

**Prequalification Unit Inspection services
WHO PUBLIC INSPECTION REPORT
(WHOPIR)**

Desk Assessment of Finished Product Manufacturer

Part 1	General information
Company information	
Name of Manufacturer	Beximco Pharmaceuticals PLC
Corporate address of manufacturer	Registered office 17 Dhanmondi R/A, Road No. 2 Dhaka 1205, Bangladesh Phone: (+880-2) 58611001-7 Website: www.beximcopharma.com Operational Headquarter 19 Dhanmondi R/A, Road No: 7, Dhaka-1205, Bangladesh Tel: +880258611001 Email: info@bpl.net Website: www.beximcopharma.com
Contact person	1. Mr. Iqbal Ahmed (Managing Director) Telephone No. : (+880-2) 58611001-7 ext.: 20080 E mail: iqa@bpl.net 2. Rabbur Reza (Chief Operating Officer) 24 hrs. Contact No. : +880 1711 522070 E mail : rra@bpl.net 3. Mr. Mohammad Tahir Siddique (Director Manufacturing and Site Operations) 24 hrs. Contact No. : +88 0171 3041342 E mail : mts@bpl.net 4. Sadaiyan Manohar (General Manager Quality) 24 hrs. Contact No. : +88 01709814284 E mail : sdn@bpl.net
Inspected site	
Name & address of manufacturing site	BEXIMCO PHARMACEUTICALS PLC. (Track-2, OSD Facility), 126 Kathaldia, Auchpara, Tongi 1711 Gazipur, Bangladesh Phone: (+880-2) 9810701 (4 lines) Geographic location: - Latitude = 23.903434 - Longitude = 90.392127 D-U-N-S Number: 731579053 FEI Number: 3008763868

Production Block/Unit	OSD Unit (Track-2, in short T-2)	
Manufacturing license number	License No. 119 and License No. 379	
Desk assessment details		
Start and end dates of review	21 – 22 February 2026	
Inspection record number	INSP-FPP-2023-0046	
Products covered by this desk assessment	HA668 - Lamivudine Tablet, Film-coated 300mg	
Part 2	Summary of SRA/NRA inspection evidence considered (from most recent to last) and comments	
<i>Therapeutics Goods Administration (TGA), Australia</i>	Dates of inspection:	26 May – 5 June 2024
	Type of inspection:	The inspection was planned to be a routine re-inspection, which covered the manufacturing, storage, quality control laboratories and quality assurance of non-sterile tablets, hard shell capsules, metered dose inhalers, dry powder inhalers as well as sterile eye drops. As identified, the scope was revised to only verify manufacture of sterile liquid ophthalmic (i.e. sterile lyophilized, suspension and steroidal ophthalmic products were removed)
	Block/Unit:	Track II Oral Solid, Inhalers & Spray (Metered Dose Inhalers [MDI] Unit I & Unit II & III) and Vision – Ophthalmic
	Type of products/Dosage forms covered:	Sterile and non-sterile finished product manufacture of capsules, tablets, pressurized inhalation, eye drops, inhalation powder and pressurized spray medicinal products.
	Physical areas inspected:	The inspection included the facilities of Track II –Oral Solids, Inhalers & Spray (Metered Dose Inhalers [MDI] Unit I & Unit II & III)), and Vision – Ophthalmic, utilities, storage and distribution.
<i>United States Food and Drug Administration (US FDA)</i>	Dates of inspection:	27 – 30 March 2023
	Type of inspection:	Preannounced CGMP inspection of a human prescription and Over the Counter (OTC) drug products manufacturer

