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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 (P) Ltd.
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)	Name: V.K.A. Polymers (P) Ltd Addresses: 1. V.K.A. Polymers (P) Ltd. - Ancillary Unit – 1 located at 779/ A. B, R. S Pudhur, Melapalayam Village, S.Vellalapatty Post, Karur-639004, Tamil Nadu, India. 2. V.K.A. Polymers (P) Ltd. - Ancillary Unit – 2 located at 172/B3, Amutha Nagar, NH-7 Semmadai Manmangalam Taluk, Karur – 639002, Tamil Nadu, India. 3. V.K.A. Polymers (P) Ltd. - Ancillary Unit – 3 located at No.4/1, Nehru Nagar, Ramanoor, Pasupathipalayam Post, Karur – 639 004, Tamil Nadu, India. 4. V.K.A. Polymers (P) Ltd. - Ancillary Unit – 4 located at S.F. No. 1557/1, Andipalayam Road Kalipalayam, Puliyur CF Post, Karur - 639 114, Tamil Nadu, India. 5. V.K.A. Polymers (P) Ltd. - Ancillary Unit – 5 located at SF.No.672, AB Nagar, Opp. Powerhouse, Puliyur CF Post, Karur– 639114, Tamil Nadu, India. 6. V.K.A. Polymers (P) Ltd. - Ancillary Unit – 6 located at S.F. No. 1351/2C, Narikattiyur S.Vellalapatty Post, Karur - 639 004. 7. V.K.A. Polymers (P) Ltd. Ancillary Unit – 8 located at:

	a) SF No. 376, Narikattiyur South, Trichy Main Road, S.Vellalapatti Post,Karur - 639 004, Tamil Nadu, India. b) SF No. 1769/5B,6B,7A,8A Uthukaranpatti, Trichy Bye Pass Roar, Puliyur Post Karur 639114, Tamil Nadu, India 8. V.K.A. Polymers (P) Ltd. Ancillary Unit – 9 located at No.9, S.F. No. 675/6, Shivaji Nagar, AB Nagar Extension, Puliyur CF Post, Karur-639114, Tamil Nadu, India. 9. V.K.A. Polymers (P) Ltd. Ancillary Unit – 10 located at No.12, SF.1412 Industrial Estate, S.Vellalapatti Post, Karur - 639 004, Tamil Nadu, India. 10. V.K.A. Polymers (P) Ltd. Ancillary Unit – 13 located at Plot No.3, New SIDCO Industrial Estate, Athur village, Vennamalai Post, Karur - 639 006, Tamil Nadu, India. 11. V.K.A. Polymers (P) Ltd. Ancillary Unit – 24 located at SF No: 672/1, Indira Nagar, Puliyur CF Post, Karur – 639114, Tamil Nadu, India 12. V.K.A. Polymers (P) Ltd. Ancillary Unit – 15 located at D.No. 1/255-2, Ottapillaiyar Kovil South Street, Vengamedu Post Karur– 639 006, Tamil Nadu, India.
Unit/Block/ Workshop	Not applicable
Inspection details	
Dates of inspection	17 -18 November 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	The activities at the above ancillary units indicated above included mixing, extrusion, knitting, stentering, and storage.

<table>
<tr><td>General information about the company and site</td><td>All Ancillary units were ISO 9001:2015 certified.

Scope: ‘‘Manufacturing and supply of mosquito Net fabric made of Polyethylene.’’

The certificates were issued by TVE certification Services Pvt Ltd.

