

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

Part 1	General information
Manufacturers details	
Name of manufacturer	Shree Dutt Agrochem
Corporate address of manufacturer	Shed No: A2/625, Hikal Road, G.I.D.C Panoli-394 116 Gujarat, India
Inspected site	
Name & address of inspected manufacturing site(s)	1. Shree Dutt Agrochem (Unit 2) Shed No: A2/625, Hikal Road, G.I.D.C Panoli-394 116 Gujarat, India. 2. Gujarat Agrochem Limited; Plot No. 2901 – 2906, GIDC, Panoli, Ankleshwar, District Bharuch, Gujarat India. (Laboratory).
Unit/Block/Workshop	Not applicable.
Inspection details	
Dates of inspection	15-16 February 2019
Type of inspection	Initial inspection. The criteria for the inspection was based on the ISO 9001:2015 standard.
Introduction	
Brief description of the manufacturing activities	<u>Shree Dutt Agrochem; Shed No: A2/625, Hikal Road, G.I.D.C Panoli-394 116, Gujarat, India</u> The activities related to manufacture of wettable powders included warehousing (storage) of raw materials and finished products, blending, packaging and labelling. <u>Gujarat Agrochem Limited; Plot No. 2901 – 2906, GIDC, Panoli, Ankleshwar, District Bharuch, Gujarat India</u> The activities carried at this site included manufacture of a range of active ingredients such as Alphacypermethrin, Permethrin etc. and laboratory testing.
General information about	Shree Dutt Agrochem manufacturers a wide range of wettable powders since 2015. The facility had two separate manufacturing

the company and site	blocks. One of the blocks was dedicated to the manufacture of Tagros products. . Gujarat Agrochem Limited is located about 2 Km from Shree Dutt Agrochem. In-process testing and finished product testing were performed at this laboratory. Gujarat Agrochem Limited was purchased by Tagros, India 12 months earlier and was in the process of changing name. WHO PQ would be informed of the change of name once the process is completed. Shree Dutt Agrochem was licensed to manufacture insecticides by the Directorate of Agriculture, Gandhi Nagar Gujarat under license number 799 and by the Directorate of Industrial safety and health Gujarat India under license number 22946. Shree Dutt Agrochem did not hold an ISO 9001:2015 certification at the time of inspection but were planning on obtaining the certification later in 2019
History	This was the first WHO audit 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 • Data integrity • Product release • Batch processing records • Laboratory test reports • Control of changes • Internal audits • Calibration and equipment maintenance Physical areas: • Quality control laboratory • Raw material and finished goods • Production areas
Exclusions and Non-applications of requirements in the QMS	Design and development were excluded from applications of the ISO 9001: 2015 standard.

Out of scope	Manufacture and testing of products not submitted to WHO for prequalification. The inspection was limited to the scope of WHO products indicated in the section below. The manufacturing activities at Gujarat Agrochem Limited were not included in the scope of this inspection. Only activities performed by the laboratory located on site were inspected.
Restrictions	None
WHO products covered by the inspection	Rubi 50 WP (Alphacypermethrin 5%) 004-001 Rubi 100 WP (Alphacypermethrin 10%) 004-002 Revival 100 WP (Lambda Cyhalothrin 10%) 004-010
Abbreviations	Meaning
CoA	Certificate of analysis
GC	Gas chromatography
PPE	Personal Protective Equipment
WP	Wettable powders

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

An organogram for Shree Dutt Agrochem was available along with the company's objectives and policy. The job descriptions for all employees were reviewed and found that it accurately reflected the roles performed by staff.

2. Quality policy and quality objectives

The facility had a documented quality policy and objectives which was appropriate to its purpose. The policy and objectives had only been developed 4 months prior to the WHO inspection and therefore evidence of implementation of measurable parameters related to the quality objectives were not available. Staff had been trained on the policy and objectives and a copy in English was available in the production area. The policy would also be availed to staff in the local language.

3. Management review

Management review minutes for the month of January 2019 were available. Review of data related to the manufacture of products at Shree Dutt Agrochem was performed by Tagros. No issues by the time of the inspection had yet been identified from the review of process performance, conformity of products and internal audits.

4. Control of documented information

Procedures and other documents such as the batch manufacturing records were all supplied and controlled by Tagros. Tagros would email the new version and would also provide a hard copy. A representative from Tagros would collect obsolete versions and return it to Tagros, Cuddalore. This process to be verified at the next inspection of the Cuddalore site.

5. Personnel competence and training

Training records for staff members at the Shree Dutt site were available.

Staff were trained in the following areas by Tagros

- Importance of PPE and how to use PPE
- Manufacturing WP BMR Writing
- How to handle WP

Staff training conducted by Shree Dutt

- Use of PPE
- Production of wettable powders

6. Risks and opportunities

Determination of risks and opportunities relating to the manufacture of Tagros products on site will be performed by Tagros.

7. Control of changes

According to the Job Work Agreement between Tagros and Shree Dutt Agrochem any changes to the manufacturing processes were to be communicated to Tagros. The impact of the change would then be assessed by Tagros and any further actions determined from the impact assessment undertaken accordingly.

8. Internal Audits

Internal audits of the manufacturing site were performed by Tagros.

Three internal audit reports performed by Tagros were reviewed.

