World Health Organization

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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 | Tropical Agro System India Pvt Limited |
| Corporate address of manufacturer | Tropical Agro System India Pvt Limited<br>530, 2B Vanagaram Road Ambattur, Chennai-600058 India |
| **Inspected site** | |
| Name & address of inspected manufacturing site(s) if different from that given above | As Above. |
| Unit/Block/ Workshop | Not applicable. |
| **Inspection details** | |
| Dates of inspection | 14-15 May 2018 |
| Type of inspection | Initial inspection.<br><br>The criteria for the inspection was the ISO 9001:2015 standard. |
| **Introduction** | |
| Brief summary of the manufacturing activities | Tropical Agro System India Pvt Limited (Tropical) is a sub-contacted manufacturer for Tagros Chemical India Private Limited (Tagros). The manufacturer was contracted to manufacture suspension concentrates including those subject to this prequalification inspection for the contract giver, Tagros for the past 3 years.<br><br>The activities at the site included warehousing (storage) of raw and bulk products, production, in-process testing, packaging and labelling of bulk products. Design and development of the products was carried out by Tagros.<br><br>The bulk products were transported to Tagros located at SIPCOT Industrial Complex Pachayankuppam Cuddalore-607005 Tamil Nadu India where final release, packaging, labelling and final distribution occurred. |
| General information | Tropical Agrosystem (India) ISO 9001:2015, date of issue 31 August 2017 expiry date 19 July 2019, certificate number 780965 was issued by Guardian Independent Certification Ltd. |


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| about the company and site | In addition, the site was licensed to manufacture insecticides under license number 11/72, issued 04 July 1972 by the Government of Tamil Nadu, Department of Agriculture.<br><br>Scope of certification by Guardian Independent Certification Ltd included: Manufacturing, formulating and supply of Bio fertilizers, Bio Pesticides, Plant growth Regulators, Antimicrobials, Biocides, Nanogluconated Fertilizers, Insecticides, Herbicides and Related products. |
| History | This was the first WHO audit conducted at the site. |
| **Brief report of inspection activities undertaken – Scope and limitations** | |
| Areas inspected | **Document review including but not limited to:**<br>• Quality Manual<br>• Training<br>• Risk management<br>• Management review<br>• Job descriptions and responsibilities of key personnel<br>• Complaints<br>• Non-conforming products<br>• Data integrity<br>• Product release<br>• Batch processing records<br>• Sampling and laboratory test reports<br>• Control of changes<br>• Internal audits<br>• Calibration and equipment maintenance<br><br>**Physical areas:**<br>• Quality control laboratory<br>• Raw material and finished goods warehouses<br>• Production areas |
| Exclusions and Non-applications of requirements in the QMS | Clause 8.3 Design and development was not applicable as this was not performed by Tropical Agro System India Pvt. Ltd. |
| Out of scope | Products not submitted to WHO for prequalification. |
| Restrictions | None. |
| WHO products covered by the inspection | PALI 50 SC (Deltamethrin 5%) 004-003<br>RUBI 50 SC (Alpha-cypermethrin 5%) 004-004<br>RUBI 100 SC (Alpha-cypermethrin 10%) 004-009 |


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| Abbreviations | Meaning |
|---|---|
| CoA | Certificate of analysis |
| GC | Gas chromatography |
| GR | Granules |
| HPLC | High performance liquid chromatography (or high performance liquid chromatography equipment) |
| LLIN | Long-lasting insecticide nets |
| MR | Management review |
| MSDS | Material safety data sheet |
| NC | Non-conformities |
| PPE | Personal Protective Equipment |
| QA | Quality assurance |
| QC | Quality control |
| QCL | Quality control laboratory |
| QMS | Quality management system |
| QRM | Quality risk management |
| RA | Risk assessment |
| SOP | Standard operating procedure |
| UV | Ultraviolet-visible spectrophotometer |
| WHOPES | World Health Organization Pesticides Evaluation Scheme |
| WP | Wettable powders |

| Part 2 | Brief summary of the findings and comments |
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**1. Organizational roles, responsibilities and authorities**

There were defined roles and responsibilities within Tropical, including an organizational chart. Management was dedicated to improvement and ensuring that the contract giver (Tagros) received the intended outputs as stated by the Technical Agreements and Job working flow charts. Overall the roles and responsibilities within the individual companies were well defined.

**2. Quality policy and quality objectives**

The facility had a documented and established quality policy which was appropriate to its purpose. The facility also had documented and established quality objectives.

**3. Management review**

The relevant procedure for management reviews and minutes of the last three meetings were reviewed. Management reviews were held every six months. Issues related to this section were addressed by the manufacturer to a satisfactory level.

**4. Leadership**

Top management of the facility was committed to development and implementation of the Quality Management System (QMS). The quality policy and objectives were communicated. Responsibilities and authorities for the different roles were assigned. The manufacturer had documented organizational structure. Reporting lines for production and quality control were independent of each other. Oversight of the facility's quality control and production activities was done by Tagros personnel.


