility & System is Acceptable, Certificate Awaited
06.	ANVISA (Agência Nacional de Vigilância Sanitária)	Brazil	July 2022	GMP Inspection for registered 23 API's	Facility & System is Acceptable, Certificate Awaited

Note: an update was submitted to this list on 5th September, regarding the TGA and ANVISA inspections of May 2022 and July 2022, which have received GMP compliant certificates.

e) Most recent product quality review(s) (PQR)(s) of the concerned WHO API(s):
Artesunate, October 2020 to September 2021. 86 batches were manufactured during this period, of which 5 batches were re-processed. There was 1 OOT result and 11 OOS results (6 finished products and 5 stability results). Deviations and changes were reported. No complaints were received, and no recalls were initiated. CpK values were calculated for identified CQAs and the process was considered capable.

f) Batch manufacturing and packaging record(s), including the analytical part, for the most recently released batch of relevant API(s):
The BMR for Artesunate (Pharm Int) was submitted, produced and tested in May to July 2022

g) Master batch manufacturing and packaging record(s) of the API(s) of interest:
The documentation for Artemether was submitted and found acceptable in principle

h) Recalls in the past three years related to APIs with quality defects:
There were no recalls in the last three years

i) Confirmation by the senior quality assurance representative that a full self-inspection or external audit dedicated to the API(s) has been performed and all matters dealt with:
A declaration was submitted, stating that self-inspections were conducted and that CAPAs were taken.

j) Copy of any warning letter, or equivalent regulatory action, issued by any authority for their market, to which the site provides or has applied to provide the API(s):
A warning letter was issued on 29 January 2016 by the USA FDA. It covered observations relating to unauthorized access to computerized systems, failure to appropriately investigate critical deviations,

failure to document and follow laboratory procedures. Ipca submitted a response to USFDA, which included certification by a third party and is waiting for an onsite inspection to take place. Ipca stated that they received an Import Alert exemption for a few APIs and continued their supply.

k) Out-of-stock situations:
No out-of-stock situation was anticipated

l) Additional documents submitted:
N/A

Part 5	Conclusion – Desk assessment outcome

Based on the previous WHO inspections and on the GMP evidence received and reviewed, it is considered that a desk assessment is acceptable in lieu of a WHO onsite inspection. The **site Ipca Laboratories Ltd** located at **Sejavta, Ratlam, Madhya Pradesh, 457001 , India**, is considered to be operating at an acceptable level of compliance with WHO GMP guidelines for APIs.

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

Part 6	List of guidelines referenced in this inspection report

1. WHO good manufacturing practices for active pharmaceutical ingredients. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fourth Report. Geneva, World Health Organization, 2010 (WHO Technical Report Series, No. 957), Annex 2. ***Short name: WHO GMP for APIs*** or ***TRS No. 957, Annex 2***
   untitled (digicollections.net)

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 GMP Guidelines or WHO TRS No. 986, Annex 2***
   https://digicollections.net/medicinedocs/documents/s21467en/s21467en.pdf

3. WHO guidance on good practices for desk assessment of compliance with good manufacturing practices, good laboratory practices and good clinical practices for medical products regulatory decisions. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-second Report. Geneva, World Health Organization, 2018 (WHO Technical Report Series, No. 1010), Annex 9. ***Short name: WHO TRS 1010, Annex 9***
   https://digicollections.net/medicinedocs/documents/s23457en/s23457en.pdf

4. WHO Good Manufacturing Practices: water for pharmaceutical use. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-fifth Report. Geneva, World Health Organization, 2021 (WHO Technical Report Series, No. 1033), Annex 3.
   Short name: WHO TRS No. 1033, Annex 3
   9789240020900-eng.pdf (who.int)

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
https://digicollections.net/medicinedocs/documents/s21440en/s21440en.pdf

6. Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-second Report Geneva, World Health Organization, 2018 (WHO Technical Report Series, No. 1010), Annex 8. **Short name: WHO TRS No. 1010, Annex 8**
https://digicollections.net/medicinedocs/documents/s23455en/s23455en.pdf

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
https://digicollections.net/medicinedocs/documents/s20108en/s20108en.pdf

8. 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
https://digicollections.net/medicinedocs/documents/s18681en/s18681en.pdf