- 12/01/2018 – Initial audit to assess suitability for contract work
- 12/09/2018 – 6 monthly audits of critical suppliers according to the Tagros procedure
- 03/12/2018 – Unannounced audit conducted according to Tagros procedure.

All three audits were performed by representatives from Tagros for one day. The audits were conducted using a checklist. Areas covered included licenses, infrastructure, health and safety, staffing levels and warehousing among others. There were no findings from the audits conducted. Reference to the audits was available in the Management Review minutes for the month of January 2019.

9. Control of non-conforming products

In-process and final release testing was performed at the contract laboratory i.e. Gujarat Agrochem Limited. In-process tests were performed on the post-blend and the packaging would only commence after approval by QC. In case the blend did not comply with specification, it would be reprocessed. The reprocessing would be performed with the oversight of the Tagros R&D department.

10. Performance evaluation

The facility did not conduct data analysis and evaluation. Batch manufacturing records were forwarded to Tagros who compiled and analyzed the product data.

Performance evaluation and analysis of the in-process parameters and active ingredient content for batches manufactured in 2018 was reviewed. 3 batches of Rubi 50 WP (Alphacypermethrin 5%) and 3 batches of Revival 100 WP (Lambda Cyhalothrin 10%) had been manufactured in 2018. The results indicated that the processes were within control.

11. Complaint handling

Complaints on products manufactured by Shree Dutt Agrochem were received and handled by Tagros. No complaints had been received by the time of the inspection.

12. Design and development of products

Design and development were excluded from applications and requirements of the ISO 9001: 2015 standard.

13. Support

Infrastructure and work environment

The facility had two separate manufacturing blocks. One of the blocks was exclusively dedicated to the manufacture of Tagros products. The manufacturing environment was well planned, maintained, and appeared clean and tidy. All staff observed were wearing PPE including safety glasses, gloves, face mask and protective apron.

Monitoring and measuring resources

A maintenance schedule was available. Most of the internal maintenance was performed by staff at Shree Dutt Agrochem with external calibration being performed on the balances and the pressure gauge.

The following equipment maintenance and calibration records were reviewed:

- Pre-blender
- Pressure Gauge
- Balances

14. Production and service provisions

Control of Production

A block was dedicated to the manufacture of Tagros products. The manufacture of wettable powders involved blending in a pre-blender, micronization using an air jet mill, blending of the micronized powder, labelling and packaging. The blended mass was fed into the air jet mill at a predetermined flow rate. The flow rate was monitored. The powder from the post-blender was sampled for analysis. The production line was equipped with a dust collector, dehumidifier and air compressor. The filter bags used in the blender were dedicated and labelled. At the time of the audit manufacturing was ongoing.

Batch production records for Rubi 50 WP (Alpha-Cypermethrin 5%) and Revival 100 WP (Lambda Cyhalothrin 10%) were reviewed.

Cleaning was performed in accordance with the relevant procedure. The cleaning was performed using china clay. Cleaning records were reviewed.

Testing of in-process samples and product testing were performed at Gujarat Agrochem Limited. Procedures for the testing of in-process samples and final release testing were available. An inward sample register was available. In-process checks included foam test wettability, pH, sieve test and appearance. Analysis of the active ingredient content was performed on the final product. Analytical testing procedures and reports were in place. The CIPAC method was used for the analysis of the active ingredient content. Access to the GC software was by use of unique passwords for the different users. The date and time on computers for the GC were locked. Chromatograms were available.

All matters raised in relation to this section were satisfactorily addressed.

Validation

The concurrent validation report for the manufacture of Deltamethrin WP 5% was reviewed. Deltamethrin WP 5% was selected as representative product for the manufacture of wettable powders since the manufacturing conditions, equipment, operating parameters were the same as those for Alphacypermethrin WP and Lambda Cyhalothrin WP. Three validation batches were used for validation of the process. The optimum flow rate of the blend into the jet mill was determined. The results of the in-process test for pH, wet sieve, persistent foam after 1 minute, wettability, flow test and active ingredient content complied with the specifications. All matters raised in relation to this section were satisfactorily addressed.

Identification and traceability

Material were identified, and status indicated. All matters raised in relation to this section were satisfactorily addressed.

Release of products and services

As stated in the contract between Tagros and Shree Dutt Agrochem product release was performed by Tagros. Upon review of the laboratory testing report and production records; products were released by the Quality Management representative and the Executive Quality Control officer from Tagros.

15. Preservation

Storage of raw material was on the ground floor of the block used for the manufacture of Tagros products. Finished products were stored in a separate warehouse. All the raw materials were approved and supplied by Tagros along with a CoA. The agreement between the Shree Dutt Agrochem and the contract giver, Tagros, required that all quality control test be performed on the raw materials prior to being delivered to Shree Dutt Agrochem. The raw materials and finished products were stored at ambient temperatures. Inventory records were available.

16. Post-delivery Activities

Stability studies had been performed on three Deltamethrin validation batches. The studies were conducted at 54±2°C for two weeks. The test results of analysis for deltamethrin content, suspensibility, pH, wet sieve test, persistent foam etc. complied with specifications. All matters raised in relation to this section were satisfactorily addressed.

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 **Shree Dutt Agrochem (Unit 2)** located at **Shed No: A2/625, Hikal Road, G.I.D.C Panoli-394 116 Gujarat, 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
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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, GHTE/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/>