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Prequalification Team Inspection services
WHO PUBLIC INSPECTION REPORT
(WHOPIR)

Desk Assessment of Active Pharmaceutical Ingredient (API) Manufacturer

Part 1	**General information**
Company information	
Name of Manufacturer	Mylan Laboratories Limited, Unit-1
Corporate address of manufacturer	Plot No 564/A/22, Road No 92, Jubilee Hills, Hyderabad-500 096 Telangana, India. Tel: 040-30866666 Fax: 040-30866699.
Inspected site	
Name & address of manufacturing site	Mylan Laboratories Limited, Unit-1. Survey No~~0~~.10/42, Gaddapotharam, Kazipally Industrial Area, PIN-502319, Sanga Reddy District Telangana, India. Tel: 08458-277248 Fax:08458277211.
Synthetic Unit/Block/ Workshop	Unit 1 Manufacturing Blocks (MB-01 to MB-11, **but only MB-01-MB-09 are used for WHO products).** Note: MB-11 is a new block that was commissioned in January 2018.
Desk assessment details	
Date of review	07 October 2019

APIs covered by this desk assessment

PQT number	Active Pharmaceutical Ingredient.
APIMF153	Artemether
APIMF161	Artesunate
APIMF214	Darunavir Ethanolate
APIMF069	Lamivudine USP
APIMF050	Lopinavir
APIMF070	Nevirapine USP (Anhydrous)
APIMF211	Oseltamivir Phosphate USP
APIMF072	Zidovudine USP
WHOAPI-153	Artemether
WHOAPI-161	Artesunate
WHOAPI-214	Darunavir Ethanolate
WHOAPI-069	Lamivudine USP
WHOAPI-050	Lopinavir
WHOAPI-070	Nevirapine USP (Anhydrous)
WHOAPI-211	Oseltamivir Phosphate USP
WHOAPI-072	Zidovudine USP

Note: In addition to the above, API from Mylan Unit 1 is used in the following FPPs : HA110 (Lamivudine), HA268 (Nevirapine anhydrous), HA286 (Zidovudine), HA291 (Lamivudine anhydrous), HA291 (Zidovudine), HA298 (Nevirapine anhydrous), HA323 (Nevirapine anhydrous), HA323 (Zidovudine), HA392 (Lamivudine anhydrous), HA392 (Zidovudine), HA396 (Nevirapine anhydrous), HA411 (Lopinavir), HA414 (Lamivudine anhydrous), HA426 (Zidovudine), HA426 (Nevirapine anhydrous), HA429 (Lopinavir), HA433 (Lamivudine anhydrous), HA433 (Zidovudine), HA433 (Nevirapine anhydrous), HA437 (Lamivudine anhydrous), HA464 (Zidovudine), HA466 (Lamivudine anhydrous), HA483 (Zidovudine), HA485 (Zidovudine), HA524 (Lamivudine anhydrous), HA524 (Nevirapine anhydrous), HA524 (Zidovudine), HA537 (Zidovudine), HA555 (Zidovudine), HA557 (Lamivudine anhydrous), HA557 (Zidovudine), HA567 (Nevirapine anhydrous), HA568 (Nevirapine anhydrous), HA569 (Nevirapine anhydrous), HA570 (Nevirapine anhydrous), HA572 (Lamivudine anhydrous, zidovudine), HA629 (Nevirapine anhydrous), HA635 (Lamivudine anhydrous) HA659 (Zidovudine), HA683 (Duranavir ethanolate), HA685 (Duranavir ethanolate), HA688 (Lamivudine anhydrous), HA697 (Lopinavir), HA721 (Lamivudine), IN009 (Oseltemavir monophosphate), IN010 (Oseltemavir monophosphate), IN011 (Oseltemavir monophosphate), MA099 (Artemether), MA100 (Artemether), NDA208255 (Lamivudine), NDA 209670 (Dolutegravir, Lamivudine)

List of documents submitted

a) Site master file document number U-1/SMF/001/05 version 5 effective date 15.09.2018.
b) Manufacturing license number 18/MD/AP/96/B/R valid till 19.05.2023 and issued by the Drugs Control Administration of Telangana.
c) Full inspection reports and proof of CAPA implementation and final decisions for inspections carried out by the USFDA, PMDA and AGES over the last three years.