<table>
<tr><th>Unit Number</th><th>ISO 9001:2015 Certificate Number</th><th>Issue date</th><th>Expiry date</th></tr>
<tr><td>Unit 1</td><td>TVEIQ08241051</td><td>24/8/2020</td><td>23/8/2023</td></tr>
<tr><td>Unit 2</td><td>TVEIQ08241053</td><td>24/8/2020</td><td>23/8/2023</td></tr>
<tr><td>Unit 3</td><td>TVEIQ08241054</td><td>24/8/2020</td><td>23/8/2023</td></tr>
<tr><td>Unit 4</td><td>TVEIQ08241055</td><td>24/8/2020</td><td>23/8/2023</td></tr>
<tr><td>Unit 5</td><td>TVEIQ08241056</td><td>24/8/2020</td><td>23/8/2023</td></tr>
<tr><td>Unit 6</td><td>TVEIQ08241052</td><td>24/8/2020</td><td>23/8/2023</td></tr>
<tr><td>Unit 8</td><td>TVEIQ09011069</td><td>24/8/2020</td><td>23/8/2023</td></tr>
<tr><td>Unit 9</td><td>TVEIQ08241057</td><td>24/8/2020</td><td>23/8/2023</td></tr>
<tr><td>Unit 10</td><td>TVEIQ09011070</td><td>24/8/2020</td><td>23/8/2023</td></tr>
<tr><td>Unit 13</td><td>TVEIQ08241058</td><td>24/8/2020</td><td>23/8/2023</td></tr>
<tr><td>Unit 15</td><td>TVEIQ09011072</td><td>24/8/2020</td><td>23/8/2023</td></tr>
<tr><td>Unit 24</td><td>TVEIQ09011071</td><td>24/8/2020</td><td>23/8/2023</td></tr>
</table>
</td></tr>
<tr><td>History</td><td>This was the first WHO audit of the ancillary sites.</td></tr>
<tr><td colspan="2">Brief report of inspection activities undertaken – Scope and limitations</td></tr>
<tr><td>Areas inspected</td><td>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
• Product release
• Batch processing records
• Control of changes
• Internal audits
• Calibration and equipment maintenance

Physical areas:
• Raw material and finished goods
• Production areas
• Quality control laboratory</td></tr>
</table>

Exclusions and Non-applications of requirements in the QMS	Design and development of products and services was also excluded from the requirements of the QMS.
Out of scope	The manufacture of other products not submitted to PQ were not included in the scope of this inspection.
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
KPI	Key Performance Indicators
PPE	Personal Protective Equipment
MR	Management Review
MRM	Management Review Meeting
QA	Quality Assurance
QMS	Quality Management System
PBO	Piperonylbutoxide
RPN	Risk Priority Number

Part 2	**Brief summary of the findings and comments**

1. Quality policy and quality objectives

The quality policy was documented in the Quality Manual. The quality policy included commitments to the continuous improvement of the QMS and satisfy applicable legal requirements. The quality policy was approved by the board of directors The quality objectives were also documented in the quality manual. The manufacturer had established quality objectives related to marketing, quality, production, training, maintenance, purchase and QMS. The quality policy and quality objectives were displayed in various locations at all the ancillary units. The quality policy and objectives were also communicated through trainings. The quality objectives were measured and monitored. Key performance indicators had been defined for each quality objectives. The quality objectives were evaluated every quarter to determine the level and extent to which the quality objectives were met.

2. Management review

Management reviews were held separately for each ancillary unit. The management review minutes for Unit 2 and 5 were reviewed. The agenda included the following: Status of actions from the previous management review meeting, changes in external and internal issues, customer satisfaction and feedback, status of quality objectives, process performance and conformity of products and services, nonconformities, and corrective actions, monitoring and measurement results, performance of external services and providers, audit results, adequacy of resources, risks, and opportunities. The minutes were found satisfactory.

3. Leadership

Top management took accountability of the effectiveness of the quality management system through management reviews. Top management demonstrated commitment with respect to the QMS by providing the necessary resources for trainings, and implementation of the QMS. The job descriptions of the Quality Assurance/Quality Control – Manager, Technical/unit in-charge and Quality lab in-charge were reviewed. The Quality Assurance/Quality Control – Manager was responsible for implementing and maintaining the quality policy in all ancillary units and implementing standard operating procedures and documentation at all ancillary units. The Quality Assurance/Quality Control – Manager was also responsible for product release. The Technical/unit in-charge was responsible among other duties for planning and execution of production activities in accordance with the master schedule. The quality lab in-charge was responsible for collecting and sending samples to the V.K.A mother unit if required. An organogram was in place. The site was headed by the Managing Director who reported to the Board of Directors. The Quality Assurance/Quality Control – Manager and the Production manager reported independently to the General Manager.

