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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	BR Agrotech Limited
Corporate address of manufacturer	BR Agrotech Limited 1505 Vikram Tower, Rajendra Place New Delhi, 110008, India
Inspected site	
Name & address of inspected manufacturing site(s)	BR Agrotech Limited 620/3, GIDC Estate, Panoli Industrial Area Bharuch, Gujarat 394115, India
Unit/Block/ Workshop	Not applicable
Inspection details	
Dates of inspection	18 -20 September 2023
Type of inspection	Initial inspection. The inspection was to establish that the applicable requirements to ISO 9001:2015 as well as WHO specific requirements were met.
Introduction	
Brief description of the manufacturing activities	Herbicides, fungicides and insecticides were manufactured at this site. The fungicides and insecticides were manufactured in a dedicated building separate from that of the herbicides. Lamba-cyhalothrin 10% WP was manufactured on a dedicated line. Only the line on which Lamba-cyhalothrin 10% WP was manufactured was inspected. The manufacture of Lambda-cyhalothrin 10% WP involved mixing, grinding, post blending, filling, packaging and labelling.
General information about the company and site	This was the first WHO inspection. The manufacturer had the following certifications: **a)** ISO 9001: 2015: Quality Management System Certificate Number: 21.GGCS.IN.091183 Issue Date: 21 June 2021 Expiry Date: 20 June 2024 **Scope:**

	Manufacture, Supply and Export of Insecticides, Pesticides, Germicides and Herbicides The certificate was issued by Geotek Global Certification Pvt. Ltd. **b)** ISO 14001: 2015: Environmental Management System Certificate Number: 21.GGCS.IN.140170 Issue Date: 21 June 2021 Expiry Date: 20 June 2024 **Scope:** Manufacture, Supply and Export of Insecticides, Pesticides, Germicides and Herbicides The certificate was issued by Geotek Global Certification Pvt. Ltd. **c)** ISO 45001: 2018: Occupational Health and Safety Management System Certificate Number: 21.GGCS.IN.450127 Issue Date: 21 June 2021 Expiry Date: 20 June 2024 **Scope:** Manufacture, Supply and Export of Insecticides, Pesticides, Germicides and Herbicides. The certificate was issued by Geotek Global Certification Pvt. Ltd. **d)** Good Manufacturing Practice Certificate Number: 21.GGCS.IN.062068 Issue Date: 21 June 2021 Expiry Date: 20 June 2024 **Scope:** Manufacture, Supply and Export of Insecticides, Pesticides, Germicides and Herbicides The certificate was issued by Geotek Global Certification 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 products not submitted to PQ were not included in the scope of this inspection.
Restrictions	None
WHO products covered by the inspection	• Lambda-cyhalothrin 10% WP

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 (where applicable)**

1. Quality policy and quality objectives

The facility had a documented and established quality policy which was appropriate for its purpose. The quality policy was displayed throughout the facility and available in both English and local language. The facility also had documented and established quality objectives. Quality objectives and targets were defined within the quality manual.

2. Management review

Management review meetings were carried out in accordance with an established procedure. The structure of the meeting was found to be compliant and structured according to the requirements of the ISO 9001 standard. The minutes were reviewed.

3. Organizational roles, responsibilities, and authorities

The roles and responsibilities of management and organogram were documented. The quality control manager and production manager reported independently to their respective managers. The QA manager reported to the Director while the QC manager reported to the General Manager. The job descriptions of the QA manager and QC manager were reviewed. The QA manager was responsible for preparing plans for internal audits, management review meetings and execution of the same. The QA manager was also responsible for validation of analytical testing methods of certain formulations not available in CIPAC, relevant journals and Bureau of Indian Standards. The Quality Manager was responsible for release of test results, rejection/approval of materials, handling customer complaints etc.

4. Control of documented information

BR Agrotech had a procedure for the control of documents in place. Documents were maintained electronically with hard copies available at the point of use. There was a hard copy distribution list available. Retention period of the documents was defined within the procedure with technical files being retained indefinitely.