9. WHO Good Practices for Pharmaceutical Products Containing Hazardous Substances. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fourth Report. Geneva, World Health Organization, 2010 (WHO Technical Report Series, No. 957), Annex 3.
Short name: WHO TRS No. 957, Annex 3
https://digicollections.net/medicinedocs/documents/s22358en/s22358en.pdf

10. 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
https://digicollections.net/medicinedocs/documents/s19959en/s19959en.pdf

11. 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
https://digicollections.net/medicinedocs/documents/s18677en/s18677en.pdf

12. 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**
https://digicollections.net/medicinedocs/documents/s18683en/s18683en.pdf

13. 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***
https://digicollections.net/medicinedocs/#d/s21438en

14. 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
https://digicollections.net/medicinedocs/documents/s18682en/s18682en.pdf

15. 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
https://digicollections.net/medicinedocs/#d/s20177en/

16. WHO guidelines on variation to a prequalified product. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-seventh Report Geneva, World Health Organization, 2013 (WHO Technical Report Series, No. 981), Annex 3.
Short name: WHO TRS No. 981, Annex 3
https://digicollections.net/medicinedocs/#d/s20175en/

17. WHO guidelines for drafting a site master file. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 14.
Short name: WHO TRS No. 961, Annex 14
http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

18. Good Manufacturing Practices: Guidelines on validation. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-third Report Geneva, World Health Organization, 2019 (WHO Technical Report Series, No. 1019), Annex 3. ***Short name: WHO TRS No. 1019, Annex 3***
https://digicollections.net/medicinedocs/documents/s23697en/s23697en.pdf

19. WHO General guidance on hold-time studies WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-ninth Report Geneva, World Health Organization, 2015 (WHO Technical Report Series, No. 992), Annex 4. ***Short name: WHO TRS No. 992, Annex 4***
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/WHO_TRS_992_web.pdf

20. 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***
Essential Medicines and Health Products Information Portal (digicollections.net)

21. Guideline on data integrity. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-fifth Report Geneva, World Health Organization, 2021 (WHO Technical Report Series, No. 1033), Annex 4. ***Short name: WHO TRS No. 1033, Annex 4***
9789240020900-eng.pdf (who.int)

22. WHO general guidance on variations to multisource pharmaceutical products. *WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fiftieth Report* Geneva, World Health Organization, 2016 (WHO Technical Report Series, No. 996), Annex 10.
Short name: WHO TRS No. 996, Annex 10
http://www.who.int/medicines/publications/pharmprep/WHO_TRS_996_annex10.pdf

23. WHO Recommendations for quality requirements when plant – derived artemisin is used as a starting material in the prosecution of antimalarial active pharmaceutical ingredients. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-ninth Report Geneva, World Health Organization, 2015 (WHO Technical Report Series, No. 992), Annex 6
Short name: WHO TRS No. 992, Annex 6
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/WHO_TRS_992_web.pdf

24. Stability testing of active pharmaceutical ingredients and finished pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-second Report Geneva, World Health Organization, 2018 (WHO Technical Report Series, No. 1010), Annex 10.
Short name: WHO TRS No. 1010, Annex 10
http://www.who.int/medicines/publications/pharmprep/WHO_TRS_996_annex10.pdf

25. Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products. Part 2: Interpretation of Guidelines on heating, ventilation and air-conditionning systems for non-sterile pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-third Report Geneva, World Health Organization, 2018 (WHO Technical Report Series, No. 1019), Annex 2. **Short name: WHO TRS No. 1019, Annex 2**
https://digicollections.net/medicinedocs/documents/s23699en/s23699en.pdf

26. Points to consider when including Health-Based Exposure Limits in cleaning validation. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-fifth Report Geneva, World Health Organization, 2021 (WHO Technical Report Series, No. 1033), Annex 2. **Short name: WHO TRS No. 1033, Annex 2**
9789240020900-eng.pdf (who.int)

27. Points to consider for manufacturers and inspectors: environmental aspects of manufacturing for the prevention of antimicrobial resistance. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-fourth Report Geneva, World Health Organization, 2020 (WHO Technical Report Series, No. 1025), Annex 6. **Short name: WHO TRS No. 1025, Annex 6**
9789240001824-eng.pdf (who.int)