4. Control of documented information

The procedure for document control was reviewed. The procedure applied to all documents related to the QMS. It described the preparation, review, and approval of documents. The procedure also described the control of documents of external origin. Any employee could raise a request for a document change. Document changes were approved by the QA/QC – manager following review of the functional heads. Documents were categorized into 4 levels (Level I, II, III, and IV). All documents were maintained for 4 years. A document master list was also in place.

5. Personnel competence and training

The procedure for training and competence was reviewed. Training plans were approved by the General Manager. On-job training was given to new employees. Trainings were evaluated and trainees whose performance was unsatisfactory were re-trained or have their job schedule switched to other activities they may best fit into. Evaluation of training was by interview, demonstration, observation and writing test. Training records were maintained. The annual training plan was in place. The training plan included trainings on PPE awareness, product specifications etc. The training records of selected personnel were reviewed and found satisfactory.

6. Risks Management

The procedure for risk management was reviewed. The procedure defined the policies and steps for identifying, mitigating, and managing risk throughout the organization. The FMEA tool was used for risk analysis and assessment. Risk were assigned risk priority number based on likelihood of occurrence, detectability, and severity. Risks were categorized into 3: low, medium, and high. The procedure required that risks be reviewed once every year. A risk matrix for year 2020 was reviewed. All the issues raised related to this section were addressed satisfactorily by the manufacturer.

7. Control of changes

The change control procedure was reviewed. The procedure applied to changes related to product, materials, manpower, machines, and methods. Changes related to materials, manpower, machines, and methods were approved by the QA/QC Manager. While changes related to product specifications such as dimensions etc. were approved by the General Manager. The impact of all changes was assessed prior to implementation. The change from manual batch mixing to automatic feed mixing was reviewed. This was found satisfactory.

8. Internal Audits

The internal audit procedure was discussed. The procedure provided the criteria for the selection of an internal auditor, which included qualification as an auditor as well as experience. Internal auditors were not allowed to audit their area of work. An internal audit checklist was in place. An internal audit schedule was in place. Root cause analysis of audit findings and the corrective actions are to be given to QA for approval within 30 days. The corrective action implementation was within 90 days. The list of internal auditors was in place. The qualification records of internal auditors were reviewed. The internal audit reports for unit 5 and 3 were reviewed.

9. Control of nonconforming products

The relevant procedure for control of non-conforming products and rework was reviewed. The scope included yarn, fabric as well as Out of Specifications test results (OOS) in the quality control lab. The procedure provided for root cause analysis, corrections, and corrective actions. Knitting defects were categorized into minor, major and critical. Defects that could be mended such as small holes and tears were mended by stitching. Mending records were maintained. Defects that could not be repaired were segregated, identified, and quarantined. All nonconforming products were communicated to the manager QA/QC by Technical/unit in-charge.

10. Performance evaluation

The procedure for performance evaluation and rating was reviewed. The purpose of the procedure was to assess and evaluate the performance of the ancillary units and address areas of concern. Production data from the ancillary units was provided by the Production Manager. Parameters monitored included time taken to complete of an order, quality and waste incurred. The performance evaluation reports for the ancillary units of the last two quarters were reviewed. The performance of all the ancillary units was satisfactory.

11. Design and development of products

Not applicable. The sites were not involved in design and development activities.

12. Customer satisfaction and complaints

A customer satisfaction survey form was also in place. Feedback and data related to the following was collected: Product quality, sample development, packing quality, deliverance, price, response to queries. Customers graded products and services as follows; 100% - Excellent, 90% - Very good, 80% - Good, 70% - Fair, and below 70% - Poor. Feedback from customers was also reviewed. VKA was highly rated by customers.

13. Complaints

The procedure for complaints was reviewed. All customer complaints were managed and maintained by the Quality Department. Based on the customer complaint, a Non-conformance report is raised and sent to the corresponding department for investigation. Investigations were to be completed within 30 days. A customer complaint form was in place. No complaints had been registered at the time of the audit.

14. Support

Infrastructure and work environment

The ancillary units were generally well maintained. The building were equipped with safety equipment such as fire extinguishers. Rodent traps were also available. The personnel had PPE (googles, gloves, safety shoes). MSDS were available in the warehousing and production areas.

