



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

Part 1	General information
Manufacturers details	
Name of manufacturer	Agrina Industry Company Limited
Corporate address of manufacturer	V.K.A. Polymers Pvt. Ltd. No. 939/9 Chinna Andan Kovil Road, Cheran Nagar, Karur - 639001, Tamil Nadu, India.
Inspected site	
Name & address of inspected manufacturing site(s)	Agrina Industry Company Limited: 38, Local Road 830D, Hamlet 5, Ben Luc District, Long a Province, Viet Nam
Unit/Block/Workshop	Not applicable
Inspection details	
Dates of inspection	15-17 June 2022
Type of inspection	Initial inspection. The criteria for the inspection were based on the ISO 9001:2015 standard.
Introduction	
Brief description of the manufacturing activities	Activities carried out at the site included warehousing of finished product and raw materials including manufacturing of Product batches through extrusion, knitting, cutting, sewing, labeling, quality control testing, baling, and packaging of LLIN. The Master formulation Batch is manufactured at VKA, India and exported to Agrina, Viet Nam for use in the manufacturing of the various production batches.



<p>General information about the company and site</p>	<p>Agrina Industry Company Limited was established in 2014. In February 2022 Agrina signed a contract to manufacture LLIN product on contract for V.K.A Polymers Pvt. Ltd, a company based in India. In accordance with the contract and quality agreement between the two parties, Agrina Industry Company Limited was responsible for the manufacture of the LLIN products with V.K.A Polymers Pvt. Ltd responsible for the supply of the Master Formulation Batch, testing and final release of the products.</p> <p>Agrina was ISO 9001:2015 certified (QMS). ISO certificate number VN15/00118. Valid from 27th May 2021 until 27 May 2024. Scope: “Manufacture of mosquito net, agriculture net”. The certificate was issued by SGS.</p> <p>Agrina was also ISO 14001:2015 certified (Environmental Control Measures). ISO certificate number VN16/00158. Valid from 05th June 2021 until 18th October 2022. Scope: Manufacture of mosquito net, agriculture net”. The certificate was issued by SGS.</p>
<p>History</p>	<p>This was the first WHO audit of the site</p>
<p>Brief report of inspection activities undertaken – Scope and limitations</p>	
<p>Areas inspected</p>	<p>Document review including but not limited to:</p> <ul style="list-style-type: none"> • 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 <p>Physical areas:</p> <ul style="list-style-type: none"> • Raw material and finished goods • Production areas • Quality control laboratory
<p>Exclusions and Non-applications of requirements in the QMS</p>	<p>None.</p>



Out of scope	The manufacture of agricultural nets and other products not submitted to the PQT programme were not included in the scope of this inspection.
Restrictions	None
WHO products covered by the inspection	<ul style="list-style-type: none"> • MAGNet LLIN (Alpha-cypermethrin 5.8 g/kg ± 25%) 014-001 • Veeralin LLIN (Alpha-cypermethrin 6.0 g/kg; Piperonyl butoxide (PBO) 2.2 g/kg) 014-002
Abbreviations	Meaning
CoA	Certificate of analysis
KPI	Key Performance Indicators
PPE	Personal Protective Equipment
QMS	Quality Management System
PBO	Piperonyl butoxide

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

V.K.A oversaw the production and quality control activities related to the manufacture of the Veeralin and MAGNet LLINs. The job description of the QA/QC in-charge was reviewed. The QA/QC in-charge was responsible for ensuring that processes are delivering their intended results and appraising the performance of production and QMS. He also reported on the performance of the QMS to top management of Agrina.

In accordance with the Agrina – VKA contract and quality agreement, VKA was responsible for deciding on the quality of the raw materials including the master batch. The responsibilities of Agrina were limited to in process inspections and finished product inspections according to the QC inspection plan.

2. Quality policy and quality objectives

Agrina had an established quality policy and quality objectives. The quality policy was displayed in various areas throughout the facility. The quality policy and quality objectives were also communicated during trainings. The quality policy included a commitment to satisfy applicable requirements. It also included a commitment to continual improvement of the QMS.

