World Health Organization

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

Prequalification Unit Inspection services
WHO PUBLIC INSPECTION REPORT
(WHOPIR)
Desk Assessment of Active Pharmaceutical Ingredient (API) Manufacturer

Part 1	**General information**
Company information	
Name of Manufacturer	Otsuka Pharmaceutical Co. Ltd, Second Tokushima Factory 224-18, Hiraishi Ebisuno, Kawauchi-cho Tokushima-shi, Tokushima, 771-0182, Japan Phone: +8188-665-2126 GPS coordinates: Latitude 34º 7' Longitude 134 º 35'
Corporate address of manufacturer	Otsuka Pharmaceutical Co., Ltd 2 – 9 Tsukasa-machi, Kanda, Chiyoda-ku Tokyo 101-8635, Japan +81332952958
Name & address of manufacturing site	Otsuka Pharmaceutical Co. Ltd, Second Tokushima Factory 224-18, Hiraishi Ebisuno, Kawauchi-cho Tokushima-shi, Tokushima, 771-0182, Japan Phone: +8188-665-2126 GPS coordinates: Latitude 34º 7' Longitude 134 º 35'
Synthetic Unit/Block/Workshop	Production - OPC-III&IV Packaging – OPC-XIII
Date of review	20 – 24, 27 – 29 April and 17 – 18 June 2020
APIs covered by this desk assessment	Delamanid
List of documents submitted	1. List of all regulatory inspections performed in the last 5 years and their outcomes 2. Inspection reports for inspections performed by EMA (Apr. 24-26, 2017), PMDA (Sep. 5-8, 2017), FDA (Mar. 12-23, 2018), PMDA (Jan. 23-25, 2019), Tokushima (Feb. 26-27, 2019), FDA (Sep. 2-10, 2019) and Tokushima (Sep. 17-19, 2019) 3. CAPA implementation and final decision by the authorities 4. Copy of the manufacturing authorization and GMP certificate granted by the Pharmaceutical Safety and Environmental Health Bureau of the Ministry of Health, Labor and Welfare 5. Site Master File of Second Tokushima Factory 6. List of all the drug substances and drug products manufactured at Second Tokushima Factory 7. Product quality reviews for conventional synthesis method and synthesis method 8. Manufacturing and packaging records and analytical part 9. Confirmation by the senior quality assurance representative that a full self-inspection has been performed and all matters dealt with

This inspection report is the property of the WHO
Contact: prequalinspection@who.int

	10. Master batch manufacturing and packaging records 11. Delamanid raw data (alternative manufacturing process) 12. Delamanid raw data (original manufacturing process) 13. Standard test procedure Delamanid Intermediate tests 14. Standard test procedure Delamanid Intermediate tests synthesis method No X 15. Standard test procedure Delamanid	
Part 2	**Summary of SRA/NRA inspection evidence considered (from most recent to last)**	
EMA (Danish Medicines Agency and Medical Products Agency, Sweden)	Dates of inspection:	24 – 26 April 2017
	Type of inspection:	GMP inspection
	Block/Unit/Workshop:	➢ OPX-X QC Laboratory ➢ OPC-XI tablet production ➢ OPC-XII Stability chambers ➢ OPC-XIII API production and sterile API production ➢ OPC-XIV API raw materials warehouse, QCL laboratory ➢ No 2 Warehouse
	Type of APIs covered:	APIs and FPP
Pharmaceuticals and Medical Devices Agency, Japan	Dates of inspection:	5 - 8 September 2017
	Type of inspection:	On-site preapproval GMP compliance inspection
	Block/Unit/Workshop:	➢ OPC-III Plant (Manufacturing facility for drug substance) ➢ OPC-IV Plant (Manufacturing facility for drug substance) ➢ OPC-X Plant (Testing facility for drug products) ➢ OPC-XI Plant (Packaging facility for drug products) ➢ OPC-XIII Plant (Manufacturing facility for drug substance) ➢ OPC-XIV Plant (Drug substance raw material warehouse and testing facility) ➢ Otsuka Warehouse No. 2 Warehouse (Storage facilities for raw materials, labeling and packaging materials, intermediate products, and finished products)
	Type of APIs covered:	APIs and FPP
FDA USA	Dates of inspection:	12 – 23 March 2018
	Type of inspection:	GMP inspection
	Block/Unit/Workshop:	➢ OPC-XIII
	Type of APIs covered:	APIs

This inspection report is the property of the WHO
Contact: prequalinspection@who.int

