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WHO Prequalification Team - Inspection services

WHO PUBLIC INSPECTION REPORT (WHOPIR)

In vitro Diagnostic product

Inspected site/s	
Name of Organization	Arkray Healthcare Pvt. Ltd.
Address/es of inspected manufacturing site/s	Plot no 336/338/340, Road no 3, G.I.D.C. Sachin (Surat) 394230 Gujarat India
Inspection details	
Start of inspection	18/09/2024
Inspection duration (in inspector days)	6
Type of inspection	Re-inspection
Introduction	
Brief description of manufacturing activities conducted at the site/s inspected	Design and development, manufacture, and distribution of in vitro diagnostic devices.
General information about the organization	Arkray, Inc. was established on June 10, 1960 and has affiliates globally, including Arkray Healthcare Pvt. Ltd. The product range includes diabetes testing devices (both portable and benchtop), urine analyzers, and medical devices for veterinary medicine.
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 0062-023-00 - ParaHIT f Ver. 1.0 Rapid Test for P. falciparum Malaria Device PQDx 0487-023-00 - Immunochromatographic One Step Rapid Visual Test for Vibrio cholera 01 Dipstick: Crystal VC 01
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

4.2 Documentation requirements

4.2.1. Quality manual

The Quality Manual adequately addressed and reflected the intended practices of the manufacturer. It contained a description of the interaction between the processes of the QMS, defined the structure of the documentation system and listed/excluded non-applicable clauses of ISO13485:2016 ("the standard"). The procedures were referenced in the quality manual.

4.2.3. Control of documents and records

There were documented procedures for document and record control which 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 non-conformity identified was successfully addressed through a CAPA process.

5. Management responsibility

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. Reporting lines for quality and production were independent of each other.

5.5.2. Management representative

The Senior Manager QA was the management representative. Their responsibility and authority included ensuring that processes needed for the quality management system were documented; reporting to top management on the effectiveness of the quality management system and any need for improvement; and ensuring the promotion of awareness of applicable regulatory requirements and quality management system requirements throughout the organization.

5.6. Management review

5.6.1. General

The organization had an established process for regular management reviews that appeared to meet 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.

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 quality management system; recommendations for improvement; and applicable new or revised regulatory requirements.

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 quality management system 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 ensured the QMS was implemented.

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 questioned were open and forthcoming with information.

The organization had an established and documented training procedure. Training files for staff were maintained and available for review during the inspection.
The non-conformity identified was successfully addressed through a CAPA process.

6.3. Infrastructure

The facility was well maintained with a logical workflow with segregation of activities 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.
The facility was well maintained, clean and orderly and clearly sign posted. Pest control management procedure was implemented.
The non-conformity identified was 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 that were provided. There were pictorials when entering an area on the gowning requirements. A mirror was available to ensure appropriate PPE was properly downed.

6.4.2. Contamination control

Procedures for the cleaning of the facility and infrastructure were available to prevent contamination of the work environment, personnel, or product. Pest control was in place.

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.

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 well 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 documented. The non-conformity identified was 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. Records of these activities were maintained. The non-conformity identified was successfully addressed through a CAPA process.

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. Records were verified and approved. The non-conformity identified was successfully addressed through a CAPA process.

7.5.5. Particular requirements for sterile medical devices

The organization maintained records of the sterilization process parameters used for each sterilization batch for lancets and alcohol swabs. Sterilization records were traceable to each production batch.

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 equipment and personnel qualification; the use of specific methods, procedures, and acceptance criteria; the criteria for revalidation; and the approval of changes to the processes. The non-conformity identified was 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.

7.5.8. Identification

There was a documented procedure for product identification throughout product realization. There was clear segregation of released and nonconforming products within the facility. The non-conformity identified was successfully addressed through a CAPA process.

7.5.11. Preservation of product

There was a well-established procedure for the preservation of product that ensured that the product was shipped with suitable shipping containers and maintained at the appropriate temperature throughout the manufacturing process. Retain samples were kept in their final packaging under controlled and monitored temperature. The non-conformity identified was successfully addressed through a CAPA process.

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, against measurement standards traceable to international or national measurement standards; had identification indicating its calibration status; and was safeguarded from adjustments that would invalidate the measurement result. Calibration records were available, and a sample was reviewed.

8. Measurement, analysis and improvement

8.2. Monitoring and measurement

8.2.1. Feedback

The organization had procedures in place to gather and monitor information relating to whether the organization has met customer requirements. Data were gathered from production as well as post-production activities.

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 non-conformity identified was successfully addressed through a CAPA process.

8.2.3. Reporting to regulatory authorities

The organization had documented procedures for providing notification of adverse events or issuance of advisory notices to the WHO.

8.2.4. Internal audits

The organization had implemented an internal audit program and was conducting internal audits at planned intervals. The audit program was planned. The audit criteria, scope, interval, and methods were defined and recorded. Auditors were selected to ensure objectivity and impartiality of the audit process. Auditors did not audit their own work. A sample of auditors' training records were reviewed and found appropriate. All nonconformities identified were captured and followed using the organization`s CAPA process. The non-conformity identified during this inspection was successfully addressed through a CAPA process.

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 shall be 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.

8.3. Control of nonconforming product

8.3.2. Actions in response to nonconforming product detected before delivery

The organization had implemented procedure to deal with nonconforming product detected before delivery by either eliminating the nonconformity, or precluding its original intended use, or authorising its use, release, or acceptance under concession.

8.3.3. Actions in response to nonconforming product detected after delivery

The organization had implemented procedure to deal with nonconforming product detected after delivery by taking action appropriate to the effects, or potential effects, of the nonconformity. Procedure for issuing advisory notices were in place.

8.4. Analysis of data

The organization had documented procedures to determine, collect, and analyse appropriate data to demonstrate the suitability, adequacy, and effectiveness of the QMS. Data analysed were gathered from customer feedback; quality control; supplier performance; and audits. The non-conformity identified was successfully addressed through a CAPA process.

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, ***Arkray Healthcare Pvt. Ltd.*** located at ***Plot no 336/338/340, Road no 3, G.I.D.C., Sachin (Surat), 394230 Gujarat, India*** 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.