

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

Part 1	General information
Manufacturers details	
Name of manufacturer	Bazhou Jintong Textile Processing Factory
Corporate address of manufacturer	Shiyou South Road, Kuoda Village, Nanmeng Township, Bazhou City, Hebei Province, China.
Inspected site	
Name & address of inspected manufacturing site(s)	As above.
Unit/Block/Workshop	Not applicable.
Inspection details	
Dates of inspection	09 May 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	Bazhou Jintong only manufactures Yorkool Long lasting insecticide nets (LLINs). No other brands of insecticide treated nets or products were manufactured at the site. Activities related to manufacture of LLIN included warehousing (storage) of raw materials and finished products, cutting and sewing of the fabric, quality control testing, labelling and packaging.
General information about the company and site	Bazhou Jintong Textile processing factory was established in 2013. The facility is a contract manufacturer (since 2016) for Tianjin Yorkool International Trading Co., Ltd, Lixian County Sangyuan Industrial Zone Baoding City Hebei Province, China. Bazhou Jintong Textile Processing Factory, Nanmeng Township, Langfang city, Hebei province, China, was ISO 9001 certified. ISO 9001:2015 certificate number 30717Q20275R0M. Date of re-issue 6th August 2018, Expiry date 25th July 2020. Issued by BAC. Scope: Bed net processing and sale services.

	The quality management system (leadership structure, role and responsibilities, policies, procedures etc) at Bazhou Jintong Textile processing factory was similar to that at Tianjin Yorkool International Trading Co., Ltd and Gaotang Xingyuan Textile Factory
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 products indicated in the section below (WHO products covered by the inspection).
Restrictions	None
WHO products covered by the inspection	Yorkool LN (Deltamethrin 55mg/m ²) Product number: 021-001

Abbreviations	Meaning
CoA	Certificate of analysis
KPI	Key Performance Indicators
PPE	Personal Protective Equipment
QMS	Quality Management System
LLIN	Long Lasting Insecticide treated Nets

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

The job descriptions of the General Manager, Management Representative and Heads of the quality and production department were reviewed. A detailed organogram defining the organizational structure of the company was in place. The Quality department and production department were independent of each other with separate reporting lines to the Management Representative. A process map was also well-defined in the Quality Manual.

2. Quality policy and quality objectives

The quality policy included commitments to satisfy applicable requirements and continual improvement. This had been defined in the Quality Manual. The policy was displayed throughout the premises. It was communicated to staff through trainings. The quality objectives were consistent with the quality policy. KPIs were measurable.

3. Management review

The procedure for management review was reviewed. Management review meetings were held once annually, usually at the end of the year or at the beginning of the year and after an internal audit. The requirements for management review were adequately documented and implemented. The last management review minutes held on 3rd July 2018 to discuss and manage the transition to ISO 9001:2015 were reviewed. Review of the minutes demonstrated compliance with the requirements for management review. The manufacturer monitored and measured the ability of the quality management system processes to meet planned results including a review of the Quality Objectives and Policy.

4. Leadership

The quality policy and quality objectives had been approved by Top management and were signed by the General Manager. Processes were mapped. The General Manager was responsible for ensuring that resources needed for the quality Management system were available. Resources necessary for implementation of the QMS were determined and provided. The importance of implementing an effective quality management system was communicated during QA trainings. A management representative had been nominated and was responsible for establishment, implementation, maintenance and improvement of quality management system according to the requirements of ISO9001:2015. The manufacturer monitored and measured the ability of the quality management system to meet planned results at the Management Reviews. Top management engaged, directed and supported personnel in fulfilling their responsibilities and roles.

5. Control of documented information

Procedure for document control was in place. The categories of documents included; the quality management manual, procedures, operation documents, management documents, records and external documents. Documents were available in both as electronic and hard copy. The General manager was responsible for approval of documents. The procedures described how documents were to be prepared and identified. Documents were distributed by the quality department. Documents were reviewed every year. The document distribution list was in place. Documents were retained for 4 years. The shelf life of Yorkool LN is 2 years.

6. Personnel competence and training

The relevant procedure was reviewed. Training records related to quality were reviewed. The topics covered during the training were documented. The effectiveness of the training was evaluated by means of an oral test. The pass mark had been determined. A record of the test results was retained. The training was deemed satisfactory.

7. Risks and opportunities

The relevant procedure for Control of Risks and Opportunities was reviewed. The procedure described how risk assessment, evaluation, control and mitigation were to be conducted. Risks were categorized as Quality risks, Environmental risks, Business risks, Market and financial risks. The procedure described the actions to be taken for each risk category. A detailed risk register was in place. All risks were scored according to the procedure and allocated as Low, Medium or High category. Mitigation was provided and target dates for review allocated.