Pharmaceuticals and Medical Devices Agency, Japan	Dates of inspection:	23 – 25 January 2019
	Type of inspection:	On-site inspection
	Block/Unit/Workshop:	➢ OPC-XIII ➢ Plant AB milling room
	Type of APIs covered:	APIs
Pharmaceutical Affairs Department, Health and Welfare Division, Tokushima Prefecture	Dates of inspection:	26 – 27 February 2019
	Type of inspection:	GMP compliance inspections
	Block/Unit/Workshop:	➢ OPC-III ➢ OPC-IV ➢ OPC-XIII
	Type of APIs covered:	Delamanid
FDA USA	Dates of inspection:	2 – 6 September and 9 – 10 September 2019
	Type of inspection:	GMP surveillance inspection
	Block/Unit/Workshop:	➢ OPC-XI ➢ OPC-XII
	Type of APIs covered:	APIs and FPPs
Pharmaceutical Affairs Department, Health and Welfare Division, Tokushima Prefecture	Dates of inspection:	17 – 19 September 2019
	Type of inspection:	GMP inspection
	Block/Unit/Workshop:	➢ OPC-IX ➢ OPC-XIII ➢ OPC-XI ➢ OPC-III ➢ OPC-IV ➢ OPC-II
	Type of APIs covered:	APIs and FPPs
Part 3	**Summary of the last WHO inspection**	
Date and conclusion of most recent WHO inspection	The site has never been inspected by the WHO	
Abbreviations	**Meaning**	
CAPA	Corrective and preventive action	
GMP	Good manufacturing practices	
API	Active pharmaceutical ingredient	
FPP	Finished pharmaceutical product	

This inspection report is the property of the WHO
Contact: prequalinspection@who.int

Part 4	Summary of the assessment of supporting documentation

a) Manufacturing authorization and GMP certificate granted by the local authority:
Licence No 36AZ000069, issued 11 April 2019

b) Site master file (SMF):
SMF submitted and reviewed. SMF written according to the WHO TRS No. 961, Annex 14

c) List of all the APIs or other products manufactured on-site:

APIs	APIs	APIs	APIs
Carteolol hydrochloride	Nadifloxacin	Aripiprazole, Parenteral grade	Sterile Aripiprazole Monohydrate
Procaterol hydrochloride hemi-hydrate	Urea (13C)	Mozavaptan hydrochloride	Delamanid
Cilostazol	Aripiprazole	Tolvaptan	Brexpiprazole

FPPs	FPPs	FPPs	FPPs
Mikelan 5-mg tablets	Acuatim cream 1%	Abilify 12-mg tablets	Aripiprazole tablets with sensor, 2 mg
Aminoleban EN powder 50g	Acuatim lotion 1%	Abilify 5-mg tablets	Aripiprazole tablets with sensor, 5 mg
Acuatim ointment 1%	Mikelan 5-mg tablets	Abilify 10-mg tablets	Aripiprazole tablets with sensor, 10 mg
Mikelan LA capsules 15-mg	Aminoleban EN powder 50g	Abilify 15-mg tablets	Aripiprazole tablets with sensor, 15 mg
Abilify 6-mg tablets	Acuatim ointment 1%	Abilify 20-mg tablets	Aripiprazole tablets with sensor, 20 mg
Abilify 3-mg tablets	Mikelan LA capsules 15-mg	Abilify 30-mg tablets	Aripiprazole tablets with sensor, 30 mg
Abilify powder 1%	Hi-Z 50-mg tablets	Pletaal OD 100-mg tablets	Brexpiprazole 0.25 mg Tablets
Meptin 50mcg tablets	Lorelco 250-mg tablets	Pletaal OD 50-mg tablets	Brexpiprazole 0.5 mg Tablets
Meptin 25mcg tablets	UNIPHYL LA 400-mg tablets	Abilify OD 3-mg tablets	Brexpiprazole 1 mg Tablets
Pletaal 100-mg tablets	UNIPHYL LA 200-mg tablets	Abilify OD 6-mg tablets	Brexpiprazole 2 mg Tablets
Pletaal 50-mg tablets	UNIPHYL LA 100-mg tablets	Abilify OD 12-mg tablets	Brexpiprazole 3 mg Tablets
Hi-Z 25-mg tablets		Abilify OD 24-mg tablets	Brexpiprazole 4 mg Tablets
Abilify 1-mg tablets	Rexulti Tablets 1-mg	Abilify 12-mg tablets	Aripiprazole tablets with sensor, 2 mg
Iclusig 15-mg tablets	Rexulti Tablets 2-mg	Abilify 5-mg tablets	

This inspection report is the property of the WHO
Contact: prequalinspection@who.int

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

Competent Authority	Date	Products and Scope (On - site inspection/Desk top inspection)
Pharmaceutical Affairs Department, Health and Welfare Division, Tokushima Prefecture	January 26-27,2017	APIs GMP inspection for export pharmaceuticals / On-site inspection
Pharmaceutical Affairs Department, Health and Welfare Division, Tokushima Prefecture	March 13-15,2017	APIs and FPPs GMP inspection for export pharmaceuticals / On -site inspection
EMA	April 24-26, 2017	APIs and FPPs Routine GMP
Pharmaceutical Affairs Department, Health and Welfare Division, Tokushima Prefecture	May 31, 2017	FPPs On -site inspection
Pharmaceutical Affairs Department, Health and Welfare Division, Tokushima Prefecture	August 3-4, 2017	API GMP inspection for export pharmaceuticals / On-site Inspection
PMDA Japan	September 5-8, 2017	APIs and FPP On-site inspections
Pharmaceutical Affairs Department, Health and Welfare Division, Tokushima Prefecture	October 16-18, 2017	API and FPPs GMP inspection for export pharmaceuticals / On-site inspection
FDA USA	March 12-23, 2018	APIs and FPPs Routine GMP / Onsite inspection
PMDA Japan	January 23-25, 2019	APIs and FPPs An unannounced inspection
Pharmaceutical Affairs Department, Health and Welfare Division, Tokushima Prefecture	February 26-27, 2019	Delamanid
Pharmaceutical Affairs Department, Health and Welfare Division, Tokushima Prefecture	June 20, 2019	API On-site inspection
FDA USA	September 02-10, 2019	APIs and FPPs Routine GMP / On-site inspection
Tokushima (JPN)	September 17-19, 2019	Inspection prior to Renewal Manufacturing License On-site inspection