	Block/Unit:	Oral Solid Dose Manufacturing Facility
	Type of products/Dosage forms covered:	Drug products for the U.S. market, for example Carvedilol Tablets USP, 3.125mg, 6.25mg, 12.5mg and 25mg; Cyproheptadine Hydrochloride Tablets USP, 4 mg; Metformin HCl Extended-Release Tablets USP, 500mg and 750mg; Sotalol HCl Tablets USP, 80mg, 120mg and 160mg; Methocarbamol Tablets USP, 500mg and 750mg; and Nadolol Tablets USP, 20mg, 40mg and 80mg
	Physical areas inspected:	A facility walk-through was conducted on all areas of manufacturing, laboratories, stability, retain samples chambers, and warehouse related to solid oral dose drug manufacturing
Part 3	Summary of the last WHO inspection	
Date and conclusion of most recent WHO inspection	15 to 18 May 2023. It was the third WHO inspection of the site with the last inspection performed on 10 to 12 March 2020.	
Summary of manufacturing activities	Production and quality control of OSD (tablets and capsules) and inhaler products were performed on-site but only OSDs were in WHO PQ scope.	
General Information about the company and manufacturing site	<p>Beximco Pharmaceuticals PLC. was a public limited company established in 1976. The company had three manufacturing sites and one R&D set-up. All three manufacturing sites and R&D were located at the site at Tongi, Gazipur, Bangladesh, approximately 10 km north of Hazrat Shahjalal International Airport, Dhaka.</p> <p>The three manufacturing sections managing operations on the Tongi site were referred to in the company as Track 1, Track 2 and Sterile Unit. Each track was functionally independent and had its own senior management group, with its own manufacturing facilities and laboratories.</p> <p>The section responsible for the product within the inspection scope (HA 668 Lamivudine Film-coated Tablets 300mg), Track 2, has five units: OSD unit, MDI unit-I, MDI unit-2, MDI unit-3 (was under commissioning) and DPI.</p> <p>The company declared that no Penicillin and Cephalosporin products are manufactured in Beximco Pharma facilities at Tongi. The company stated that Cephalosporin products were manufactured by third parties via CMO contracts.</p> <p>No non-therapeutic products, veterinary products, food, cosmetics, insecticides, herbicides and animal poisons were manufactured in Beximco Pharma facilities at Tongi, and no toxic substances, hormones,</p>	

	immunosuppressants, steroids, vaccines, biological agents, gases and cytotoxins were handled at this site.
Focus of the last WHO inspection	Routine re-inspection related to the production of Lamivudine Film-coated Tablets 300mg in OSD production block, Track 2
Areas inspected	<ul style="list-style-type: none"> • Quality management system • OSD production block, Track 2 • Warehouses of Track 2 • QC including chemical and microbiological laboratories • Stability study area • FG sample retention area
Out of scope and restrictions (last WHO inspection)	The inspection was restricted to the production of the product listed in the inspection scope. Products and production areas outside of the inspection scope were not inspected.
WHO products covered by the last WHO inspection	HA 668 Lamivudine Film-coated Tablets 300mg
Additional products to be covered by this desk assessment	None.
Abbreviations	Meaning
AHU	Air handling unit
API	Active pharmaceutical ingredient
BMR	Batch manufacturing record
BPR	<i>Batch production record</i>
CAPA	Corrective and preventive action
CC	Change control
FPP	Finished pharmaceutical product
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
SMF	Site master file
SOP	Standard operating procedure

Part 4	Summary of the assessment of supporting documentation
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a) List of all regulatory inspections performed in the last 5 years and their outcomes:

A comprehensive list of inspections conducted by various authorities was provided below:

No	Date of Inspection	Inspection Body	Outcome
1.	4 – 5 December 2024	Tanzania Medicines and Medical Devices Authority (TMDA), Tanzania	GMP Compliance report (CAPA acceptance) has been received.
2.	26 May – 5 June 2024	Therapeutics Goods Administration (TGA), Australia	GMP Certificate received
3.	6 – 8 and 12 February 2024	Ministry of Health, Libya	GMP Certificate received
4.	16 – 17 October 2023	Ministry of Health, Iraq	GMP Certificate received
5.	15 – 18 May 2023	World Health Organization	Inspection closing letter received
6.	27 – 30 March 2023	US FDA cGMP Inspection	EIR Received
7.	26 – 27 March 2023 (Desktop Audit)	Pharmacy and Poisons Board, Kenya	GMP Certificate received
8.	6 – 9 February 2023	Medicines Control Authority of Zimbabwe	GMP Certificate received

b) Manufacturing authorization granted by national authorities:

The following documents were submitted and found acceptable:

1. Certificate of Good Manufacturing Practice (GMP) for Pharmaceutical Products No: DA/6-3/96/50 dated 01.01.2026.

The certificate covered the activities of Sourcing and Procurement of RM/PM, Formulation design and accelerated stability, Analytical method development/verification and validation, Dispensing of RM/PM, Production including Granulation, Compression, Coating (if applicable), Packaging, Primary Packaging, Secondary Packaging; and Quality Assurance including In-process Quality Control, Manufacturing Environment Control, Finished Product Analysis, Product Quality Review, Analytical Method Validation, Process Validation and Batch Release Certificate