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**5. Control of documented information**

Tropical had in place a procedure for the control of documents. According to the Technical Transfer agreements it was the responsibility of Tagros to provide raw materials, standard operating procedures, related documents and a copy of the master batch manufacturing record. Issues related to this section were addressed by the manufacturer to a satisfactory level.

**6. Personnel competence and training**

Training of staff for the production and QC of the Tagros products was the responsibility of Tagros. The inspectors were informed that all training records for these procedures were controlled by Tagros and were available at the Tagros site.

**7. Risks and opportunities**

Risk assessment was performed by Tagros. Issues regarding the risk assessment were satisfactorily addressed by the manufacturer. Please refer to the WHOPIR for Tagros for more information.

**8. Control of changes**

The manufacturer had a documented procedure for change control. The procedure provided for impact assessment. No changes to the product had been registered.

**9. Internal Audits**

The facility had a procedure for Internal audit. Tagros inspected external contractors biannually. Tropical Agro System had been audited by Tagros on 8th February 2018. Please refer to the WHOPIR for Tagros for more information

**10. Control of non-conforming products**

The procedures for handling of non-conforming goods and corrective actions from Tagros were also reviewed. There had been no recorded non-conforming goods identified from the Tropical site. All raw materials were delivered to Tagros who performed the initial Quality Control tests, this material was sent to Tropical who then performed QC on the delivered items (visual check only). Product was then produced and sent back to Tagros where the final QC was performed. There were no records of any non-conforming product returned from Tagros to Tropical.

**11. Performance evaluation**

Batch manufacturing records were forwarded to Tagros who then compiled, analyzed and evaluated the data related to the products specified in the scope of this inspection. Please refer to the WHOPIR for Tagros for more information.

**12. Complaint handling**

The relevant procedure for handling of complaints was reviewed. The procedure allowed for investigations to be conducted and time lines were defined. No complaints had been registered.

**13. Design and development of products**

There was no design and development of products conducted at the site.


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## 14.Support

**Infrastructure and work environment**

Overall the facility had been well maintained, there was signage available to distinguish between different production areas with staff provided with separate facilities for eating and breaks.

Production of Tagros products (including WHO prequalified products) was performed in a dedicated, separate area. Issues related to this section were addressed by the manufacturer to a satisfactory level.

**Monitoring and measuring resources**

There was a preventive maintenance schedule and records. Calibration of laboratory equipment was carried out by external service providers i.e. Perfect Calibration Centre Pvt Ltd and Vel Hi-Tech services.

## 15. Production and service provisions

**Control of Production**

The manufacturing process involved premixing, milling, post mixing and packaging. The manufacture of Tagros products was carried out in a dedicated area. At the time of the inspection premixing of Deltamethrin 5% SC was ongoing. Milling was performed at temperatures below 20ºC. This temperature was monitored. The temperature indicator was calibrated. The production equipment was made of stainless steel.

A record of production activities was maintained within the batch manufacturing records. Records and documented information included batch planning record, dispensing records, production instructions, in-process test results and packaging records. In-process checks included density, sieve test, foam test, pH and appearance. Completed and approved batch manufacturing records for Deltamethrin 5% SC were reviewed. The process validation protocol and report for Deltamethrin 5% SC were reviewed. Issues related to this section were addressed by the manufacturer to a satisfactory level.

**Identification and traceability**

Materials were uniquely identified, and the status clearly indicated. Records were maintained to enable traceability. Issues related to this section were addressed by the manufacturer to a satisfactory level.

**Release of products and services**

The bulk products were sampled and sent to Tagros. On receipt of the approved analysis report from Tagros the products were then released and transported to Tagros for labelling and distribution. The bulk products were transported to Tagros located at SIPCOT Industrial Complex Pachayankuppam Cuddalore-607005 Tamil Nadu India where final release, packaging, labelling and final distribution occurred.


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**16. Preservation**

The bulk products were packaged in plastic containers. The bulk products were stored on pallets under ambient storage conditions.

The transport agreement between Tagros and the road transport company was reviewed. This company was the only transport company contracted by Tagros for road transport. It was responsible for the transportation of raw material to the two contracted sites, including transport of bulk finished goods back to and from from Tagros. Deliveries from Tropical took approximately 3 hours to reach Tagros. International shipping/ sea freight was contracted to another company. The cost of shipping was borne by the customer. Issues related to this section were addressed by the manufacturer to a satisfactory level.

**17. Post-delivery Activities**

**Storage Stability**

The storage stability study program and reports for PALI 50 SC (Deltamethrin 5%) were reviewed. The studies were conducted in accordance with the WHO requirements and the results complied with the specifications. The study was conducted at Tagros.

**18. Control of externally provided processes and products**

Tagros had an established process of inspecting the external contractors biannually. Thio Chemi was inspected by Tagros on 23rd March 2017, and again on 10th August 2017. Tropical Agro System was inspected by Tagros on 8th February 2018. Issues related to evaluation and contracts of external providers were addressed by the manufacturer to a satisfactory level.

| Part 3 | Conclusion – Inspection outcome |
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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 ***Tropical Agro System India Pvt Limited*** located at ***530, 2B Vanagaram Road Ambattur, Chennai-600058 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 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.


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


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