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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	Fujian Jiahe Textile Co., Ltd
Applicant/ Corporate address of manufacturer	Fujian Yamei Industry & Trade Co. Ltd No 83, 5th Floor, Hongxing Business Building, No.56 Changle South Road, Taijiang District, Fuzhou, Fujian China.
Inspected site	
Name & address of inspected manufacturing site(s)	No. 288, Meiban Village, Baizhong Town, Minqing County, Fuzhou City, Fujian, China
Unit/Block/ Workshop	Not applicable
Inspection details	
Dates of inspection	22 – 23 May 2025
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	The site manufactured both Yahe LN and Yahe 4.0. The site also manufactured other products such as mosquito tents, military nets, window screen nets. The activities related to the manufacture of Yahe LN included formulation, treatment (coating), release testing, cutting, sewing labelling, packaging, and storage. The activities related to the manufacture of Yahe 4.0 included release testing, cutting, sewing labelling, packaging, and storage. This product is not prequalified by WHO.

General information about the company and site	The site was established in 2024. This was the first WHO inspection of the site. The manufacturer held the following ISO certificates: **a) ISO 9001: 2015: Quality Management System** Certificate number: 11424Q45950RIS Scope: ‘‘Production and related management activities of Textiles (long-lasting insecticide treated mosquito net)’’. Issue date: 06 November 2024 Expiry Date: 05 November 2027 The certificate was issued by Beijing East All reach Certification Centre Co. Ltd. **b) ISO 45001:2018: Occupational Health and Safety Management System** Certificate number: 11424S25850RIS Scope: ‘‘Production and related management activities of Textiles (long-lasting insecticide treated mosquito net)’’. Issue date: 06 November 2024 Expiry Date: 05 November 2027 The certificate was issued by Beijing East All reach Certification Centre Co. Ltd. **c) ISO 14001:2015 Environmental Management System** Certificate number: 11424E45980RIS Scope: ‘‘Production and related management activities of Textiles (long-lasting insecticide treated mosquito net)’’. Issue date: 06 November 2024 Expiry Date: 05 November 2027 The certificate was issued by Beijing East All reach Certification Centre Co. 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	None
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	• Yahe 4.0 (6.5 g/kg Alpha-cypermethrin, 2.2 g/kg Piperonyl Butoxide) - P-04983 – (Product not WHO prequalified). • Yahe LN (Deltamethrin - 1.4 g/kg) - 015-001
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. Management Review

Management reviews meetings were carried out in accordance with an established procedure and were to be held bi-annually. Recent management review minutes were reviewed. The areas planned to be covered within the management review meetings were documented in both the procedure and in the Quality Manual. A management review plan was available. All quality objectives were recorded as being met. The manufacturer had not received any complaints during the review period. An attendance sheet was available with members from all departments being present. It was verified via the meeting minutes that the quality policy and objectives had been discussed with no changes.

A detailed presentation was provided by each department, and a copy was available with the minutes. There was minimal data analysis or trending available. It was noted that the WHO product had only had one batch manufactured so data was limited.

2. Leadership, responsibilities, and authorities

The quality policy had been endorsed and approved by top management. Top management were committed to ensuring that an effective quality management system was implemented through internal audits and management reviews. Roles and responsibilities of the management representative were defined in the quality manual.

3. Quality policy and Quality objectives

The manufacturer had an integrated policy and objectives in place that had been signed and dated. Targets had been set for each of the objectives. The extent to which the objectives were achieved was monitored in the management review meetings.

4. Document control

The manufacturer had in place a procedure for the control of documents. The management representative was responsible for the release of manuals, procedures, system instructions and records. There was a process for the control of documents where a “controlled” or “uncontrolled” seal would be applied. The procedure stated that the document manager was responsible for providing the document distribution number. There was a process for the control of obsolete documents. The manufacturer had an established process for the control of external documents. A list of documents of external origin was available.

5. Personnel competence and training

The manufacturer had an established procedure for the training of staff with records available. The job descriptions for the following staff members were reviewed:

- Job description for QA
- Job description for QC supervisor
- Job description for testing room staff

An annual training plan was in place. 18 training sessions had been planned for the year 2025. The training records of the laboratory staff were reviewed.

6. Risk Management

The risk, opportunity, and management procedure was reviewed. The procedure applied to the identification and evaluation of internal and external environmental factors, products and services covered by the company's quality and environmental management system, and implementation of actions to risks and opportunities. Risks were categorized into quality risks, environmental risks, business risks, market risks, financial risks, and operational risks. The procedure described the criteria for risk assessment. A risk and opportunity identification and assessment form was in place. The manufacturer also performed an evaluation of the effectiveness of risk and opportunity control measures.

