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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	Ganesh Agricare
Corporate address of manufacturer	Tagros Chemicals India Private Limited, Tagros House, No.4, Club House Road. Anna Salai, Chennai 600002, Tamil Nadu, India.
Inspected site	
Name & address of inspected manufacturing site(s)	1. Name: Ganesh Agricare Address: Plot No.408/1 &2, Near Fire Station, GIDC, Bharuch District, Panoli, Gujarat 394116 India. 2. Name: Tagros Chemicals India Pvt Ltd. (Quality Control Laboratory) Address: Plot No.2901-2906 and 2806, GIDC, Ankleshwar, Bharuch District, Panoli, Gujarat 394116 India.
Unit/Block/ Workshop	Not applicable
Inspection details	
Dates of inspection	9 -11 November 2022
Type of inspection	Initial inspection. The criteria for the inspection were based on the ISO 9001:2015 standard.
Introduction	
Brief description of the manufacturing activities	a) Ganesh Agricare: Plot No.408/1 &2, Near Fire Station, GIDC, Bharuch District, Panoli, Gujarat 394116 India. Ganesh Agricare belongs to Ganesh Group of Companies. The Ganesh companies are engaged in the manufacture of pesticides, Bio-fertilizers, plant growth regulators etc. Ganesh Agricare was engaged only in the manufacture of pesticides. The facility manufactured the following formulation categories: Wettable Powder (WP) Water Dispersible Granule (WDG), Dusting Powder (DP), Suspension Concentrate (SC), and Emulsifiable Concentrate (EC). b) Tagros Chemicals India Pvt Ltd. (Quality Control Laboratory), Plot No.2901-2906 and 2806, GIDC, Ankleshwar, Bharuch District, Panoli, Gujarat 394116 India.

	Only the quality control laboratory was inspected. The laboratory performed both physical and chemical tests on the in-process samples and finished products from Ganesh Agricare.
General information about the company and site	This was the first WHO inspection. The site did not have any ISO certifications. The site had adopted and implemented the QMS from Tagros Chemicals India Pvt Ltd.
History	This was the first WHO inspection of the site.
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 were not applicable as the site was not involved in design and development.
Out of scope	The manufacture of other of pesticides not submitted to WHO PQ were not included in the scope of this inspection.
Restrictions	None
WHO products covered by the inspection	• 004-004 Rubi SC (Alphacypermethrin 10% SC) • 004-005 Rubi 250WG-SB (Alphacypermethrin 25% WG-SB) • 004-008 Pali 250WG, WG-SB (Deltamethrin 25%WG-SB) • 004-018 2Gard WP-SB (Clothianidin 50% + Deltamethrin 6.25% WP-SB) • 004-019 Klypson 500 WG (Clothianidin 50% WG)

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	Brief summary of the findings and comments

1. Quality policy and quality objectives

The quality policy included commitments to satisfy applicable requirements and continual improvement. The quality policy stated in part ‘‘Continually improve our manufacturing practice in order to achieve progress in quality of our product, personnel and environmental safety”. The quality policy was signed by the Managing Partner. Established quality objectives were in place. Quality objectives related to on-time delivery, legal compliance, waste minimization and zero accidents. The quality objectives and quality policy were communicated through trainings. The quality objectives and policy were displayed at various locations within the facility. The quality objectives were measured and monitored.

2. Management review

Management reviews were conducted every six months. The latest Management review minutes were discussed. The agenda items discussed included Context of the organization, customer satisfaction and feedback, process performance and conformity of products and services, non-conforming products, data integrity, production performance, product release, service providers, audit results, adequacy of resources, complaints, policy, legal requirements, opportunities for improvement etc. There had been no complaints, non-conforming products, or deviations during the review period.

3. Leadership

Top management had established a quality policy and quality objectives. These were discussed in management review. Top management promoted improvement through internal audits and trainings. Top Management took accountability for the effectiveness of the quality management system by determining the parameters of the quality management system to monitor.

4. Control of documented information

Documents were controlled based on instructions outlined in the procedure for document control. The procedure described the identification, review, approval, and authorization of documents. Documents were categorized into 4 levels as follows:

Level 1: Management system manual. The Management Manual defined the structure of the organization, the roles, and responsibilities of the different personnel. It also described the structure of the integrated system, applicable laws and regulations and management commitment to quality, environment, and safety.

Level 2: Integrated system procedures. These procedures were related to the planning, operation and control of processes such as change request for revision of documents.