Monitoring and measuring resources

A calibration schedule was in place. The preventive maintenance records of the machines and instruments was reviewed. The maintenance performed on the knitting machines included cleaning, chain greasing, bearing change and full service. The calibration records of the timer, fabric cutter, weighing balance, mesh counter, vernier calliper were in place.

15. Production and service provisions

Control of Production

V.K.A. Polymers (P) Ltd. – ***Ancillary Unit – 1*** located at 779/A. B, R. S Pudhur, Melapalayam Village, S.Vellalapatty Post, Karur-639004, Tamil Nadu, India.

The master batch and other ingredient were received from the mother unit. Inventory records were in place. Raw materials from the mother unit were received along with a delivery challan. A stock register was in place. The stock register contained information of the quantities of the raw materials received, quantities issued to production, available balance etc.

The master batch was mixed with other ingredients. The mixing record was in place. Procedure for cleaning the mixing tank was in place. Cleaning was performed whenever there was a product change, colour change or a new trial. Cleaning records were in place. In-process parameters included mesh count and GSM and yarn diameter. Records were maintained. The test for GSM was demonstrated by the QA analysts.

The temperatures at which extrusion was carried out were monitored. The extrusion job sheet was in place. The temperatures of the water bath were also monitored. The setting for the extrusion process were made using a control panel. Access to the control panel was controlled with use of unique passwords. The stentering production report was reviewed. The fabric was then transported to mother units for further processing.

V.K.A. Polymers (P) Ltd. ***Ancillary Unit – 8*** located at:

a) SF No. 376, Narikattiyur South, Trichy Main Road, S.Vellalapatti Post,Karur – 639 004, Tamil Nadu, India.

Mixing and extrusion were carried out at this site. The extrusion process was controlled by use of a customized software. The preventive maintenance schedule for the extruders was in place. The die and mesh change records were also available. There was adequate traceability during production. The beams were adequately labelled with extruder number, date, lot, weight etc. The beams were then transported to site Unit 8 (b) for further processing.

b) SF No. 1769/5B,6B,7A,8A Uthukaranpatti, Trichy Bye Pass Roar, Puliyur Post Karur 639114, Tamil Nadu, India

Beams were received from unit 8a. The activities at this site included knitting, stentering and storage. The fabric was inspected for defects. A Pictogram showing the different types of defects such as hole, stains, open seams etc. was in place. Repairable defects were corrected by mending. Mending records were maintained. The product name, batch number, quantities of the fabric manufactured, and quantities released to mother units for further processing were recorded in the fabric outward record.

V.K.A. Polymers (P) Ltd. – Ancillary ***Unit – 6*** located at S.F. No. 1351/2C, Narikattiyur S.Vellalapatty Post, Karur – 639 004

The activities at this site included mixing, extrusion, knitting, stentering, and storage. The material safety data sheets were readily available. The extrusion job sheet was available. The knitted fabric was inspected for defects. A pictogram showing defects was in place. The defects were categorized into major and minor defects.

V.K.A. Polymers (P) Ltd. – Ancillary ***Unit – 4*** located at S.F. No. 1557/1, Andipalayam Road Kalipalayam, Puliyur CF Post, Karur – 639 114, Tamil Nadu, India

The raw materials used in the manufacture of the fabric were received from the mother unit. Inventory records were in place. The activities at this site included mixing, extrusion, knitting, stentering, and storage. The Master batch was mixed with HDPE, colour, and other ingredients. The quantities were added to the mixer were as indicated on the master formula. The mixing was timed. Access to the control panel on the extruder was controlled with unique passwords. The production records for Veeralin LLIN were reviewed. The procedure for knitting was also reviewed. The nonconforming yarn and fabric was stored in a segregated area.

V.K.A. Polymers (P) Ltd. – Ancillary ***Unit – 3*** located at No.4/1, Nehru Nagar, Ramanoor, Pasupathipalayam Post, Karur – 639 004, Tamil Nadu, India.