Electronic copies of the files were stored in an electronic database. Issued documents were stamped with the relevant stamp.

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

5. Personnel competence and training

The manufacturer had an established procedure for the training of staff. The training records of the supervisors was reviewed. The training schedule was reviewed and was found to meet the requirements of the standard. The manufacturer was planning on participating in proficiency testing in the latter part of 2023.

6. Risk Management

The manufacturer had a process in place for review and identification of risk described in the relevant procedure for Hazard Identification and Risk Assessment. The risk matrix was documented and defined. Business and production related risks had been identified.

7. Control of changes

The procedure for change control was reviewed. Risk impact assessments were to be performed prior to implementation of any changes. There had been no changes to the Prequalified product or the production processes since submission. The manufacturer was in the process of expanding the site to include new warehousing areas. The change control process for this had not started as the development was still in design.

8. Internal Audits

The relevant procedure for Internal Audits was reviewed. Internal audits were performed biannually, and an internal audit program had been implemented. Internal audit reports were reviewed. According to the procedure, the severity of the findings (critical, major, or minor) was to be recorded within the audit report. External training on the relevant standards was planned for the third quarter of 2023.

9. Control of nonconforming products

The manufacturer had in place a procedure for the control of nonconforming products. At the time of inspection there had been no non-conforming products identified. The procedure stated that upon identification of a non-conforming product, a correction, corrective action, and preventive action would be triggered. Rework would be performed if required.

The procedure stated that for nonconforming product, the head of department for production would be notified and they were responsible for destroying or returning the product.
A procedure describing deviations, including planned and unplanned deviations, was also available. It was the responsibility of the QA department to review deviations and assign the appropriate team to investigate the root cause of the deviation. No deviations had been recorded at the time of inspection.

10. Recalls
The relevant procedure for Product recall was reviewed. The procedure applied to all types of recalls voluntarily initiated by BR Agrotech Limited or by National Regulatory Authority (NRA). Recalls could be initiated in the following situations:

- In response to a complaint received, where serious product quality issue was detected, or product was found to have potentially caused adverse reactions to consumers
- defective product detected by BR Agrotech Limited
- Recall order for a regulatory authority.

Recalls were classified into two categories:

- Class I – when a product poses a life-threatening situation to users. These recalls were accorded the highest urgency and were reported to NRAs.
- Class II – When the defect or problem was unlikely to cause serious harm to users.

Recalled products were to be quarantined in a designated area. Recipients of the affected products were to be notified by means of telephone, and appropriate mass media communication may also be considered. The recall letter was to be prepared by the designated responsible person and sent to all recipients of the affected product. The final report was to be issued with a reconciliation report between the delivered and recovered quantities of the product. A mock recall was to be performed yearly to assess the effectiveness of the recall system in place.

11. Design and development of products
Not applicable. The site was not involved in design and development activities.

12. Customer satisfaction
The customer satisfaction survey for the year 2023 was in place. The customer satisfaction survey was conducted by use of questionnaires.

A five-point rate scale was used by customers to assess the manufacturer:

- Excellent - 5
- Satisfactory - 4
- Average - 3
- Needs improvement - 2
- Unsatisfactory – 1

13. Complaints
The customer complaint procedure was reviewed. The procedure described the handling of customer complaints and investigation to eliminate the cause and prevent recurrence. Complaints were classified as follows:
a) Critical: related to suspected contamination, adulteration, mislabelling, or situation that results in permanent damage, handicap, or death
b) Major: Product not meeting its predetermined critical attributes or damage to primary packaging

c) Minor: Product not meeting noncritical attributes or damage to secondary packaging or shortages

The marketing department was responsible for receipt of complaints from the market. Complaints were entered into the complaints log upon receipt. The Head QA was responsible for selection of a team to investigate the complaint, determine the root cause, propose corrections, and corrective actions to be implemented. The Head QA was responsible for reviewing and approving the investigation report. The investigation was to be completed within 30 days from receipt of the complaint. The marketing department was responsible for providing feedback to the complainant. No complaint related to Lambda cyhalothrin WP had been registered.

