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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	Shobikaa Impex Private Limited
Corporate address of manufacturer	SF No. 558,559 – Athur SIDCO Industrial Estate, Vennaimalai (po), Karur-639 006 Tamil Nadu, India
Inspected site	
Name & address of inspected manufacturing site(s)	1. Shobikaa Impex Private Limited: SF No. 558,559 – Athur SIDCO Industrial Estate, Vennaimalai (po), Karur-639 006 Tamil Nadu, India. 2. Shobikaa Impex Private Limited: SF No.37A/1, B & C, D, E Coimbatore Road, Thannerpandhal, Karur Tamil Nadu India.
Unit/Block/ Workshop	Not applicable.
Inspection details	
Dates of inspection	11 - 13 February 2019
Type of inspection	Initial inspection. The inspection was based on the standards as per ISO 9001:2015.
Introduction	
Brief description of the manufacturing activities	Shobikaa Impex Private Limited: SF No. 558,559 – Athur SIDCO Industrial Estate, Vennaimalai (po), Karur-639 006 Tamil Nadu, India. The activities related to manufacture of the LLIN included warehousing (storage) of raw materials and finished products, production of the master batch and fabric, quality control testing, packaging and labelling. Shobikaa Impex Private Limited: SF No.37A/1, B & C, D, E Coimbatore Road, Thannerpandhal, Karur Tamil Nadu India The fabric from Vennaimalai was transported to Thannerpandhal for further processing which involved cutting, sewing and stitching, labeling and baling. The packaged finished bed nets were transported back to the warehouse in Vennaimalai for storage and distribution.

General information about the company and site	Shobikaa Impex Private Limited started the manufacture of LLINs in 2001. Shobikaa Impex Private Limited SF No. 558,559 – Athur SIDCO Industrial Estate, Vennaimalai (po), Karur-639 006 Tamil Nadu India, was ISO 9001 certified. ISO 9001:2015 certificate number 99 100 16065/03, Issued 14th May 2018, Expiry date 13th May 2021; Issued by TUV SUD South Asia Private Limited, Mumbai. Scope: Manufacture and export of long-lasting insecticide incorporated bed nets. In addition, the site was licensed to manufacture insecticides under license number 473/2014, issued 21st July 2017 by the Department of Agriculture, Government of Tamil Nadu, India.
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. The site was not involved in design and development.

Out of scope	Products not submitted to WHO for prequalification.
Restrictions	None
WHO products covered by the inspection	Duranet® LLIN (Alphacypermethrin 5.8g/kg ±25%) 006-001 DuraActive® LLIN (Deltamethrin 1.4% g/Kg±25%) 006-002
Abbreviations	**Meaning**
CoA	Certificate of Analysis
GC	Gas Chromatography
PPE	Personal Protective Equipment
LLIN	Long Lasting Insecticide treated Nets
QMS	Quality Management System

Part 2	**Brief summary of the findings and comments (where applicable)**

1. Organizational roles, responsibilities and authorities

The organization had a documented quality management system that defined roles and responsibilities of management. An organizational chart was also available. Reporting lines for production and quality control were independent of each other. Management were committed and dedicated to improvement of processes and of the system.

2. Quality policy and quality objectives

The facility had a documented and established quality policy which was appropriate for its purpose. Quality objectives were also adequately documented. Quality policy and Quality objectives were displayed throughout the facility. Quality objectives and targets were defined within the quality manual and were consistent with the quality policy.

3. Management review

There was an established procedure for management review. Management review inputs and outputs were adequately documented and implemented. Management review meetings were held every 6 months and records maintained. The meetings incorporated all sites with management representation at the meeting. The quality objectives, policy and the ability of the quality management system to meet planned results were also reviewed. The records of the management review demonstrated compliance with the ISO 9001:2015 requirements for management review.

4. Leadership

Top management of the facility were committed to the development and implementation of the QMS. Responsibilities and authorities for the different roles were assigned. The quality policy and objectives were communicated to all staff. Regular training in local language was conducted for all staff on the quality policy and objectives. Training records were maintained.

5. Control of documented information

The manufacturer had in place a procedure for the control of documents. Documents were maintained electronically with hard copies available at the point of use. The QMS incorporated both sites. Documents were reviewed every three years. Changes were reviewed and approved in accordance with the established procedure. All the issues raised in relation to this section were satisfactorily addressed.

6. Personnel competence and training

The training plan for the year 2017, 2018 and 2019 were reviewed. Training programs included trainings on quality policy and objectives, awareness of 9001:2015 among others. Effectiveness of the training was assessed using training evaluation forms. Trainings were conducted as planned and training records were maintained.

7. Risks and opportunities

The manufacturer had a documented procedure on risk and opportunities. A risk register was in place. Risk assessment took into consideration the lifecycle of the product. The risks and mitigation measures were well documented.

