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Prequalification Team Inspection services
WHO PUBLIC INSPECTION REPORT
(WHOPIR)
Vector Control Product Manufacturer

Part 1	**General information**
Manufacturers details	
Name of manufacturer	Gharda Chemicals Limited
Corporate address of manufacturer	Gharda Chemicals Limited 48 Hill Road, Bandra (West) Mumbai 400050, India
Inspected site	
Name & address of inspected manufacturing site(s)	Gharda Chemicals Limited D-1/2, MIDC, Lote Parshuram, Taluka Khed, District-Ratnagiri Khed Maharashtra 415722 India
Unit/Block/ Workshop	Not applicable
Inspection details	
Dates of inspection	23,26 and 27 August 2024
Type of inspection	Initial inspection The inspection aimed to establish that the applicable requirements of ISO 9001:2015 as well as WHO specific requirements were met.
Introduction	
Brief description of the manufacturing activities	The facility was founded initially at Dombivli and later established a facility in Lote, Parashuram in 1967. The site manufactured both technical materials (active ingredients) and end use products (finished products). The facility manufactured insecticides, herbicides, and fungicides. Only the formation lines used for the manufacture of Pendulum SC and Temeguard EC were inspected. These lines were dedicated to the manufacture of EC and SC insecticide formulations.
General information about the company and site	The site was ISO certified and held an integrated management system certificate that indicated the following ISO standards: - ISO 9001:2015 - ISO 14001:2015 - ISO 45001:2018

	Scope: Manufacture and dispatch of Agrochemicals, their intermediates, and formulations Certificate number: IND.22.10249/IM/U Issued: 20 December 2020 Expiry date: 10 January 2026 The certificate was issued by Bureau Veritas
History	This was the first inspection of the site by WHO.
Brief report of inspection activities undertaken – Scope and limitations	
Areas inspected	**Document review including but not limited to:** • Quality Manual • Training • Risk management • Management review • Job descriptions and responsibilities of key personnel • Complaints • Non-conforming products • Product release • Batch processing records • Control of changes • Internal audits • Calibration and equipment maintenance **Physical areas:** • Raw material and finished goods • Production areas • Quality control laboratory
Exclusions and Non-applications of requirements in the QMS	Design and development of products were not applicable as the site was not involved in the design and development activities.
Out of scope	The manufacture of other products not submitted to PQ were not included in the scope of this inspection.
Restrictions	None
WHO products covered by the inspection	• 007-001- Pendulum 6 SC (Alphacypermethrin 6%) • 007-002 - Pendulum 10 SC (Alphacypermethrin 10%) • 007-009 - Temeguard EC (Temephos 50%)

Abbreviations	Meaning
CoA	Certificate of analysis
FMEA	Failure Modes and Effects Analysis
KPI	Key Performance Indicators
PPE	Personal Protective Equipment
MR	Management Review
MRM	Management Review Meeting
QMS	Quality Management System
RPN	Risk Priority Number

Part 2	Summary of the findings and comments

1. Quality policy and quality objectives

The manager had documented the integrated management policy and objectives. The objectives and policy were displayed in various areas throughout the facility. The policy and objectives were signed by the managing director. The level and extent to which the quality objectives were achieved were monitored and measured.

2. Management review

According to the Integrated Management System (IMS) Manual, management reviews were conducted every quarter in April, July, October, and January. The meetings were chaired by the Factory Operations Manager or Site Head. Management review records are maintained for 2 years. The latest 2024 management review meetings were reviewed.

3. Organizational roles, responsibilities, and authorities

The manufacturer had an organogram in place. The reporting lines for production and quality control were found to be independent of each other. The job descriptions of the production manager and quality assurance manager were reviewed. Top management demonstrated leadership and commitment with respect to the quality management system by promoting improvement through internal audits, implementation of corrections and corrective actions, management reviews etc.

4. Document control

The procedure for document control was reviewed. The procedure applied to all Integrated Management System (IMS) documents and data related to QA. The procedure described the numbering of forms and working instructions. A copy of any obsolete document was retained for 1 year. The procedure did not describe the numbering of procedures. The procedures were part of the manual. Obsolete documents and records were disposed of under the authority of the respective department head by either burning or shredding.