8. Control of changes

A procedure for control of changes was in place. Changes were categorized into management changes, equipment and production process changes, document changes, regulatory changes and raw material supplier changes. Change application form was in place. The procedure provided for impact assessment of change prior to approval and implementation. Changes were reviewed by the relevant department and approved by the management representative. No change had been registered.

9. Internal Audits

The procedure for internal audits was reviewed. Internal audits were conducted at least once a year. The manufacturer implemented an internal audit program and schedule. Internal audit report for 2018 was reviewed. The internal audit records were consistent with the procedure. Corrective actions and follow up had been completed.

10. Control of non-conforming products

The procedure for control of nonconforming products was in place. Defects were categorized as critical, major or minor based on the impact on the quality of the product. The procedure allowed for rework of repairable defects. If the defect was unrepairable the products would then be rejected. No products had been rejected by the time of the audit. The manufacturer had a number of measures in place for quality control and detection of nonconforming products. These included in quality control tests such as height, width, length and visual inspection of sewn bed nets and received fabric. All the received fabric was inspected. Bed nets were sampled and visually inspected for defects. Inspection records were maintained.

11. Performance evaluation

The procedure for data analysis control was reviewed. The procedure described the data to be collected and analyzed by each of the three departments i.e. the quality control department, supplier and sales department and production departments. Evaluation reports were reviewed. All the issues raised related to this section were addressed satisfactorily by the manufacturer.

12. Complaint handling

The procedure for customer satisfaction was reviewed. The procedure required that customer surveys be conducted every quarter. Customer feedback including complaints were to be used to improve the quality management system. Feedback included product quality, delivery, product packing, and service delivery. Complaints were to be investigated. Complaints were managed by the management representative. The customer survey reports for the year 2018 were reviewed and indicated that the customer was satisfied with the performance of Bazhou Jingtong. No complaint had been received. Bazhou Jingtong had only one customer i.e. Tianjin Yorkool.

13. Design and development of products

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

14. Support

Infrastructure and work environment

The infrastructure was well maintained. The manufacturing environments were well planned, maintained satisfactorily and appeared clean and tidy. The work environment was found adequate with personnel wearing suitable PPE. The infrastructure was considered suitable for the activities undertaken.

Monitoring and measuring resources

The maintenance schedule for 2019 and 2018 were in place. Maintenance records for the sewing machines were reviewed. Calibration certificates for the balance and the 5-meter tapes measure were reviewed.

15. Production and service provisions

Control of Production

All the impregnated fabric received from Tianjin Yorkool was inspected for defects such as stains, holes, tears etc at receipt. Inspection records were maintained. The inspected fabric was then sewed, labelled and packaged. The sewn bed nets were sampled and inspected. Only physical tests were performed on site by the quality control department. Quality control tests performed included weight, height, width, length and visual inspection for defects such as presence of stains, holes, tears etc. The equipment was identified. Quality control test reports (physical) for Yorkool LN were reviewed. The sewed bed net inspection records indicated the number and type of defects identified. Bed nets with defects were repaired and inspected again prior to approval for packaging. Labels were adequately controlled. Label artwork and information was approved by Tianjin Yorkool prior to printing. The printing of label was subcontracted. Production batch records were reviewed.

The wastes from production were collected by another company, Tai Cang San Feng chemical Fiber Ltd, China The waste was used to produce other products.

Identification and traceability

Material were identified, and status indicated.

Release of products and services

Following review of the production and quality control records the bed nets were released to Tianjin Yorkool by the Quality Control Chief.

The finished bed nets were then sampled and tested by Tianjin Yorkool prior to release to the market.

16. Preservation

There were separate ware houses for the finished products and raw materials. Raw material receipt and issuance records were reviewed. The status of the raw materials was indicated. No raw materials had been rejected. Finished goods and raw materials were stored at ambient temperatures. The impregnated fabric was supplied by Tianjin Yorkool following chemical analysis and approval by Tianjin Yorkool, Baoding City, Hebei, China.

17. Post-delivery Activities

Stability studies were conducted by the contract giver, Tianjin Yorkool International Trading Co, Ltd. Stability studies were not conducted at this facility. Retention samples were retained by Tianjin Yorkool.

18. Control of externally provided processes, products and services

The relevant procedure and supplier assessment check were available. The Supplier assessment checklist covered the following areas; Quality management system, raw material management, production management, equipment, instrument management, product inspection, storage management and change.

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 ***Bazhou Jintong Textile Processing Factory*** located at ***Shiyou South Road, Kuoda Village, Nanmeng Township, Bazhou City, Hebei 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
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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, GHTEF/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/>