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

WHO Prequalification Team - Inspection services
WHO PUBLIC INSPECTION REPORT (WHOPIR)
In Vitro Diagnostic product

Inspected site/s	
Name of Organization	Beijing Wantai Biological Pharmacy Enterprise Co., Ltd
Address/es of inspected manufacturing site/s	No. 31 Kexueyuan Road 102206 Beijing China
Inspection details	
Start of inspection	06/11/2024
Inspection duration (in inspector days)	6
Type of inspection	Re-inspection
Introduction	
Brief description of manufacturing activities conducted at the site/s inspected	Beijing Wantai Biological Pharmacy Enterprise Co., Ltd designs, develops, manufactures, stores, and distributes in vitro diagnostic tests
General information about the organization	Beijing Wantai Biological Pharmacy Enterprise Co., Ltd., founded in 1991, has grown from a small laboratory to one of the largest manufacturers of in vitro diagnostic tests in China in the field of infectious disease diagnostics. The product line includes ELISA kits and rapid tests, chemiluminescence and clinical chemistry reagents for diagnosing infectious diseases such as HIV, Hepatitis B and C, Syphilis, and Tuberculosis. Their products are used by blood banks, hospitals, clinics, and research institutes worldwide.
Brief report of inspection activities undertaken – Scope and limitations	
Areas inspected	As detailed below, the areas inspected were sampled from the areas of activities performed on site that were relevant to the products in scope. The sampling was performed using a risk-based approach considering, for example, the impact of the area inspected on the product, as well as past inspection findings.

Products in scope	- PQDx 0005-005-00 Rapid Test for Antibody to Human Immunodeficiency Virus (HIV) (Colloidal Gold Device). - PQDx 0006-005-00 AiD anti-HIV 1+2 ELISA. -PQDx 0545-005-00 Rapid Test for Antibody to Hepatitis C Virus (Colloidal Gold Device). - PQDx 0544-005-00 HIV SELF TEST BY URINE – Human Immunodeficiency Virus (HIV) type-I urine antibody diagnostic kit (colloidal gold).
Criteria	• All applicable clauses of ISO 13485:2016 • WHO PQ requirements • Organization's own requirements
Objective(s)	Verify continued compliance to the inspection criteria.
Limitations	None.
Out of scope	Any processes or activities not related to the products in scope were considered out of scope of this inspection.

Abbreviations	**Meaning**
CAPA	Corrective and Preventive Action
CoA	Certificate of analysis
IQ	Installation qualification
IVD	In vitro device
MR	Management review
MRM	Management review meeting
MSDS	Material safety data sheet
NC	Non-conformity
PPE	Personal protective equipment
OOS	Out-of-specifications test result
OQ	Operational qualification
PM	Preventive maintenance
PMS	Post Market Surveillance
PQ	Performance qualification
PW	Purified water
QA	Quality assurance
QC	Quality control
QMS	Quality management system
QRM	Quality risk management
RA	Risk assessment
RCA	Root cause analysis
SOP	Standard operating procedure

Summary of the findings and comments

4. Quality management system

4.1 General requirements

The organization and management structure of the facility was documented and defined within the organisational chart. Roles and responsibilities were available with the overall reporting structure available with clear delineation for release of product.

4.2 Documentation requirements

4.2.2. Quality manual

The organization's Quality Manual adequately addressed and reflected the intended practices of the organization, with clear commitment from top management for the continual improvement and support of the QMS. The nonconformity identified was successfully addressed through a CAPA process.

4.2.4/5. Control of documents and records

There were documented procedures for document and record control that appeared to meet the requirements of the standard. There were no significant changes to the previously inspected document control system that had been implemented to manage QMS documentation, including procedures, work instruction, records, CAPAs including quality incidents and NCs and other documents. Document control practices were compliant where the procedures and the records reviewed provided evidence of conformity and completion of requirements. Generally, records and documents were readily available. The nonconformities identified were successfully addressed through a CAPA process.

5. Management responsibility

5.1. Management commitment

Top management provided evidence of its commitment to the development and implementation of the QMS and maintenance of its effectiveness by communicating to the organization the importance of meeting customer as well as applicable regulatory requirements, establishing the quality policy, ensuring that quality objectives were established, conducting management reviews, and ensuring the availability of resources.

5.3. Quality policy

Top management had an established Quality Policy. The inspectors verified that the organization had established processes that mostly met the requirements of ISO 13485:2016 (the standard) and other applicable regulations (notwithstanding the nonconformities identified during this inspection).

The quality policy was applicable to the purpose of the organization; included a commitment to comply with requirements and to maintain the effectiveness of the QMS, provided a framework for establishing and reviewing quality objectives, and was communicated and understood within the organization.