2. Certificate of Renewal of License to Manufacture Drugs dated 28 December 2025

The document certified that License No. 379, granted on the 12 October 1979, and License No. 119, granted on the 12 October 1979, had been renewed for a period of two years from the date 12 October 2025 to 11 October 2027.

c) Site Master File (SMF):

Site Master File for Oral Solid Dosage Unit (Track 2) was submitted. Overall, the content of the SMF has been in accordance with the WHO guidelines for drafting a site master file, WHO Technical Report Series, No. 961, Annex 14.

The Beximco Pharmaceuticals PLC. had three manufacturing sites and one R&D set-up. All manufacturing sites and R&D were located at Tongi, Gazipur, Bangladesh.

d) List of all the products and dosage forms manufactured on-site:

The list of products was available in Appendix 2 of the SMF. WHO Product, Lamivudine 300 mg Tablets (Lamivudine USP), was included in the list. No issues of concern were found with respect to the list provided.

e) Most recent product quality review(s) (PQR)(s) of the concerned WHO product(s):

Product Quality Review Report for Lamivudine 300 mg Tablets (Review Period January 2024 to December 2024) was submitted for review. The PQR was reviewed and found satisfactory.

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

The completed batch manufacturing and packaging records, including the full analytical documentation, for the most recently manufactured batch of Lamivudine 300 mg Tablets were submitted.

The manufacturing processes of Lamivudine 300 mg Tablets Batch No. 10235 were performed and recorded according to instructions in the batch production records. No issues were identified from the batch records. The in-process checks were performed, manufacturing time cycle was tracked, and verification by a second person was conducted.

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

According to the previous inspection report, batch documents were prepared by production with final QA review and authorisation. Batch documents were photocopied and released to production as required by the production schedule. Batch numbers were assigned and recorded in the batch number register.

BMR and BPR were available for each stage of manufacturing. The documents were generally found acceptable.

h) If any of the products are sterile, the completed batch records for the most recent media fill validation that is relevant to the product(s) of interest and report on its outcome:

Sterile product is not under the scope of the assessment.

i) Recalls in the past three years related to products with quality defects:

The company stated that there has been no product recall in the past three years.

j) 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:

The company submitted a signed declaration, confirming that:

1. Regulatory inspections and customer audits have been conducted across the entire facility, including the manufacturing and packaging lines where Lamivudine Tablets, Film Coated 300 mg were manufactured and packed.
2. Regulatory inspection reports and customer audit reports have been received, and CAPAs were submitted accordingly. All audits are now closed.

3. Bi-annual self-inspections of the facility, including the manufacturing and packaging lines where Lamivudine Tablets, Film-Coated 300 mg were manufactured and packed, were performed and all self-inspection CAPAs have been closed within the stipulated timelines.

k) 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:

The company stated that no warning letter or equivalent regulatory action has been issued.

l) Out-of-stock situations:

The company stated that no orders were received, and no stock-out situation arose.

m) Additional documents submitted:

The company submitted List of notification of upcoming regulatory inspection (Next 6 Months).

Part 5	Conclusion – Desk assessment outcome
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Based 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 **Beximco Pharmaceuticals PLC** located at **126 Kathaldia, Auchpara, Tongi 1711 Gazipur, Bangladesh** is considered to be operating at an acceptable level of compliance with WHO GMP guidelines.

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
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1. 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**
<https://digicollections.net/medicinedocs/documents/s21467en/s21467en.pdf>
2. 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 TRS No. 957, Annex 2**
[untitled \(digicollections.net\)](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 \(who.int\)](https://www.who.int/publications/m/item/9789240020900-eng.pdf)
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 \(digicollections.net\)](https://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 \(who.int\)](http://www.who.int/medicines/publications/pharmprep/WHO_TRS_996_annex10.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 TRS No. 996, Annex 10
http://www.who.int/medicines/publications/pharmprep/WHO_TRS_996_annex10.pdf
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. 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, 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>
25. 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 \(who.int\)](http://www.who.int/medicines/publications/pharmprep/WHO_TRS_996_annex10.pdf)

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**
[9789240001824-eng.pdf \(who.int\)](https://www.who.int/publications-detail/978-92-4-000182-4)
27. 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>
28. 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>