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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 Yamei Industry & Trade Co. Ltd
Corporate address of manufacturer	Building #2-#3, No. 116 Xikou Industrial area, Zhuxi village, Zhuqi country, Minhou District Fuzhou City Fujian Province China.
Inspected site	
Name & address of inspected manufacturing site(s)	As above.
Inspection details	
Dates of inspection	17 May 2019
Type of inspection	Follow up inspection. The criteria for the inspection was based on the ISO 9001:2015 standard.
Introduction	
Brief description of the manufacturing activities	The facility manufactures several brands of long-lasting insecticide treated nets (LLIN) impregnated with *Deltamethrin*. The activities related to manufacture of the Yahe® LLIN included warehousing (storage) of raw materials and finished products, processing of fabric (coating), cutting, sewing and stitching, labeling, packaging and quality control testing.
General information about the company and site	Fujian Yamei Industry & trading Co. Ltd was ISO 9001 certified. ISO certificate number 04318Q32857R1S01, Issued 30th October 2018 Expiry date 29th October 2021. Scope of certification: Production of knitting textile (mosquito net for insect prevention), Sale of tents. Certificate issued by Beijing United Intelligence Certification Co. Ltd.

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 not applicable. Design and development were not conducted at this site
Out of scope	Manufacture and testing of products not submitted to WHO for prequalification. The inspection was limited to the scope of products indicated in the section below (See WHO products covered by the inspection).
Restrictions	None
WHO products covered by the inspection	Yahe® (Deltamethrin 55mg/m^2 ±25%) 015-001
Abbreviations	**Meaning**
CoA	Certificate of Analysis
PPE	Personal Protective Equipment
LLIN	Long Lasting Insecticide treated Nets
GSM	Grams per Square Meter

Part 2	Brief summary of the findings and comments

1. Organizational roles, responsibilities and authorities

The roles and responsibilities of the Quality Control in-charge, Quality Assurance Manager and departments were described in the quality manual. Quality Control in-charge and Quality Assurance Manager were responsible for product release. An organizational chart indicating the reporting lines was in place. Job descriptions were also available.

2. Quality policy and quality objectives

The facility had a documented quality policy and quality objectives in place. These were reviewed and considered adequate to the purpose and context of the organization. The quality policy also included commitment to continual improvement of the quality management system. The policy was communicated within the organization by posters, induction training and publication on the website.

3. Management review

An established procedure for management review was in place. Management reviews were held once a year. Management review minutes of the meeting held on 20th July 2018 were reviewed. Quality objectives and departmental performance reports were also reviewed. Management review was performed in accordance with the established procedure and met the requirements of the standard.

4. Leadership

Leadership commitment with respect to the quality management system were demonstrated by establishing quality policy and quality objectives, promoting improvement and supporting management roles in their areas of responsibility. Leadership commitment was described in the quality manual.

5. Control of documented information

The procedure for control of documents was described in the Quality Manual. Documented information included the quality manual, procedures, work instructions, records etc. SOPs were readily available for reference. Documents were identified. Documents were issued, retrieved and approved in accordance with the established procedure. Documents were approved by the General Manager. Documents were maintained in both electronic and hard copy formats. A document distribution list was available.

6. Personnel competence and training

The relevant procedure was reviewed. The training plan for the year 2018 was reviewed. This detailed the internal and external trainings for the year 2018. Training records and lists of attendees were presented and reviewed. Trainings were evaluated to determine the effectiveness of the trainings.

7. Risks and opportunities

The procedure for risk management was in place. A risk register was in place. There procedure described the risk register and its creation. The risk register provided details of the risks and mitigation measures. A SWOT analysis had also been performed.

8. Control of changes

The relevant procedure was reviewed. Changes were reviewed by the Management Representative and approved by the General Manger. Changes requests were made using a change request form. A change related to the fabric record template was reviewed. The reviewed changes were handled in accordance with the procedure.

9. Internal Audits

The facility had an established procedure on internal audits. The internal audit report, corresponding nonconformance report and attendance sheets for opening and closing meetings for the audit conducted in 2018 were in place. The audit plan was in place. Areas to be audited, audit team members among others were indicated. A check list was used for audits.

