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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	V.K.A. Polymers Pvt Ltd
Corporate address of manufacturer	V.K.A. Polymers Pvt Ltd No.137/9 Cheran Nagar, Karur, Tamil Nadu, India
Inspected site	
Name & address of inspected manufacturing site(s) if different from that given above	1. V.K.A. Polymers Pvt Ltd (UNIT-I), 169/1, 170/1, 192/3 Balarajapuram Village, Veerarakkiam, Karur District, 639114 Karur, Tamil Nadu, India. 2. V.K.A. Polymers Pvt Ltd (UNIT-II), 1/79 Maduari By-pass Road, Kakavadi, Karur, Tamil Nadu, India. 3. V.K.A. Polymers Pvt Ltd (UNIT-IIA) No.137/9 Cheran Nagar, Karur, Tamil Nadu, India
Unit/Block/ Workshop	Not applicable.
Inspection details	
Dates of inspection	23-27 July 2018
Type of inspection	Initial inspection. The criteria for the inspection was based on the ISO 9001:2015 standard
Introduction	
Brief summary of the manufacturing activities	V.K.A. Polymers Pvt Ltd (UNIT-I), 169/1, 170/1, 192/3 Balarajapuram Village, Karur, Tamil Nadu India: Activities carried out included the manufacture of Alphacypermethrin and Alphacypermethrin-PBO master batch and Long Lasting Insecticide treated nets (LLIN). The activities related to manufacture of the LLIN included warehousing (storage) of raw materials and finished packaged bed nets, production of the master batch and nets, physical quality control testing, packaging, labelling and dispatch. V.K.A. Polymers Pvt Ltd (UNIT-II), 1/79 Maduari By-pass Road, Kakavadi, Karur, Tamil Nadu: Activities carried out at the site included warehousing of raw materials and knitted fabric, extrusion, in-process checks and knitting. V.K.A. Polymers Pvt Ltd (UNIT-IIA) No.137/9 Cheran Nagar, Karur, Tamil Nadu:

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	Activities carried out at the site included cutting, sewing and stitching, labeling, quality control testing, packaging, baling, warehousing of the fabric and packaged finished bed nets and dispatch
General information about the company and site	This was the first WHO audit. V.K.A. Polymers Pvt Ltd (Unit-I), ISO 9001:2015 certificate date of issue 02nd February 2017, Expiry date 17th December 2018, Certificate number 99 100 16534. Issued by TUV SUD. Scope: Manufacture and supply of Mosquito Nets made of polyethylene, polypropylene and polyester. In addition Unit-I was licensed to manufacture insecticides under license number 467/2012, issued 06th August 2012 by the Ministry of Agriculture, Government of Tamil Nadu, India. V.K.A. Polymers Pvt Ltd (Unit-II), ISO 9001:2015 certificate date of issue 12th February 2017, Expiry date 17th December 2018, Certificate number 99 100 16534/02. Issued by TUV SUD. Scope: Manufacture long lasting insecticide incorporated bed nets. Unit-II was licensed to manufacture insecticides under license number 522/2016, issued 19th May 2016 by the Ministry of Agriculture, Government of Tamil Nadu, India. V.K.A. Polymers Pvt Ltd (Unit-IIA), ISO 9001:2015 certificate date of issue 27th July 2018, Expiry date 17th December 2018, Certificate number 99 100 16534/03. Issued by TUV SUD. Scope: Manufacture and supply of Long lasting insecticide bed nets.
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

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	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	Products not submitted to WHO for prequalification
Restrictions	None
WHO products covered by the inspection	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
GC	Gas chromatography
GR	Granules
HPLC	High performance liquid chromatography (or high performance liquid chromatography equipment)
LLIN	Long-lasting insecticide nets
MR	Management review
MSDS	Material safety data sheet
NC	Non-conformities
PPE	Personal Protective Equipment
QA	Quality assurance
QC	Quality control
QCL	Quality control laboratory
QMS	Quality management system
QRM	Quality risk management
RA	Risk assessment
SOP	Standard operating procedure
UV	Ultraviolet-visible spectrophotometer
WHOPES	World Health Organization Pesticides Evaluation Scheme
WP	Wettable powders

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Part 2	Brief summary of the findings and comments

1. Organizational roles, responsibilities and authorities

The organization had a documented quality management system that defined roles and responsibilities for management, including an organizational chart that was separate for the three sites. Management were committed and dedicated to improvement of processes and of systems. Reporting lines for production and quality control were independent of each other.

2. Quality policy and quality objectives

The facility had a documented and established quality policy which was appropriate to its purpose. The facility also had documented and established quality objectives. The Quality policy was displayed at all three sites in both English and the local language, Tamil. Quality objectives and targets were defined within the quality manual.