The procedure for preparation, approval, and control of SOPs was also reviewed. QA manager or designated person was responsible for distribution and retrieval of controlled copies. Head QA was responsible for control of master copies. Documents were reviewed every 5 years or whenever procedures were changed. If there was no change after the review period, the document was stamped ‘reaffirmed’.

The procedure for control of records was in place. Data generated from software such as analytical test results and raw data were periodically backed up (daily backup) on the server.

5. Risk Management

The procedure for planning was in place. It defined and described the criteria for calculation of the RPN. The risk register was in place. Probability of occurrence/likelihood of occurrence and severity were defined. The quality assurance risks assessed covered risks related to quality of packaging and labeling, customer complaints, handling, and disposal of hazardous chemicals in the lab, chemical analysis, instrumental analysis, and preservation of finished products. The risks related to production activities, including EC and SC formulations were also reviewed.

6. Internal Audits

The internal procedure was described in the IMS manual. Internal audits were conducted once every year. A documented list of approved internal auditors was in place. The 2023 internal audit schedule was also in place. The internal audit schedules were created by the management representative and issued to the concerned departments. The internal audit schedule took into consideration changes and results of the previous audit. The internal auditors were independent of the areas audited. The procedure provided for root cause determination, corrections, and corrective actions in response to the nonconformities raised in the nonconformity report. The corrections and corrective actions were verified by the internal auditor prior to the closure of the inspection. The management representative maintained records of non-conformity reports and corrective actions taken for a period of three years.

7. Customer Satisfaction and Complaints

The manufacturer did not conduct customer satisfaction surveys. Instead, the company's marketing department located in Mumbai conducted the surveys. A copy of an international evaluation form for selected customers was verified. The survey considered the following parameters: products quality, product delivery, pricing and terms, technical assistance, post sales-services, safety, health, and environmental factors.

The procedure for Operations was reviewed. Complaints related to products and services were received by the HOD -Marketing. These were presented and discussed in Management Review Meetings. Complaints were registered in the customer complaints database. The site Head, head - customer care and concerned HOD were responsible for the review of complaints. The concerned HOD and head - customer care were responsible for the investigation, analysis, and preparation of the report detailing the root cause, corrections, and corrective actions. The investigation report was shared with the Site Head and Director operations for final feedback. It was then forwarded to Marketing department for communication with customer. Complaints were to be closed within 30 days of receipt.

The manufacturer also had another procedure for Improvements which described the handling of complaints. Complaints were received by HOD by email. The HOD briefed QA officials about the nature of the complaint and guided the investigation to be conducted. QA Official would then locate the retention sample for reanalysis and submit results to QA Manager/HOD and maintain records of related to the complaint in the investigation report. HOD ensured that the corrective actions were implemented. Selected complaints were reviewed by the inspection team.

8. Change Control

The procedure for change control was reviewed. The procedure applied to new products, chemicals, process changes, technology changes, facility changes, change of specifications, modifications/installations, materials handling, and storage, change of personnel in critical roles, documentation, instruments, suppliers etc. Changes were implemented following their review and approval. The different types of changes were defined (major change, temporary changes, organizational changes etc.). There were different management of Change (MOC) forms for the different types of changes:

- Technology and facility changes - C/HSE/F/10A
- Personnel - C/HSE/F/10B
- Security systems - C/HSE/F/10C

The MOC forms provided for impact assessment. Changes related to Technology and facility were approved by the Site head. Selected changes were reviewed by the inspection team.

9. Design and development of products

Not applicable. The site was not involved in design and development activities.

10. Support

Infrastructure and work environment

The infrastructure at the site was well maintained. The manufacturing environments were well planned and maintained. The warehouses were equipped with fire extinguishers, rodent traps, eye wash and spill kits.

Monitoring and measuring resources.

The list of critical equipment was checked. The 2024 preventive maintenance schedule for instruments located in the auxiliary plant were in place. The list was maintained in SAP. Breakdowns were also captured in SAP. The preventive maintenance records and calibration reports for selected equipment were reviewed.