Level 3: Integrated system records such as inspections and test reports, calibration reports etc.
Level 4: Documents related to identification and distribution
Documents were reviewed every 3 years. The master list of documents was in place. An 'Issue control register' showing the distribution of documents and 'disposal register' with obsolete documents were also in place. Documents of external original were also identified.

5. Personnel competence and training
The procedure for competence and training of personnel was reviewed. Competency was evaluated either orally, questionnaire (pass mark 80%) or performance review. Retraining was provided for trainees who did not meet the pass mark. External training was also identified as a means of improving the knowledge base of personnel. Training records for the following were reviewed:

- Handling of customer property
- Good manufacturing Practices
- Quality Management system (ISO 9001:2015)
- Inversion test cycle awareness
- SOP of MSDS
- SOP on wettable powder formulation, water dispersible granules.

The lists of trainees and trainers for each training session were in place.

6. Risks Management
The Hazard identification and risk assessment procedure and the Risk and opportunity assessment procedure were reviewed. The FMEA tool was to be used for identification and assessment of risks. The RPN was calculated using on the severity, occurrence, and detectability.

7. Control of changes
The change authorization procedure was reviewed. Templates for the form for ''change management authorization'', change management and authorization issue control register were place. The procedure provided for assessment of the impact of the changes. An expert team comprising of the heads of safety, QA /QC, R&D, Production, Engineering, and site in-charge were responsible for reviewing changes. Changes were categorized into critical, major, and minor depending on the impact on quality of products and management systems. At the time of the inspection no changes had been registered by the manufacturer as the QMS from Tagros had just recently been implemented.

8. Internal Audits
The relevant procedure for internal audits was reviewed. The procedure described the scope of internal audits, selection of auditors, planning and reporting of audit results. The procedure emphasized impartiality during the audit process. The audit team was to be selected ensuring that there was no conflict of interest. Internal audits were conducted twice a year. Corrections and corrective actions addressing the non-conformities raised in the internal audits were to be verified and approved within 30 days following the internal audit. The latest internal audit report was reviewed. The schedule was reviewed by the Head of QA and approved by the Site Manager. Audit

schedule covering five departments i.e., administration, production, warehouse, engineering, and quality control was reviewed. The observed nonconformances were documented in the Non-conformance Report. The criteria of the internal audits was the ISO 9001:2015 standard. Corrections and corrective actions had been taken to address the non-conformities raised in the internal audits report.

9. Control of nonconforming products

The procedure for non-conformance management was reviewed. The procedure described the non-conformances related to raw materials, packaging materials, intermediate materials and finished products, actions to be taken and timelines. The following are some of the processes that could be reworked: blending, drying sieving etc. If nonconforming products were reworked, they were subjected to re-verification. At the time of the inspection the manufacturer had not encountered any nonconforming product.

10. Performance evaluation

The manufacturer had determined to monitor and measure the following parameters:
Raw material consumption, non-conformities, deviations, incidents, on-time delivery, Personal Protective Equipment (PPE) and waste management. The manufacturer had just recently begun commercial production at this site and therefore no performance evaluation had yet been performed.

11. Design and development of products

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

12. Customer satisfaction

Customer satisfaction was monitored through customer satisfaction surveys. A template of the customer satisfaction survey was in place. Customer satisfaction was to be measured using a scoring approach to determine the extent to which customer expectations were met, areas of for improvement and identify customer dissatisfaction. A customer satisfaction survey had not yet been conducted as the manufacturer had recently started production.

13. Complaints

Complaints were received by Tagros and communicated to the site for investigated. The complaint handling procedure was reviewed. The Head QA together with a cross functional team comprised of members from other technical departments were responsible for handling complaints. The procedure provided for root cause investigation, corrections, and preventive actions. Complaints were closed after verification of the effectiveness of the corrections and corrective action undertaken. Templates of the complaint register, and corrective and preventive report were in place. Complaints were categorized into critical, major, and minor. At the time of the inspection no complaint related to the products manufactured at Ganesh Agricare had been received.

14. Contract with Tagros

The contract between Tagros Chemical India Pvt Ltd and Ganesh Agricare – ‘‘Job Work Agreement for Formulation and packaging and the Technology Transfer Agreement were reviewed. The responsibilities of either party were clearly defined. Tagros was responsible for recalls.

15. Support

Infrastructure and work environment

The workers were appropriately donned with overcoats, safety shoes, googles, and gloves**.** The facility was well maintained.