3. Management review

Management review meetings were carried out in accordance with an established procedure. The meeting minutes for the following dates were reviewed, 25 August 2017 and 10 February 2018. The meetings incorporated all three sites with management representation at the meetings.

4. Leadership

Top management (consisting of 4 directors) of the facility were committed to development and implementation of the Quality Management System (QMS). The quality policy and objectives were communicated. Responsibilities and authorities for the different roles were assigned. The manufacturer had a documented organizational structure for the three sites.

5. Control of documented information

VKA Polymers had in place a procedure for the control of documents. Documents were maintained electronically with one system and one overarching quality manual that incorporated all three sites. Master copies were stored at headquarters (Unit-IIA). Documents were reviewed on a three-yearly cycle and changes recorded in the Document change control record. Electronic access to documents was available to all supervisors with a hard copy available at site of task. A distribution list was available for documents on display and in use at all three sites. The issues related to document control were addressed satisfactorily.

6. Personnel competence and training

Training needs were identified by departmental heads. The training plan for the year 2018 was reviewed. Training programs included training on quality policy and objectives, awareness of 9001:2015 Standard among others. Effectiveness of the training was assessed. Training was conducted as planned and training records were available.

7. Risks and opportunities

VKA Polymers had a documented procedure within the quality manual on risk and opportunity that was set in line with requirements of the ISO 9001:2015 Standard. Risks were revised every 6 months but there was no documented review period or evidence that this occurred, other than a brief description in the management review minutes.

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8. Control of changes
The facility had an established procedure for change control. The facility maintained a change control register. There were no product changes registered. The issues related to change control were addressed satisfactorily.

9. Internal Audits
The facility had an established procedure on internal audits. Internal audits were planned, and an internal audit program implemented. Internal audits were conducted biannually for each department by qualified internal auditors. Internal audit schedule for the year 2018 was reviewed. Internal audit checklists were in place. Audit results were communicated to top management and were reviewed in management review meetings.

10. Control of non-conforming products
The manufacturer had several measures in place for quality control and detection of nonconforming goods including testing of raw material before being sent into production, visual check of knitted fabric and final visual check of sewn nets. All the in-process materials (100%) were visually checked for defects and defects recorded. The issues related to control of non-conforming products were addressed satisfactorily.

11. Performance evaluation
The manufacturer monitored key processes and product quality parameters such as denier, GSM, bursting strength. The records reviewed showed that processes were within control limits. Feedback from customers on performance of the finished products on the market was in place. The issues related performance evaluation were addressed satisfactorily.

12. Complaint handling and Customer satisfaction
The manufacturer had an established procedure for complaint handling. This applied to all the 3 units. The procedure described the actions to be taken when a complaint had been received. A complaints register was available. The issues related to control of complaint handling were addressed satisfactorily.

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 at the 3 units was generally well maintained. The floors and external environment were kept clean and free of litter and rubbish. There was no sign of pest droppings or birds within the facility storage areas. MSDSs were available.

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Monitoring and measuring resources

The facility had a maintenance team on site. Maintenance and calibration of laboratory equipment such as balance and GC was performed by a third party. Maintenance records and calibration records were available for the equipment requested. Maintenance was carried out in accordance with the relevant procedure. A log book was available that logged maintenance performed. The issues raised under this section were satisfactorily addressed by the manufacturer.

15. Production and service provisions

Control of Production

VKA Polymers Pvt Ltd (Unit I)

The manufacture of Alpha-cypermethrin master batch involved mixing of the Alpha-cypermethrin Technical grade with Low density polyethylene, extrusion, cooling, cutting into granules and packaging. Demineralized water was used for cooling. The manufacture and storage of the master batch was done in a dedicated area. There was a storage area dedicated to the storage of active ingredients and the master batch separate from the main warehouse. At the time of the inspection the manufacture of master batch of Alpha-cypermethrin was ongoing. Alpha-cypermethrin content in the granules was ascertained prior to release of the granules for the manufacture of the fabric (MAGNet).

The manufacture of the fabric involved blending of Alpha-cypermethrin master batch with HDPE followed by extrusion, cooling, presetting, wrapping, knitting and stentering. Demineralized water was used for cooling. The manufacture of the fabric was done in dedicated areas. The fabric was then cut, sewed, stitched, packaged and baled according to customer specifications. The fabric was inspected for defects such as holes and tears. Records on defects were maintained. The manufacture of the MAGNet was ongoing at the time of inspection. Documented information such as batch route cards, in-process test results for critical quality parameters such as denier and GSM were maintained.

Inactive raw materials, uncut fabric and finished packaged bed nets were stored in the main warehouse. A stock register of the inventory in the warehouse was maintained.

The laboratory equipment was uniquely identified and calibrated. Only physical tests were carried out at Unit- I and these included homogeneity, thickness of yarn, denier, GSM, fabric weight and mesh count among others. Chemical analysis was performed at unit- IIA.