5.4. Planning

5.4.1. Quality objectives

Quality objectives, including those needed to meet applicable regulatory requirements and requirements for product, were established at relevant functions and levels within the organization. Quality objectives were measurable and consistent with the quality policy.

5.5. Responsibility, authority and communication

5.5.1. Responsibility and authority

Responsibilities and authorities were defined, documented, and communicated within the organization. The interrelation of all personnel who managed, performed, and verified work affecting quality were documented and ensured the independence and authority necessary to perform these tasks. The nonconformity identified was successfully addressed through a CAPA process.

5.6. Management review

5.6.1. General

The organization had an established process for regular management reviews that met the requirements of the standard. Records from management reviews were maintained. The review included assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives.

5.6.2. Review input

The input to management review included feedback, complaint handling, reporting to regulatory authorities, audits, monitoring and measurement of processes, monitoring and measurement of product, corrective action, preventive action, follow-up actions from previous management reviews, changes that could affect the QMS, recommendations for improvement, and applicable new or revised regulatory requirements. The nonconformities identified were successfully addressed through a CAPA process.

5.6.3. Review output

The output to management review were documented and included decisions and actions related to improvement needed to maintain the suitability, adequacy, and effectiveness of the QMS and its processes, improvement of product related to customer requirements, changes needed to respond to applicable new or revised regulatory requirements, and resource needs.

6. Resource management

6.1. Provision of resources

The facility was well resourced, with trained personnel and adequate facilities for the function and activities that were performed. This aimed to ensure the QMS was implemented, and its effectiveness maintained, and that applicable regulatory and customer requirements were met.

6.2. Human resources

The facility was staffed with personnel who had the necessary education, training, technical knowledge, and experiences for their assigned functions. Staff interviewed were open and forthcoming with information. The organization had an established and well documented training procedure. Training files for staff were maintained and available for review during the inspection. The nonconformity identified was successfully addressed through a CAPA process.

6.3. Infrastructure

The facility was clean, well maintained, with a logical workflow with segregation of activities, and with rooms of suitable size and design to suit the functions and to perform the operations to be conducted in them. This prevented product mix-up and ensured orderly handling of product. Pest control management procedure was implemented. The organization had documented requirements for the maintenance activities that applied to equipment used in production, to the control of the work

environment, and to monitoring and measurement. The nonconformities identified were successfully addressed through a CAPA process.

6.4. Work environment and contamination control

6.4.1. Work environment

All production rooms were controlled and monitored for temperature and relative humidity with recordings available. Staff were observed to be wearing appropriate PPE, with access to appropriate coats, shoes, masks, and hair nets. There were pictorials when entering an area on the gowning requirements. A mirror was available to ensure appropriate PPE was properly downed.

7. Product realization

7.1. Planning of product realization

The organization's approach to the planning of production and service provision was adequately documented in the QMS, with procedures for document management, risk management, product production, material verification, process validation, monitoring, inspection, and test activities.
The organization had determined and documented the required verification, validation, monitoring, measurement, inspection and test, handling, storage, distribution, and traceability activities specific to the product together with the criteria for product acceptance. The nonconformities identified were successfully addressed through a CAPA process.

7.3. Design and development

7.3.9. Control of design and development changes

The organization had an established and well documented procedure for the control of design and development that incorporated informing WHO of such changes as per the WHO requirements. At the time of inspection, there had been no changes to the design of the product since the last WHO inspection.

7.4. Purchasing

7.4.1. Purchasing process

The organization had an established and documented process for the purchasing of materials and services, that included a traceable inventory, release, and verification of critical incoming material.
Supplier management and qualification procedures were available and implemented with supplier agreements for critical suppliers available. Criteria for selection, evaluation, approval, and re-evaluation of suppliers were available. The nonconformities identified were successfully addressed through a CAPA process.

7.4.2. Purchasing information

The organization had signed quality agreements with relevant suppliers of materials and services that indicated that the supplier must notify the organization of changes in the purchased product prior to implementation of any changes that affect the ability of the purchased product to meet specified purchase requirements.

7.4.3. Verification of purchased product

The organization had implemented processes for the verification of purchased products to ensure that they met specified purchasing requirements. The extent of verification activities was proportionate to the risks associated with the purchased product. Records of these activities were maintained.

7.5. Production and service provision

7.5.1. Control of production and service provision

Production and service provision was carried out, monitored, and controlled to ensure that product conformed to specifications. The organization had a documented process for the control of production that included, but was not limited to, qualification of infrastructure and monitoring and measuring equipment. Batch manufacturing records were available and records were verified and approved.