	d) A list of all the APIs or other products manufactured on site. e) Product quality reviews for nine WHO PQ APIs. f) The completed batch manufacturing and packaging record including the analytical part for six WHO PQ APIs and declaration of batches not manufactured. g) Blank master batch manufacturing and packaging records of the APIs of interest. h) Declaration signed by the Head Quality Unit I, confirming that no recalls were initiated for products manufactured at the site within the last three years. i) Declaration signed by the Head Quality Unit I, confirming that self-inspections are being performed with regards to the activities related to APIs being manufactured at the site and that the site is in compliance with principles of GMP. j) Declaration signed by the Head Quality Unit I, confirming that no warning letter or equivalent regulatory action has been issued by any regulatory authority with regards to any API manufactured at Mylan Laboratories Limited Unit 1. k) Declaration signed by the Head Quality Unit I, confirming that no out of stock situation occurred in the last 3 years or foreseen in the next year for the products manufactured at Mylan Unit I	
Any documents missing?	All documents required for the desk assessment were duly submitted.	
Part 2	**Summary of SRA/NRA inspection evidence considered (from most recent to last) and comments**	
USFDA	Dates of inspection:	15-19 October 2018
	Type of inspection:	Pre-approval Inspection
	Block/Unit/Workshop:	Unit 1 (MB-01 to MB-11) and Unit 2 (not inspected)
	APIs covered:	API by chemical synthesis
	Physical areas inspected:	Production facilities (MB06, MB07, MB08), Materials management systems, quality control laboratories, utilities, and quality management systems.
USFDA	Dates of inspection:	12-16 March 2018.
	Type of inspection:	Post Approval Audit Inspection
	Block/Unit/Workshop:	Unit 1 and Unit 2 Note: Only Unit 1, MB-03, MB02 and cleanrooms were inspected and some of the manufacturing areas used for Lamivudine USP (SVL) in Unit 2
	APIs covered:	APIs by chemical synthesis
	Physical areas inspected:	Quality systems for both units, Unit I: Solid materials warehouse,

		manufacturing block MB-03, MB-02 and Cleanrooms with a focus on equipment used for efavirenz and ancillary areas.
PMDA	Dates of inspection:	24-26 October 2017
	Type of inspection:	GMP Inspection
	Block/Unit/Workshop:	Unit 1
	APIs covered:	Atomoxetine HCl
	Physical areas inspected:	Quality control laboratory and activities, QMS systems and material management
AGES	Dates of inspection:	16-17 March 2016
	Type of inspection:	Pre-approval inspection
	Block/Unit/Workshop:	Unit 1
	APIs covered:	Olmesartan Medoxomil, and Paroxetine hydrochloride
	Physical areas inspected:	Production, utilities, warehousing, packaging and quality control areas.
Part 3	**Summary of the last WHO inspection**	
Date and conclusion of most recent WHO inspection	Mylan unit 1 was last inspected by the WHO from 21-24 January 2015. This was the fourth inspection of the site by WHO. The inspection was closed with a compliance letter after the submission of CAPA to 3 major and 7 other deficiencies.	
Summary of manufacturing activities	The site is involved in the warehousing, production and quality control of APIs.	
General information about the company and manufacturing site	The manufacturing facility of Mylan unit 1 is situated at Sangareddy District in the state of Telangana, India about 60 km away from Hyderabad airport and located in Kazipally Industrial Area (17" 35' 39" N 78" 22'47" O). The manufacturing site was established in 1984, formerly known as Vorin Laboratories Ltd. In the year 2000 the site was acquired by Matrix Group and later acquired by Mylan Laboratories Ltd in2007. Since 2011 the facility is operating as Mylan Laboratories Ltd. Unit 1. The total area of the plot is 60713 m^2 and the main production blocks are built in an area of 22000 m^2. There are nine production blocks, one warehouse, research and development, quality control, quality assurance, utilities located on site. Products are manufactured in the specified production blocks. For the production of the last stages, the intermediates are transferred into specific pharma areas to handle the finished products, the pharma production operations are carried out in classified clean room areas. A total number of 54 APIs are manufactured on site. Inspections by the following agencies have been carried out within the last five	