The relevant procedure for process validation was in place. Revalidation of manufacturing processes was to be performed once every twelve months. Process validation protocol and report for both the manufacture of the master batch and MAGNet LLIN were reviewed. Critical process and quality parameters had been identified and the results indicated that the manufacturing process was operating in a validated state. The manufacturing process of Veeralin LLIN was still undergoing validation. No commercial batches of Veeralin LLIN had yet been manufactured. Computer validation had not been performed for the software used for the control of production of the master batch.

The relevant cleaning procedure and cleaning records for the die were reviewed. All the issues raised related to control of production at Unit-I were addressed satisfactorily by the manufacturer.

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VKA Polymers Pvt Ltd (Unit-II)

The Alpha-cypermethrin master batch from Unit-I and inactive raw materials were stored in the warehouse at ambient temperatures. Inventory control records were reviewed.

The manufacturing activities included mixing of the master batch with HDPE, extrusion, cooling, presetting, knitting and stentering. At the time of the inspection the manufacture of MAGNet was ongoing. The production records were reviewed. In-process checks included homogeneity, yarn size, denier, GSM etc. Records of the results of the in-process checks were maintained. Chemical analysis of the Alpha- cypermethrin content was performed at Unit-IIA. The wrapping process had been eliminated. The yarn was directly woven onto the bobbins. The qualification of the knitting machine and the process validation report for the direct wrapping process were reviewed. The fabric was inspected for presence of extraneous material, defects such as holes, tears and manufacturing defects. Records of the defects identified were maintained. Further processing of the fabric and chemical analysis for Alpha- cypermethrin content was performed at Unit-IIA.

All the issues raised related to control of production at Unit-II were addressed satisfactorily by the manufacturer.

VKA Polymers Pvt Ltd (Unit-IIA)

Fabric from Unit-II was cut, sewed and stitched and packaged according to customer requirements. Inventory control records (Inward fabric notes) were reviewed. At the time of the inspection MAGNet was being processed. Counter reports with details on the batch number, tailor's names, number of labels received etc. were reviewed. Batch numbers of the fabric undergoing further processing was displayed at different production stages. The fabric was inspected for presence of extraneous material, holes, tears and manufacturing defects. Records on the defects found during the inspection were maintained. Bed nets with defects were transported to Unit I where the defects were corrected.

The laboratory carried out physico-chemical test on the bed nets. These included bursting strength, GSM, Alpha-cypermethrin content. The equipment in the laboratory was calibrated. Analytical test reports were reviewed. The test for bursting strength was witnessed during the inspection.

All the issues raised related to control of production at Unit-IIA were addressed satisfactorily by the manufacturer.

Identification and traceability

Materials were uniquely identified, and the status clearly indicated. Records were maintained to enable traceability. All the issues raised related to identification and traceability were addressed satisfactorily by the manufacturer.

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Release of products and services

There was a general process of batch release that was for all three sites and this was captured in the Batch Validation (Lot-wise) record. Quality assurance plans for the two products was available. The quality assurance plans listed the parameters that were to be reviewed, sample size and sampling frequency. Depending on customer requirements a third-party inspection could be conducted before final release. Release of the finished goods in the warehouses at Unit-I and IIA was only done after issuance of a warehouse release note by the Chief Executive Officer. The warehouse release note was issued after review of the laboratory test records and production records.

16. Preservation

Products were packed depending on customer requirements. The storage conditions were ambient. The labelling was found adequate. All the issues raised related to preservation were addressed satisfactorily by the manufacturer.

17. Post-delivery Activities

Storage stability

Storage stability study reports for Veeralin and MAGNet were reviewed. The Stability studies were conducted following the method specified in Manual on development and use of FAO and WHO specifications for pesticides, first edition-third revision ISSN 0259-2517. The results complied with the specifications.

18. Control of externally provided processes and products

The relevant procedure provided details on the criteria for evaluation of external providers. Evaluation of suppliers was conducted once every six months. The evaluation parameters were quality, delivery and price. Supplier evaluation reports were available.

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 ***V.K.A. Polymers Pvt Ltd*** located at respectively:

a) ***169/1, 170/1, 192/3 Balarajapuram Village, Veerarakkiam, Karur District, 639114 Karur, Tamil Nadu, India. (V.K.A. Polymers Pvt Ltd -Unit I)***
b) ***1/79 Maduari By-pass Road, Kakavadi, Karur, Tamil Nadu, India. (V.K.A. Polymers Pvt Ltd -Unit-II)***
c) ***No.137/9 Cheran Nagar, Karur, Tamil Nadu, India. (V.K.A. Polymers Pvt Ltd -Unit-IIA)***

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.

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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/