10. Control of non-conforming products

The relevant procedure for control of nonconforming products was reviewed. Defective bed nets were identified and controlled. The manufacturer had documented criteria for assessment of nonconformities such as holes, tears, etc. Repairable defects such as holes were repaired by stitching. The repaired bed nets were inspected again to ensure that they conform to the specified requirements. All nonconformities were documented. The manufacturer also had in place instructions for handling of nonconforming results in the laboratory. The instructions allowed for investigations to be conducted in the laboratory and production area. A detailed flow diagram was in place. This was found satisfactory.

11. Performance evaluation

The relevant procedure for product monitoring and measurement was reviewed. Data arising from the monitoring and measurement processes such as cutting, sewing was analysed and evaluated. The performance evaluation reports were reviewed. The performance evaluation reports indicated that the processes were within control.

12. Complaint handling

The manufacturer had an established procedure for handling of complaints and conducting customer surveys. The procedure provided for investigations, root cause analysis and corrective action. No complaint had been registered by the manufacturer. Customer surveys were conducted every year. The customer satisfaction survey report for the survey conducted in 2018 was reviewed. From to the customer survey report it was indicated that the customers were satisfied with the performance and products of the manufacturer. The manufacturer also had an established procedure for recalls. In case there was need for a recall; a recall team would be constituted, and notification sent to relevant agencies or institutions. The report for the dummy recall conducted by the manufacturer was available.

13. Design and development of products

Design and development were not applicable. Design and development were not conducted at this site

14. Support

Infrastructure and work environment

The environment was generally clean. The staff in the production and quality control laboratory were found wearing adequate PPE. MSDSs were available in the warehouse. The waste water was collected and sent to Nanjin Red Sun Ltd, China for treatment. All the issues raised in relation to this section were satisfactorily addressed.

Monitoring and measuring resources

The calibration and preventive maintenance schedules for the year 2018 were in place. The calibration report for the HPLC was reviewed and found satisfactory.

15. Production and service provisions

Control of Production

The manufacture of Yahe LN involved inspection fabric, chemical treatment (coating), stentering, cutting, sewing, stitching, labelling, packaging and baling. The temperatures of the drying chambers were monitored and controlled. Temperature zones on the extruders were identified. The in-process test included GSM, mesh size. At the time of inspection, the manufacture of Yahe LN bed nets was ongoing. Cutting of the fabric was done manually. A calibrated tape measure was used to cut the fabric. Production records were maintained. The sewed bed nets were inspected for holes, defects and extraneous material. Labelling, packaging and baling were done according to customer specifications. Completed batch production records for Yahe LLIN bed nets were reviewed.

The laboratory equipment was uniquely identified and calibrated. Laboratory test records for analysis of Deltamethrin content were reviewed. Raw data was maintained. The date and time on the HPLC computer were locked. Laboratory data controls to prevent deletion of data were in place. Laboratory data was backed up at the end of every work day. Prepared solutions were adequately labelled. Retention samples were kept under ambient conditions and records maintained. The retention samples were adequately stored, away from direct sunlight. All the issues raised in relation to this section were satisfactorily addressed.

Identification and traceability

Material were identified, and status indicated. Records were maintained to enable traceability.

Release of products and services

Quality Control in-charge and Quality Assurance Manager were responsible for product release. Products were released following review of the QC and production records.

16. Preservation

Raw materials and finished products were stored at ambient conditions. The containers of the raw materials were adequately labelled, and status indicated. Inventory records for the fabric were reviewed. The fabric was sampled, inspected on receipt and fabric inspection records maintained. The chemical raw materials were supplied with the Certificate of analysis, packing list among others from the supplier. The raw materials were sampled following established sampling criteria. All the issues raised in relation to this section were satisfactorily addressed.

17. Post-delivery Activities

Stability study report performed in 2015 was presented for review. The stability study was performed by a third party. The stability batches were subjected to temperatures of 40±2ºC for 8 weeks. The results of analysis were reviewed and found to comply with specifications.

18. Control of externally provided processes and products

A procedure for selection and review of vendors was in place. There was established criteria for selection of vendors. The supplier evaluation reports were reviewed. Samples of products are also tested, and the result used in support of the overall supplier selection process. The annual performance of suppliers was assessed based on a number of parameters such as delivery, quality. Suppliers were categorized into four categories. Suppliers in the lowest category would be eliminated from the approved suppliers list.

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 ***Fujian Yamei Industry & Trade Co. Ltd*** located at ***Building #2-#3, No. 116 Xikou Industrial area, Zhuxi village, Zhuqi country, Minhou District Fuzhou City Fujian Province 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. 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/