3. Management review

The Management Review Control Procedure was reviewed. The procedure as described inter alia the following inputs had to be prepared for discussion: Report on operation status of the quality management system; Audit report of the quality management system; Customer information feedback and satisfaction reports. Management Review Meetings were held at Agrina at least once per year with the QA/QC inhouse V.K.A. attending the meeting. The minutes of the last Management Review Meeting were reviewed. Minutes are written addressing high level comments. The scope and agenda of the management review included discussions on CAPAs



implemented, handling of complaints, Product performance, Non-Conformities, Internal audits, and Risks. It was a requirement that Heads of Departments attend the meeting including Production, QA, and Engineering.

4. Leadership

An organogram was in place. Roles and responsibilities had been assigned and communicated. Management demonstrated leadership and commitment by taking accountability for the effectiveness of the quality management system through management review meetings, establishing, monitoring, and measuring quality objectives and providing necessary resources. Management had also established a quality policy that was communicated within the organization and reviewed in management reviewed meetings.

5. Control of documented information

The procedure on how to write an SOP was available. A master list of document information (SOPs) was available together with a Master List of Retained Documented Information - (Records), List of Internal Auditors and Quality Manual. All the issues raised related to this section were addressed satisfactorily by the manufacturer.

6. Personnel competence and training

The relevant procedure for Training Management System and Skill matrix - Competence Criteria and Qualification Record was reviewed together with the records of the latest training provided. The different categories of trainings included induction training, on-the-job training and professional skills training were defined. All the issues raised related to this section were addressed satisfactorily by the manufacturer.

7. Risks Management

The risk and opportunity control procedure was available, and it described the types of risks and opportunities and the criteria for risk evaluation. Risks associated with product, staff, facility, and materials. Agrina utilised the FMEA – Failure Mode and Effect Analysis tool for risk identification, assessment, and mitigation.

The Risk and Opportunity Identification, Response Measures Evaluation register which defined the risks and opportunities identified within related processes and relevant departments was reviewed.

8. Control of changes

The change control procedure, Quality Standard Procedure was reviewed. The procedure applied to changes related to documents, processes, equipment, active ingredients, and personnel. Changes were categories into two i.e., Minor and Major changes. Changes were authorized by QA from VKA. Various SOPs were available that addresses “changeover” within the manufacturing process i.e., Change from production tailoring to complete product together with a corresponding check list. In addition, as per the management review requirements; risk assessment were conducted for major process change, and customer request, changes in the RPN number and major quality or delivery issue.



9. Internal Audits

The Internal audit procedure was described in the Quality Manual. Internal audits were conducted every 6 months. The latest planned internal audits and the corresponding Noncompliance report were reviewed. The audited areas included document maintenance, recording of nonconformances, rework, changes, risks, quality objectives, equipment calibrations, warehousing etc. The auditors were from V.K.A.

10. Control of nonconforming products

The procedure for control of nonconforming products was reviewed. The procedure was applicable to out of specification results from the quality control laboratory, nonconforming fabric, yarn, and finished products. The QA/QC in-charge was responsible for managing the control of nonconforming products. The procedure also involved determination of corrections, and corrective actions and root cause investigations. Quality control measures in place for the detection of nonconforming products included visual inspection of the knitted fabric and sewed bed nets and quality control tests (physical) such as denier, GSM etc. Records on defects were maintained. The bed nets with defects were repaired and inspected again to ensure that they meet the expected requirements before packaging.

11. Complaints and customer satisfaction

Market complaints were received by V.K.A Polymers Pvt. Ltd. Depending on the nature of the complaint, the complaint is communicated to Agrina Industry Company Limited for investigation. The procedure for complaint handling was reviewed. Investigations were to be completed within 30 days. The procedure for complaint handling involved root cause analysis, implementation of corrections and corrective actions. No complaints had been received. The template of the customer satisfaction survey form was also in place. The customer satisfaction survey form included information on the product, sales, support provided among others.