14. Support

Infrastructure and work environment

The infrastructure at the site was mostly well maintained.

Monitoring and measuring resources

The preventive maintenance schedule was in place. The maintenance records for the equipment on the Lambda Cyhalothrin WP line were reviewed. Calibration certificates of selected balances were also reviewed.

15. Production and service provisions

Control of Production

The manufacture of Lambda-cyhalothrin 10% WP involved mixing of the weighed raw materials in a Pre-blender, grinding, post blending in a post blender, filling, packaging, and labelling. The weighing of the raw materials was carried out on a calibrated weighing scale following an approved manufacturing formula or recipe. The powder was filled in soluble bags. The weight of each bag after filling was verified. The seal integrity of the soluble bags was checked for leakages prior to packaging of the soluble bags in LDPE liner bag. The LDPE liner bags were then packaged in a drum. Records of the weight of each drum were maintained. A sample of the mixed powder was collected from the post blender for analysis. The manufacturer also collected samples of the packaged Lambda-cyhalothrin 10% WP for finished product testing. Lambda-cyhalothrin 10% WP was under production at the time of the inspection.

The batch manufacturing records for Lambda cyhalothrin 10% WP were reviewed. The procedure for sampling in-process, finished and packaging materials was also reviewed. The sampling plan for the different materials was defined.

Quality control laboratory

The Quality Control Laboratory was well maintained and clean with appropriate equipment that was fit for purpose. The laboratory for analysis of fungicides and insecticides was separate and segregated from that for analysis of herbicides. A sample receipt register was in place. The procedure for sampling and release of raw materials was reviewed. The procedure for handling of OOS (Out-of-specifications) was also reviewed. The procedure provided for both laboratory investigation was followed by an investigation in production and review of BMR if no assignable cause was determined in the laboratory. Analytical test reports and raw data for Lambda cyhalothrin technical material and Lambda cyhalothrin 10% WP were verified. The CIPAC method was followed for the analysis of Lambda cyhalothrin. The Certificates of Analysis for

Lambda cyhalothrin technical material and Lambda cyhalothrin 10% WP were available. Standards used were stored in a refrigerator within the laboratory. The procedure for cleaning of glassware was reviewed.

Control of waste

The procedure for the control of waste was available. The site was regulated by local and national waste disposal rules and regulations. The records for waste collection were made available, including supplier agreement and collection documents between the manufacturer and the waste disposal company.

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

16. Preservation

The quantity and physical appearance of the raw materials was verified at receipt. Raw materials were received along with a Certificate of Analysis (COA). Raw materials were sampled for testing on receipt. The raw materials were sampled by QC personnel following intimation from the warehouse. The procedures for receipt, handling and storage of raw materials in the store and the procedure for receipt, handling, and storage of packaging materials were reviewed. Inventory in the warehouse was managed by the use of SAP software. The status of the materials in the warehouse was identified by use of colour codes. All the issues raised related to this section were addressed satisfactorily by the manufacturer.

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

The procedure for evaluation of suppliers was reviewed. The procedure was applicable to suppliers of packaging materials. It described the selection and evaluation of suppliers of packaging materials. The procedure for vendor development was also reviewed. The procedure was applicable to suppliers of raw materials. The evaluation of suppliers involved both onsite audits and use of questionnaires. The auditor was responsible for assessing the quality system, manufacturing process, process capabilities, delivery, and commitment to prevent quality problems. The Head QA was responsible for approving the vendors and preparing the approved vendor list. An approved vendor list was in place.

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 **BR Agrotech Limited** located at **620/3, GIDC Estate, Panoli Industrial Area Bharuch, Gujarat 394115, 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.

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/