7.5.6. Validation of processes for production and service provision

The organization had validated processes for production and service provision that followed procedures that included the equipment qualification and qualification of personnel; the use of specific methods, procedures, and acceptance criteria; the criteria for revalidation; and the approval of changes to the processes. The nonconformities identified were successfully addressed through a CAPA process.

7.5.7. Particular requirements for validation of processes for sterilization and sterile barrier systems

The organization documented procedures for the validation of processes for sterilization. Of note, these procedures had been developed and implemented by the critical suppliers of these sterile products. The nonconformity identified was successfully addressed through a CAPA process.

7.5.8. Identification

There was a documented procedure for product identification that was suitable throughout product realization.

7.5.11. Preservation of product

There was a documented procedure for the preservation of product that ensured that the product was maintained at the appropriate temperature throughout production. Retained samples were kept in their final packaging under controlled and monitored temperature.

7.6. Control of monitoring and measuring equipment

The organization had implemented procedures for the control of monitoring and measuring equipment. Measuring equipment was calibrated and/or verified, at specified intervals, or prior to use, and had identification indicating its calibration status. Calibration records were available, and a sample was reviewed. The nonconformities identified were successfully addressed through a CAPA process.

8. Measurement, analysis and improvement

8.2. Monitoring and measurement

8.2.2. Complaint handling

The organization had implemented a procedure for the timely handling of customer complaints. The procedures included requirements and responsibilities for evaluating information to determine if the feedback constitutes a complaint; investigating complaints; determining the need to report the information to the appropriate regulatory authorities; handling of complaint-related product; and determining the need to initiate corrections or corrective actions. Corrections and corrective actions were documented. Complaint handling records were maintained. The nonconformities identified were successfully addressed through a CAPA process.

8.2.4. Internal audits

The organization had implemented an internal audit program and was conducting internal audits at planned intervals. Auditors were selected to ensure objectivity and impartiality of the audit process. Auditors did not audit their own work.

8.2.5. Monitoring and measurement of processes

Trending and regular review of monitoring and measurement of processes was verified at the time of inspection. Detailed reports were available for the management review meetings and other relevant meetings.

8.2.6. Monitoring and measurement of product

The organization had implemented procedures to monitor and measure the characteristics of the product to verify that product requirements had been met. This was carried out at applicable stages of the product realization process. Evidence of conformity to the acceptance criteria were maintained. The identity of the person authorizing release of product and the test equipment used to perform measurement activities were recorded. Product release did not proceed until the planned and documented arrangements had been satisfactorily completed. The nonconformities identified were successfully addressed through a CAPA process.

8.3. Control of nonconforming product

8.3.3. Actions in response to nonconforming product detected after delivery

The organization had implemented a procedure to deal with nonconforming product detected after delivery by taking action appropriate to the effects, or potential effects, of the nonconformity.

Conclusion – Inspection outcome

Based on the areas inspected, the people met, and the documents reviewed, and considering the findings of the inspection, including the observations listed in the Inspection Report the company, ***Beijing Wantai Biological Pharmacy Enterprise Co., Ltd*** located at ***No. 31 Kexueyuan Road, 102206 Beijing, China*** was considered to be operating at an acceptable level of compliance with ISO 13485:2016 and WHO *Information for Manufacturers on Pre-qualification Inspection Procedures for the Sites of Manufacture of Diagnostics* (PQDx_014).

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

This WHOPIR will remain valid for 3 years, provided the outcome of any WHO pre-qualification inspection or other audit from regulatory authorities that WHO relies on conducted during this period provides evidence of current compliance with the audit criteria.

List of WHO Guidelines referenced in the inspection report

1. WHO Information for Manufacturers on Prequalification Inspection Procedures for the Sites of Manufacture of Diagnostics (PQDx_014). (https://www.who.int/diagnostics_laboratory/evaluations/en/)
2. ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes
3. WHO Post-market surveillance of in vitro diagnostics 2020 (ISBN 978 92 4 001532 6)
4. Medical devices - Application of risk management to medical devices - ISO14971:2019
5. GHTF/SG3/N19:2012 “Quality management system – Medical devices - Nonconformity Grading System for Regulatory Purposes and Information Exchange”
6. GHTF/SG4/(99)28 'Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers - Part 1: General Requirements
7. GHTF/SG4/N30R20:2006 'Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers - Part 2: Regulatory Auditing Strategy
8. GHTF/SG4(pd1)/N33R16:2007 'Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers - Part 3: Regulatory Audit Reports ISO 13485:2016, Commitments to WHO PQ.