Raw materials were received from the mother unit. The raw material were mixed in accordance with the master formula. This was then followed by extrusion, knitting, stentering, and storage. A stock register was in place. The procedure for mixing was in place. Mixing records were reviewed. The procedure for Screw and Barrel cleaning of the extruder was also reviewed. Cleaning was performed whenever there was a product change, colour change or a new trial.

V.K.A. Polymers (P) Ltd. ***Ancillary Unit – 10*** located at No.12, SF.1412 Industrial Estate, S.Vellalapatti Post, Karur – 639 004, Tamil Nadu, India.
The activities carried out this site included mixing, extrusion, knitting, stentering, and storage. A stock register, fabric outward record were in place. At the time of the inspection the manufacture of Veeralin LLIN was ongoing. In-process records for the yarn thickness, GSM and mesh count were reviewed. The fabric was inspected for defects and records maintained. The width of the fabric was also verified using a calibrated tape measure.

V.K.A. Polymers (P) Ltd. ***Ancillary Unit – 9*** located at No.9, S.F. No. 675/6, Shivaji Nagar, AB Nagar Extension, Puliyur CF Post, Karur-639114, Tamil Nadu, India.
The activities at this site included mixing, extrusion, knitting, stentering, and storage. The raw materials were received from the mother unit. Inventory records were in place. The batch manufacturing formula in place. The different ingredients were mixed for a defined time. The timer was calibrated. The equipment were identified. The temperature zones of the extruder were duly monitored and recorded. The extrusion job sheet was also in place. The weight of the filaments was recorded using a calibrated withing scale. A fire extinguisher and PPE were available. There was an identified area for storage of nonconforming yarn and fabric. The stentering production record was checked. The fabric was inspected for defects. In the mending area was a pictogram showing the different types of defects.

In-process parameters included mesh count and GSM and yarn diameter. Records were maintained. The technician in-charge demonstrated how the mesh count was carried out. A sample register was place. There was an identified and segregated area for the storage of the inspected fabric. The fabric was adequately labelled.

V.K.A. Polymers (P) Ltd. – ***Ancillary Unit – 5*** located at SF.No.672, AB Nagar, Opp. Powerhouse, Puliyur CF Post, Karur– 639114, Tamil Nadu, India.
Raw materials were stored in a segregated area. Material safety data sheets were in place. Inventory records were in place. A thermo-hygrometer was used to monitor the temperature and humidity of the storage areas. The temperatures at which extrusion was performed were monitored and records maintained. The temperature zones of the extruder were identified.
The knitting machines were all uniquely identified. Production records were in place. Temperatures of the stenter were also monitored and records maintained. The procedure for knitting was checked. The knitted fabric was inspected for defects. The repairable defects were mended. The knitted fabric was stored in an identified and segregated area before transportation to the mother units for further processing.

V.K.A. Polymers (P) Ltd. ***Ancillary Unit – 15*** located at D.No. 1/255-2, Ottapillaiyar Kovil South Street, Vengamedu Post Karur– 639 006, Tamil Nadu, India.
The raw materials were stored in was well lit and clean. The materials were segregated. Inventory records were reviewed. Inventory records for the master batch were reviewed. The procedures for cleaning of the mixing machine and product change were reviewed. Mixing records and extrusion job sheet were available. Areas were provided for storage of nonconforming yarn and fabric. Sample collection register logbook was in place. In process test results for the GSM, yarn diameter were reviewed and found satisfactory.

V.K.A. Polymers (P) Ltd. **– *Ancillary Unit – 2*** located at 172/B3, Amutha Nagar, NH-7 Semmadai Manmangalam Taluk, Karur – 639002, Tamil Nadu, India.

The storage area had a material entry and material exit doors. The inventory records were in place. A thermohygrometer was used to monitor the temperature and humidity of the storage areas. Inventory records were in place. The mixing and extrusion records were reviewed. The knitting machines were uniquely identified. The stentering production report was reviewed and found satisfactory. The knitted fabric was inspected for defects. A pictogram showing the different types of defects was in place. The fabric was transported to the mother units for further processing.

V.K.A. Polymers (P) Ltd. ***Ancillary Unit – 13*** located at Plot No.3, New SIDCO Industrial Estate, Athur village, Vennamalai Post, Karur – 639 006, Tamil Nadu, India.