8. Internal Audits

The facility had an established procedure for internal audits. Internal audits were conducted biannually. Internal audit reports for the year 2018 were reviewed. Internal audits were conducted with a team of internal auditors. Findings from the internal audits were discussed at the management review meetings. Appropriate corrections and corrective actions were taken and documented.

9. Control of non-conforming products

The manufacture had in place a procedure for control of nonconforming products that allowed for corrective actions and the control of nonconforming products. It covered all aspects of production including receiving, in-process, final inspection and customer complaints. The manufacturer also had a procedure for handling of test failures in place. In case of a test failure the procedure required the respective head of department be informed. No test failures had been registered by the manufacturer.

10. Performance evaluation

The manufacturer monitored key process parameters such as yarn thickness, temperature etc. Performance evaluation reports for the months of February and March 2019 were reviewed and found satisfactory.

12. Complaint handling

Customer complaints were forwarded to management and a decision on the actions to be taken would be decided. Actions taken could include investigation. Records were to be maintained. No complaint had been received at the time of the audit.

13. Design and development of products

Design and development were not applicable. The site was not involved in design and development.

14. Support

Infrastructure and work environment

The infrastructure at the 2 sites was well maintained. The manufacturing environments were well planned, maintained satisfactorily and appeared clean and tidy. The inspectors were informed during the construction of the facility a rodent repelling chemical was used in the foundation. There was no sign of pest droppings or birds within the facility storage areas. Production was performed under ambient temperature. The work environment was found adequate with personnel wearing suitable PPE. MSDS were available.

Monitoring and measuring resources

Maintenance and calibration records were available for the equipment requested. A log of maintenance records and schedules was also available.

15. Production and service provisions

Control of Production

The manufacturing of the Alphacypermethrin master batch involved mixing, extrusion, cooling, cutting and packing. Water generated by reverse osmosis was used for cooling. The process validation report was reviewed. The manufacture of the master batch was carried out in a dedicated area. In-process tests carried out included chemical analysis to determine Alphacypermethrin content in the master batch.

The manufacturing of the fabric involved extrusion, cooling, presetting, warping and knitting. At the time of the audit manufacture of Duranet® fabric was ongoing. Production records were maintained. The temperatures at which stentering was performed were monitored and records maintained. In-process checks monitored included thickness of the yarn and denier. The weighing balances and dial gauge used to measure the thickness of the yarn were calibrated.

The fabric was then cut, sewed, stitched, labelled and packaged depending on the customer specifications. All nets were inspected for defects such as holes, tears, stains at various stages during the manufacture and the weight of the fabric with defects noted at the end of the shift.

Fabric from the manufacturing facility at Vennaimalai was transported to Thannerpandhal for further processing of fabric which involved cutting, sewing and stitching, labeling and baling. The packaged finished bed nets were transported back to the warehouse in Vennaimalai for storage and distribution.

Completed batch manufacturing records for Duranet® LLIN were reviewed.

The waste water from production was treated at the sewage plant located onsite. The final treated water tested to ensure that it meets the relevant specifications by a third-party company before being released for use in the environment. This water was used to water plants in the compound.

The Quality Control Laboratory was well maintained and clean. The laboratory equipment was uniquely identified and calibrated.

The analytical test reports for Duranet® LLIN were reviewed. Access to the computer for the GC was by unique passwords for the analyst and files were protected from deletion. The laboratory data was backed up every month to a central server. Chemical reference standards were appropriately stored and certificates available. A stability study was reviewed. The study test results indicated that the Duranet® LLIN met specifications.

At the time of the audit no commercial batches of DuraActive® LLIN had yet been manufactured. It was planned to have a separate line for the manufacture of the master batch for DuraActive®. A separate and dedicated manufacturing area for the DuraActive® LLIN was under construction at the time of the audit. 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. All the issues raised in relation to this section were satisfactorily addressed.

Release of products and services

Products were released by the Quality Assurance Manager following review of the QC and production records. The release was performed in accordance with the procedure for product release. All the issues raised in relation to this section were satisfactorily addressed.

16. Preservation

Upon receipt, the containers of raw materials were visually examined for damages, appropriate labelling and weight of the consignment was taken. A CoA was to be provided at receipt of the raw materials. The raw materials were quarantined until they had been sampled, tested and approved by the quality control laboratory. The activities including sampling were found to comply with the procedure for supply chain/stores. Inventory control of the materials in the ware houses was by use of bin cards. A segregated area for rejected materials was in place. No materials had been rejected. There were separate warehouses for the raw materials and finished goods. All the materials in the ware houses were stored at ambient temperatures. All the issues raised in relation to this section were satisfactorily addressed.

17. Control of externally provided processes and products

The manufacturer had an established procedure for Supplier evaluation. The criteria for selection and evaluation of suppliers was based on cost, legal and regulatory compliance, financial stability, quality and lead time. The assessment was on the quality and lead time was performed for each consignment provided. Supplier assessment records were reviewed.

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

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   and

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were 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/