<table>
<tr><td></td><td>years: WHO, USFDA, AGES, PMDA, COFEPRIS, EDQM, ANSM and KFDA.</td></tr>
<tr><td>Focus of the last WHO inspection</td><td>The last WHO inspection focused on the production and quality control of APIs listed with the PQ programme.</td></tr>
<tr><td>Areas inspected</td><td>Warehousing, production, QMS, quality control and utilities.</td></tr>
<tr><td>Out of scope and restrictions (last WHO inspection)</td><td>The last WHO inspection was restricted to the WHO PQ APIs. The manufacturer mentioned that nevirapine hemihydrate was discontinued from the PQ program in 2015, so this was excluded from the scope of this inspection.</td></tr>
<tr><td>WHO APIs covered by the last WHO inspection</td><td>
<table>
<tr><th></th><th>PQT Number</th><th>Active Pharmaceutical Ingredient.</th></tr>
<tr><td>1</td><td>Artemether</td><td>WHOAPI-153</td></tr>
<tr><td>2</td><td>Artesunate</td><td>WHOAPI-161</td></tr>
<tr><td>3</td><td>Darunavir Ethanolate</td><td>WHOAPI-214</td></tr>
<tr><td>4</td><td>Dihydroartemisinin</td><td>WHOAPI-178</td></tr>
<tr><td>5</td><td>Lamivudine USP</td><td>WHOAPI-069</td></tr>
<tr><td>6</td><td>Lopinavir</td><td>WHOAPI-050</td></tr>
<tr><td>7</td><td>Moxifloxacin Hydrochloride</td><td>WHOAPI-228</td></tr>
<tr><td>8</td><td>Nevirapine USP (Anhydrous)</td><td>WHOAPI-070</td></tr>
<tr><td>9</td><td>Oseltamivir Phosphate USP</td><td>WHOAPI-211</td></tr>
<tr><td>10</td><td>Pyronaridine Tetraphosphate</td><td>WHOAPI-190</td></tr>
<tr><td>11</td><td>Tenofovir Disoproxil Fumarate</td><td>WHOAPI-038</td></tr>
<tr><td>12</td><td>Zidovudine USP</td><td>WHOAPI-072</td></tr>
</table>
</td></tr>
<tr><td>Additional products to be covered by this desk assessment:</td><td>No available information to suggest additional products to be covered by this desk assessment.</td></tr>
<tr><th>Abbreviations</th><th>Meaning</th></tr>
<tr><td>BMR</td><td>Batch manufacturing record</td></tr>
<tr><td>BPR</td><td>Batch production record</td></tr>
<tr><td>CAPA</td><td>Corrective and preventive action</td></tr>
<tr><td>CC</td><td>Change control</td></tr>
<tr><td>GMP</td><td>Good manufacturing practices</td></tr>
</table>

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:
Manufacturing license number 18/MD/AP/96/B/R valid till 19.05.2023 and issued by the Drugs Control Administration of Telangana was submitted.

b) Site master file (SMF):
Site master file document number U-1/SMF/001/05 version 5 effective date 15.09.2018 was reviewed and found adequate in content and in line with the WHO guidance for site master files.

c) List of all the APIs or other products (intermediates, dosage forms) manufactured on-site:
A list of all APIs manufactured at the site was provided. The list contained 54 APIs. No penicillin or other highly sensitising products were manufactured at this site. There is thus no foreseen risk of cross-contamination from this category of products.

d) List of all regulatory inspections performed in the last 3 years and their outcomes:
A list of regulatory inspections performed in the last 3 years and their outcomes was provided. The site was inspected by the USFDA, AGES, PMDA and CAPA reports were submitted and accepted by the respective agencies. These inspection reports are overall acceptable and comprehensive in lieu of an onsite inspection.

e) Most recent product quality review(s) (PQR)(s) of the concerned WHO API(s):
PQRs for 9 APIs were submitted. PQR for lamivudine API for the period January 2018- December 2018, document number APR/U-1/2018/SVL/00. It was noted that no batches were manufactured during the review period. However, the company performed a review of other parameters such as suppliers, technical agreements, complaints, ongoing stability, change controls, recalls, regulatory variations among others. There were no significant findings from the review.