The facility had safety equipment such as the fire extinguisher were in place. The sample and quality control procedure was checked. The raw materials were segregated to avoid mix ups. Mixing record were reviewed. Access to the control panels of the extruders was controlled. The knitting machines were uniquely identified.

V.K.A. Polymers (P) Ltd. ***Ancillary Unit – 24*** located at SF No: 672/1, Indira Nagar, Puliyur CF Post, Karur – 639114

The activities carried out this site included mixing, extrusion, knitting, stentering, and storage. The inventory records were reviewed. The equipment such as the weighing balances, mixer, extruders were identified.

Waste generated during production from all the ancillary units was collected and treated by a third-party company.

All the issues raised related to this section were addressed satisfactorily by the manufacturer.

16. Post-delivery Activities

The fabric from the ancillary units was transported to the mother units for further processing. Retention samples were collected from the mother units and retained there.

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

The selection of suppliers was performed by the QA at the mother unit. The ancillary unit received all the raw materials from the mother unit. The procedure for evaluation of suppliers was reviewed. The criteria for selection and evaluation of suppliers was defined. Evaluation of suppliers was performed once annually. The supplier evaluation reports were reviewed and found satisfactory.

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 (P) Ltd.*** located at:

1. V.K.A. Polymers (P) Ltd. - Ancillary Unit – 1 located at 779/ A. B, R. S Pudhur, Melapalayam Village, S.Vellalapatty Post, Karur-639004, Tamil Nadu, India.

2. V.K.A. Polymers (P) Ltd. - Ancillary Unit – 2 located at 172/B3, Amutha Nagar, NH-7 Semmadai Manmangalam Taluk, Karur – 639002, Tamil Nadu, India.

3. V.K.A. Polymers (P) Ltd. - Ancillary Unit – 3 located at No.4/1, Nehru Nagar, Ramanoor, Pasupathipalayam Post, Karur – 639 004, Tamil Nadu, India.

4. V.K.A. Polymers (P) Ltd. - Ancillary Unit – 4 located at S.F. No. 1557/1, Andipalayam Road Kalipalayam, Puliyur CF Post, Karur - 639 114, Tamil Nadu, India.

5. V.K.A. Polymers (P) Ltd. - Ancillary Unit – 5 located at SF.No.672, AB Nagar, Opp. Powerhouse, Puliyur CF Post, Karur– 639114, Tamil Nadu, India.

6. V.K.A. Polymers (P) Ltd. - Ancillary Unit – 6 located at S.F. No. 1351/2C, Narikattiyur S.Vellalapatty Post, Karur - 639 004.

7. V.K.A. Polymers (P) Ltd. Ancillary Unit – 8 located at:

   a) SF No. 376, Narikattiyur South, Trichy Main Road, S.Vellalapatti Post,Karur - 639 004, Tamil Nadu, India.

   b) SF No. 1769/5B,6B,7A,8A Uthukaranpatti, Trichy Bye Pass Roar, Puliyur Post Karur 639114, Tamil Nadu, India

8. V.K.A. Polymers (P) Ltd. Ancillary Unit – 9 located at No.9, S.F. No. 675/6, Shivaji Nagar, AB Nagar Extension, Puliyur CF Post, Karur-639114, Tamil Nadu, India.

9. V.K.A. Polymers (P) Ltd. Ancillary Unit – 10 located at No.12, SF.1412 Industrial Estate, S.Vellalapatti Post, Karur - 639 004, Tamil Nadu, India.

10. V.K.A. Polymers (P) Ltd. Ancillary Unit – 13 located at Plot No.3, New SIDCO Industrial Estate, Athur village, Vennamalai Post, Karur - 639 006, Tamil Nadu, India.

11. V.K.A. Polymers (P) Ltd. Ancillary Unit – 24 located at SF No: 672/1, Indira Nagar, Puliyur CF Post, Kurur – 639114, Tamil Nadu, India

12. V.K.A. Polymers (P) Ltd. Ancillary Unit – 15 located at D.No. 1/255-2, Ottapillaiyar Kovil South Street, Vengamedu Post Karur– 639 006, Tamil Nadu, India.

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/