Monitoring and measuring resources

The calibration certificates for balances and standard weights and digital thermometer were available. A maintenance and calibration schedule was in place.

16. Production and service provisions

Control of Production

Rubi SC was manufactured in the EC and SC plant. The manufacture of Rubi SC (Alphacypermethrin 10%) involved mixing, wet milling, addition of gum and post mixing, packaging, and labelling. Some of the major equipment used on the SC production line included bead mill, Gum-tank, SC-reactor, SC-High speed reactor etc. The equipment were uniquely identified. The batch production records for Alphacypermethrin 10% SC were also reviewed. The batch numbers and quantities of the raw materials used in production were recorded. The mixing times, temperature of the mill were monitored. Some of the in-process tests performed included pH, persistence foam, specific gravity etc.

Rubi 250WG-SB, Pali 250WG, Pali 250WG-SB, 2Gard WP-SB and Klypson 500 WG were manufactured in the WP and WDG plant. The manufacture of 2Gard WP-SB involved mixing, jet milling, post blending, and packaging and labelling. The manufacture of Rubi 250WG-SB, Pali 250WG, Pali 250WG-SB, and Klypson 500 WG involved mixing, jet milling, post blending, dough making, extrusion, drying, sieving, and packaging. The filter bags were dedicated. The inprocess controls included pH, persistent foam, wettability, and wet sieve test. The powders (2Gard) and granules (Rubi 250WG and Pali 250WG) were filled manually into the water-soluble bags.

The following batch production records were reviewed:

- Deltamethrin 25% (Pali 250WG)
- Alphacypermethrin 25% (Rubi WG-SB)
- Clothianidin 50%, Deltamethrin 6.25% (2 Gard WP-SB)
- Clothianidin 50% WDG (Klypson 500 WG)

The procedures for Cleaning of the reactors (mixing tanks) and Cleaning of solid product equipment were reviewed. Cleaning records were in place. Cleaning was verified visually.

The following process validation protocols and reports were reviewed:

- Alphacypermenthrin 25% WDG
- Clothianidin 50%, Deltamethrin 6.25% WP
- Alphacypermethrin 10% SC
- Clothianidin 50% WDG

The batch records were checked by the shift manager, reviewed by the plant manager. The Quality Management representative (from Tagros) released the products after review of the production records and QC test results. The products are released to Tagros. Tagros was responsible for the dispatch of the products to the customers.

The laboratory was located about 2 Km from the Ganesh Agricare. The laboratory had been divided into two: Formulations Lab (testing finished products and in-process control samples) and technical lab (testing of the samples of the technical material). The formulations lab was inspected. A finished product sample register was in place. The procedure for sampling of finished and retention of samples and the procedure for handling out of specification were reviewed. Analytical test reports were reviewed.

Analysis was performed using secondary standards prepared by the R&D department. The secondary standards were appropriately stored.

Waste generated from production was collected and dispatched to Tagros. The waste was then collected from Tagros by a third-party company for treatment.

17. Post-delivery Activities

Retention samples were stored dedicated area. The samples were adequately labelled. The samples were retained for a period equivalent to the shelf life of the product plus one year. A register for retention samples was in place. A sample of every batch was retained. The quantities of the samples to be retained were described in the SOP for sampling of finished and retention of samples.

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

A qualified vendor list was available. All the raw materials except demineralized water were supplied by Tagros. The procedure for New Vendor Development which described the selection, evaluation and monitoring of the performance of the vendors was reviewed. Samples of the raw materials from prospective vendors were sent to the laboratory for analysis. Three batches were manufactured with the raw material from the prospective vendor before the vendor was added to the qualified vendor list. The vendor evaluation reports were reviewed and found satisfactory.

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 **Ganesh Agricare** located at: Plot No.408/1 &2, Near Fire Station, GIDC, Bharuch District, Panoli, Gujarat 394116 India and **Tagros Chemicals India Pvt Ltd. (Quality Control Laboratory)** located at Plot No.2901-2906 and 2806, GIDC, Ankleshwar, Bharuch District, Panoli, Gujarat 394116 India were 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 as well as those reflected in the WHOPIR, 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. Quality management system – Medical devices - Nonconformity Grading System for Regulatory Purposes and Information Exchange" Final Document, Global Harmonization Task Force, November 2, 2012, GHTF/SG3/N19:2012
   https://www.imdrf.org

3. 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/