PQR for darunavir Ethanolate for the review period January 2018 to December 2018, document number APR/U-1/2018/DRE/00 was reviewed. It was noted that seven batches were reprocessed, no reworks, 5 rejected batches due to OOS, no customer complaints, recalls and returned goods. CpK calculations were made for various critical quality attributes.

Separate reviews were performed for the packaging materials, water system, compressed air, nitrogen, and HVAC systems. All parameters were generally within the prescribed limits.

PQR for other APIs were briefly reviewed. It was noted that the company did not in many cases manufacture any of the PQ APIs during the period of review.

f) Batch manufacturing and packaging record(s), including the analytical part, for the most recently released batch of relevant API(s):

Batch manufacturing and testing records for Artemether batch number 20056611 batch size 74kg manufactured on 11.03.2016 and released on 24.08.2016, lopinavir batch number 20102621 batch size 108kg manufactured on 14.02.2019 and released on 27.02.2019 were reviewed. No remarkable issues were noted.

g) Master batch manufacturing and packaging record(s) of the API(s) of interest:

Blank master batch manufacturing and packaging records of 9 PQ APIs were submitted.

h) Recalls in the past three years related to APIs with quality defects:

Declaration signed by the Head Quality Unit I, confirming that no recalls were initiated for products manufactured at the site within the last three years was submitted.

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:

Declaration signed by the Head Quality Unit I, confirming that self-inspections are being performed with regards to the activities related to APIs being manufactured at the site and that the site is in compliance with principles of GMP was submitted.

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):

Declaration signed by the Head Quality Unit I, confirming that no warning letter or equivalent regulatory action has been issued by any regulatory authority with regards to any API manufactured at Mylan Laboratories Limited Unit 1 was submitted.

k) Out-of-stock situations:

Declaration signed by the Head Quality Unit I, confirming that no out of stock situation occurred in the last 3 years or foreseen in the next year for the products manufactured at Mylan Unit I was submitted.

l) Additional documents submitted:

Not applicable.

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. **Mylan Laboratories Limited unit 1** located at **Survey N0.10/42, Gaddapotharam, Kazipally Industrial**

Area, PIN-502319, Sanga Reddy District Telangana, 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 during 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***
   http://apps.who.int/medicinedocs/documents/s20119en/s20119en.pdf

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***
   http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_986/en/

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://www.who.int/medicines/areas/quality_safety/quality_assurance/TRS1010annex9.pdf?ua=1

4. WHO Good Manufacturing Practices: water for pharmaceutical use. *WHO Expert Committee on Specifications for Pharmaceutical Preparations*. Forty-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. Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products. Part 2: Interpretation of Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products. *WHO Expert Committee on Specifications for Pharmaceutical Preparations*. Fifty-Third Report Geneva, World Health Organization, 2019

(WHO Technical Report Series, No. 1019), Annex 2. **Short name: WHO TRS No. 1019, Annex 2**
https://apps.who.int/iris/bitstream/handle/10665/312316/9789241210287-eng.pdf?ua=1

7. 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://apps.who.int/iris/bitstream/handle/10665/312316/9789241210287-eng.pdf?ua=1

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. 957, Annex 1
http://www.who.int/medicines/publications/44threport/en/

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
http://www.who.int/medicines/publications/44threport/en/

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
http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

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
http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

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
http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

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

http://whqlibdoc.who.int/trs/WHO_TRS_943_eng.pdf?ua=1

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
http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

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
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_981/en/

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
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_981/en/

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. WHO Guidelines on good manufacturing practices: validation, Appendix 7: non-sterile process validation. *WHO Expert Committee on Specifications for Pharmaceutical Preparations*. Forty-Ninth Report Geneva, World Health Organization, 2015 (WHO Technical Report Series, No. 992), Annex 3. ***Short name: WHO TRS No. 992, Annex 3***
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/WHO_TRS_992_web.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***

http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/WHO_TRS_992_web.pdf

21. 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

22. 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

23. 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

24. 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