12. Performance evaluation

The performance for key quality indicators was analysed and evaluated. The following are some of the indicators monitored and measured: distribution of granules in the mixture thickness of the yarn, denier, GSM, number of holes per square inch etc. All the indicators were within control. They were summarized using descriptive statistical tools such as graphs and tables. This information was discussed in management review.

13. Design and development of products

The design and development of the product was undertaken by VKA Polymers Pvt. Ltd. Agrina Industry Company Limited is a contract manufacturer of the products and was not involved in the design and development of MAGNet LLIN and Veeralin LLIN. This was therefore not included in the scope of the audit.



14. Support

Infrastructure and work environment

Personnel were adequately gowned in overalls, shoes, ear plugs etc. The infrastructure was generally well maintained.

Monitoring and measuring resources

An equipment master list was in place. Equipment were uniquely identified and calibrated. The calibration statuses were indicated and monitored. The calibration certificates for the following equipment were reviewed: Tachometer, temperature gauge, balances. Maintenance records for the extruder were also reviewed.

15. Production and service provisions

Control of Production

The manufacture of MAGNet LLIN and Veeralin LLIN included mixing of the master batch with HDPE and color, extrusion, warping, knitting, cutting, sewing, packaging, and labelling. A batch mixing record was maintained. Mixing records were in place.

The temperature zones of the extruders were monitored, and records maintained. The extrusion job sheets was in place. Several of these stenters were found running at the time of the audit. The thickness of the yarn was recorded in the daily thickness record. The limits for the yarn thickness were in place. The yarn was wound onto beams. The beams were adequately identified. The procedures for cleaning of the mixing tank, cleaning of the extruder were reviewed. Cleaning was performed whenever there is a product trial, product change or color change etc.

Knitting log sheets were maintained. The in-process test records were maintained. The fabric was cut, sewed, packaged, and labelled according to the customer specifications. All the sewed bed nets were inspected for defects. The records for rework of Nets and fabric were also in place. Labels were adequately controlled. The packaged bed nets were sampled following AQL levels.

Waste generated from production was collected by a third-party company that used the waste to produce other products such as agricultural chain links. The water used for cooling the yarn in production was filtered and recycled.

The laboratory only carried out physical quality control tests. The Quality plan describing the testing methods to be employed in quality control was in place. Test results were maintained. Test records for GSM, Denier, mesh size were reviewed.

A sample of every batch was sent to V.K.A Polymers Pvt Ltd - India for finished product testing. Both physical and chemical tests were performed by V.K.A Polymers Pvt Ltd - India prior to release of the bed nets. The bed nets were released by the QC/QC in-charge following the receipt of the test results from V.K.A Polymers Pvt Ltd and review of in-process data.

Retention samples were kept in a dedicated place at ambient temperature. A sample of every batch was retained. The retention samples were kept for 4 years. All the issues raised related to this section were addressed satisfactorily by the manufacturer.



Identification and traceability

There was adequate traceability of the raw materials, samples, and finished products in the production records. Equipment were uniquely identified. All the issues raised related to this section were addressed satisfactorily by the manufacturer.

16. Preservation

The masterbatch used for the manufacture of MAGNet LLIN and Veeralin LLIN was supplied by V.K.A Polymers Pvt. Ltd. The color and HDPE were sourced locally from approved suppliers. The procedure for Quality Control described the handling of materials in the warehouse was reviewed. Inventory in the warehouse was managed by use of stock cards. An incoming goods checklist and inventory register were in place. The quantity, physical condition of the containers, label information were verified upon receipt of the raw materials. The raw materials were supplied along with Certificate of Analysis (COA). There was a segregated area for storage of nonconforming materials.

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

Contract exists between Agrina and VKA. Contract giver audit report was available and was conducted by VKA prior to signing of contract. An approved supplier list was available. The relevant SOP required an audit of the critical supplier every 6 months. Rating of suppliers are allocated 3 levels of compliance, A, B, C with A the highest level of compliance. Other rating criteria include pricing, timely delivery etc.

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 *Agrina Industry Company Limited* located at **38, Local Road 830D, Hamlet 5, Ben Luc District, Long a Province, Viet Nam.** 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/>