11. Production and service provisions

Control of Production

The manufacture of Temeguard EC (Temephos 50%) involved mixing of a solvent with Temephos technical material and other ingredients, homogenization, filtration, packaging, and labeling. The mixing time was monitored. The instructions for preparation of EC formulation products were in place. The recipe for preparation of Temephos 50% EC was in place. Calibrated weighing balances were in place.

The manufacture of Pendulum SC (Alphacypermethrin) involved mixing of Alphacypermethrin technical material with demineralized water, silica, and other ingredients (premix), and milling. The premix was then mixed with other ingredients, packaged, and labeled. The inlet pressure of the mill and RPM were monitored. The procedure for product changeover was in place. The procedure described the cleaning approach whenever there was a product change.

Selected batch production records for Temephos 50% EC and Pendulum 10% were reviewed. Batch numbers of the raw materials used in production were traceable. SOP for receiving, storing, and dispatch of finished goods was in place. Batches were reviewed by the QA manager prior to release of the batch.

Quality control laboratory

The equipment in the quality control lab was identified and calibration statuses were indicated. A sample register was in place. Samples and freshly prepared solutions were adequately labeled. The procedure for sampling of raw materials and finished products was reviewed. The sampling plan was defined.

The procedure for determination of Alphacypermethrin content in SC formulation by HPLC and the procedure for determination of Temephos content in EC formulation by HPLC method were reviewed.

The analytical test reports and raw data for Temephos 50% EC were verified. The standards for Temephos and Alphacypermethrin were appropriately stored. The certificates for the standards were in place. The laboratory was equipped with an eyewash. The temperature and humidity of the quality control laboratory were monitored.

Retention samples

A sample of each batch was retained in a dedicated area. The temperature of the retention storage area was monitored. The samples were appropriately labelled. Retention sample registers were in place. Samples were retained for a period longer than the shelf life of the product.

All the issues raised related to this section were addressed satisfactorily by the manufacturer.

12. Preservation

The manufacturer had separate warehouses for storage of finished goods and raw materials. Inventory control was managed by SAP. Information on the material name, quantity received, sampling date, etc. was retained. The finished good warehouse was also managed by the automatic storage and retrieval system that stored and retrieved materials from a location assigned by SAP. A compatibility chart for hazardous materials was in place. The procedures for receipt of raw materials in the warehouse and receipt of packaging materials were reviewed.

13. Retention samples

A sample of each batch was retained in a dedicated area. The temperature of the retention storage area was monitored. The samples were appropriately labelled. Retention sample registers were in place. Samples were retained for a period longer than the shelf life of the product.

14. Control of externally provided processes, products, and services

The procedure for supplier selection was reviewed. The procedure applied to suppliers of all raw materials and packaging materials. The criteria for selection of vendors included cost, competitiveness, acceptability of specifications, etc. The procedure also included trial testing. The procedure for supplier evaluation and re-evaluation was also reviewed. The criteria for performance evaluation were defined. The supplier evaluation records for selected suppliers were reviewed. All the issues raised related to this section were addressed satisfactorily by the manufacturer.

Part 3	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, as well as the corrective actions taken and planned by **Gharda Chemicals Limited** located at **D-1/2, MIDC, Lote Parshuram, Taluka Khed, District-Ratnagiri Khed Maharashtra 415722 India** was considered to be operating at an acceptable level of compliance with the ISO 9001: 2015 Standard.

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

This WHOPIR will remain valid for 3 years, provided that the outcome of any inspection conducted during this period is positive.

Part 4	List of Standards and Guidelines referenced in the inspection report

1. Quality management systems – Requirements, International Standard (ICS 03.120.10), 5th edition (2015), ISO/FDIS 9001: 2015 ***Short name: ISO 9001:2015***
   https://www.iso.org

2. Manual on the Development and Use of FAO and WHO Specifications for Pesticides, First edition -third revision. Pesticide specifications. FAO plant production and protection paper (228), FAO/WHO Joint Meeting on Pesticide Specifications (JMPS), Rome 2016
   http://www.fao.org/agriculture/crops/thematic-sitemap/theme/pests/jmps/manual/en/