7. Internal Audits

The procedure for internal audits was reviewed. The procedure applied to the three ISO standards (ISO 9001:2016, ISO 24001:2016 and ISO 4500:2020). The management representative was responsible for the internal audit plan, team selection and scheduling. The procedure described that the internal auditors were not to audit their own areas of work. It was noted that all areas were audited against the three standards. The procedure provided for corrective actions and compliance evaluation.

8. Control of Changes

The procedure for change control was reviewed. The purpose of the procedure was to control changes in documents, facilities, equipment, material suppliers and packaging materials. Changes were reviewed by the QA Manager. A change control form was in place. The change control process provided for impact assessment of the change. No changes had been registered yet as this was a recently commissioned site.

9. Recalls

Not reviewed due to time constraints.

10. Complaint Handling

The procedure for complaint handling was reviewed. The purpose of the procedure was to ensure that complaints were handled promptly and effectively, improve customer satisfaction, maintain the company's reputation and brand image, and comply with ISO management system requirements. The salesperson was responsible for receiving complaints and notifying the quality department and General Manager of the complaints in a timely manner. The quality department was responsible for preliminary investigation and analysis of complaints. The quality department was also responsible for documenting all the information related to the complaint. The General Manager was responsible for approving the complaint handling plan. Complaints were to be handled within 15 days following approval of the complaint handling plan. The complaint handling form was in place. The procedure provided for investigations, root cause analysis, corrections, and corrective actions. The quality department was responsible for verifying the implementation of the corrections and corrective actions. The salesperson was responsible for providing progress on the complaint investigation to the complainant. It was claimed that the facility had not received any complaints by the time of the inspection.

11. Design and development of products

This site was not involved in design and development activities. This area was therefore not inspected.

12. Support

Infrastructure and work environment

The site comprised of 3 buildings. The activities carried in the buildings were as follows: Building 1 – Cutting and sewing
Building 2 – Coating and Packing
Building 3 – Warehouse
The infrastructure at the site was mostly well maintained and clean. There was evidence of regular cleaning of the warehouse and production area. All staff observed were wearing appropriate PPE.

Monitoring and measuring resources

The maintenance records/plan was reviewed. The maintenance records/plan included records and plans for all equipment including mixers, balances, air compressor, baling machines etc. The calibration certificates of selected balances were reviewed.

13. Production and service provisions

Control of Production

The manufacture of Yahe LN involved cutting of the fabric according to specifications of the customers, sewing, labelling, preparation of the coating solution, coating, packaging, and storage. The recipe (formula) for preparation of the coating solution was in place. The different ingredient were weight on calibrated balances. The mixing tank was also equipped with a dipstick. The amount of water used for preparation on the coating solution was weight on a balance and verified using a dipstick. Instructions for the coating process were reviewed. The mixing time was monitored. Preparation of the coating solution was followed by coating of the sewed nets. At the time of the inspection Yahe LN was being manufactured. The pressure of the rollers and the temperatures of the different zones of the stenter were monitored and documented on the coating process daily temperature and pressure record.

The manufacture of Yahe 4.0 involved cutting, sewing labelling, packaging, and storage. The fabric used for the manufacture of Yahe 4.0 was received with the active ingredients already incorporated. The incorporation was carried out at Fujian Defu New Materials Technology Co. Ltd located at No.18 Lianguan Avenue, Lianfeng Town, Liancheng County, Fujian 366200, China.

The cutting of fabric was witnessed. The relevant procedure for this process was available. The procedure defined the length of the side panels to be cut.

The manufacturer outsourced the printing of labels, and these were stored in a smaller warehouse in the sewing area. A 100% visual check for stains or holes was performed for all the sewed nets.

Quality Control Laboratory

The Quality Control Laboratory was mostly well maintained and clean with appropriate equipment that was fit for purpose. The laboratory was temperature controlled. A sample register was available. Sample labelling and the sampling procedures were inspected.

The primary reference material for Deltamethrin was stored in a refrigerator. A certificate of analysis was in place. Calculations for active ingredient content (as part of the HPLC test method) were performed using an excel sheet, that was locked. The QC Supervisor reviewed all calculations. The date and time on the computers used for HPLC were locked.

Glassware was washed in the hand sink. There was a procedure for cleaning of glassware.

Control of Waste

The procedure for waste was checked. Wastewater was collected by a third party. The waste fabric was also used for making loops.

14. Preservation

Bulk raw materials were stored in the incoming raw material warehouse. The fabric was received in bulk. The manufacturer received both the treated fabric and greige fabric. A MSDS was available in the bulk chemical warehouse,

15. Retention samples

The samples that were retained in the QC laboratory. A procedure for retention of samples was in place. The procedure stated that samples were retained for 3 years.

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

The supplier agreements between Fujian Jiahe Textile Co. Ltd and other suppliers were reviewed. The responsibilities of each party were defined.

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 **Fujian Jiahe Textile Co., Ltd** located at **No. 288, Meiban Village, Baizhong Town, Minqing County, Fuzhou City, Fujian, China** 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/