This inspection report is the property of the WHO
Contact: prequalinspection@who.int

e) Most recent product quality reviews (PQRs) of the concerned WHO API:
Submitted and reviewed:
- Delamanid Drug Substance (synthesis Method)
- Delamanid Drug Substance (Conventional synthesis Method)

f) Batch manufacturing and packaging records, including the analytical part, for the most recently released batch of relevant API:
Submitted and reviewed:
- Delamanid Manufacturing Instruction and Operation Record, Process 1 (original)
- Delamanid Manufacturing Instruction and Operation Record, Process 2 (original
- Delamanid Manufacturing Instruction and Operation Record, Process 3 (original)
- Delamanid Manufacturing Instruction and Operation Record, Process 1 (alternative)
- Delamanid Manufacturing Instruction and Operation Record, Process 2 (alternative)
- Delamanid Manufacturing Instruction and Operation Record, Process 3 (alternative)
- Delamanid Manufacturing Instruction and Operation Record, Process 4 (alternative)
- Delamanid Manufacturing Instruction and Operation Record, Process 9 (common): packaging
- Delamanid raw data (alternative manufacturing process) Lot No`s ZZ, XX, YY
- Delamanid raw data (original manufacturing process) Lot No`s ZZ, XX, YY

g) Master batch manufacturing and packaging records of the API of interest:
Submitted and reviewed:
- Delamanid Manufacturing Instruction and Operation Record, Process 1 (original)
- Delamanid Manufacturing Instruction and Operation Record, Process 2 (original
- Delamanid Manufacturing Instruction and Operation Record, Process 3 (original)
- Delamanid Manufacturing Instruction and Operation Record, Process 1 (alternative)
- Delamanid Manufacturing Instruction and Operation Record, Process 2 (alternative)
- Delamanid Manufacturing Instruction and Operation Record, Process 3 (alternative)
- Delamanid Manufacturing Instruction and Operation Record, Process 4 (alternative)
- Delamanid Manufacturing Instruction and Operation Record, Process 9 (common): packaging

h) Recalls in the past three years related to APIs with quality defects:
Not reported

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:
Submitted and confirmed

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):
Not reported

k) Out-of-stock situations:
Not reported

l) Additional documents submitted:
N/A

This inspection report is the property of the WHO
Contact: prequalinspection@who.int

Part 5	Conclusion – Desk assessment outcome

Based on GMP evidence received and reviewed, it is considered that a desk assessment is acceptable in lieu of a WHO onsite inspection. The site ***Otsuka Pharmaceutical Co. Ltd, Second Tokushima Factory***, located at ***224-18, Hiraishi Ebisuno, Kawauchi-cho Tokushima-shi, Tokushima, 771-0182, Japan*** 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 WHO 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 TRS No. 986, Annex 2***
   http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_986/en/

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

4. 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

5. 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**
   http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_1010/en/

6. 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

This inspection report is the property of the WHO
Contact: prequalinspection@who.int

7. 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/

8. 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 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 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

14. 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/

This inspection report is the property of the WHO
Contact: prequalinspection@who.int

15. 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/

16. 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

17. 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

18. 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

19. 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

20. WHO Recommendations for quality requirements when plant – derived artemisin is used as a starting material in the production 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

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 GDRMP guidance or WHO TRS No. 996, Annex 5
http://www.who.int/medicines/publications/pharmprep/WHO_TRS_996_annex05.pdf

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 Multisource guidance or WHO TRS No. 996, Annex 10
http://www.who.int/medicines/publications/pharmprep/WHO_TRS_996_annex10.pdf

This inspection report is the property of the WHO
Contact: prequalinspection@who.int

23. 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

24. Production of water for injection by means other than distillation. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-fourth Report. Geneva, World Health Organization, 2020 (WHO Technical Report Series, No. 1025), Annex 3.
Short name: WHO TRS No. 1025, Annex 3
https://www.who.int/publications-detail/978-92-4-000182-4

25. Good chromatography practice. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-fourth Report. Geneva, World Health Organization, 2020 (WHO Technical Report Series, No. 1025), Annex 4.
Short name: WHO TRS No. 1025, Annex 4
https://www.who.int/publications-detail/978-92-4-000182-4

26. 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
https://www.who.int/publications-detail/978-92-4-000182-4

27. 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

This inspection report is the property of the WHO
Contact: prequalinspection@who.int