

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

Part 1	General information
Manufacturers details	
Name of manufacturer	Sunshine World Net 2003 Co. Ltd
Corporate address of manufacturer	Sunshine World Net 2003 Co. Ltd 91 Moo 9 Donsai Photharam Ratchaburi 70120, Thailand
Inspected site	
Name & address of inspected manufacturing site(s) if different from that given above	As above
Unit/Block/Workshop	Not applicable.
Inspection details	
Dates of inspection	19-20 September 2018
Type of inspection	Initial inspection. The criteria for the inspection was the ISO 9001:2015 standard.
Introduction	
Brief summary of the manufacturing activities	Activities carried out included the manufacturing of long lasting insecticide treated nets (LLINs). The activities related to manufacture of LLINs included warehousing (storage) of raw materials and finished products, processing of fabric (coating), cutting, sewing and stitching, labeling, packaging and quality control testing.
General information about the company and site	This was the first WHO audit. Sunshine World Net 2003 Co. Ltd. held a valid ISO 9001:2015 certificate, date of issue 28th May 2018, Expiry date 21st October 2019, Certificate number QMC/R66/0008. Issued by ISC Global.
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 warehouses • 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	Interceptor (Alphacypermethrin) 002-001 Interceptor G2 (LLIN)- (Alpha-cypermethrin; chlorfenapyr) 002-002
Abbreviations	Meaning
CoA	Certificate of analysis
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
WHOPES	World Health Organization Pesticides Evaluation Scheme

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

The organogram documented in the Quality Manual reflected the company structure.
The current reporting lines indicated that the QC team reports to the production manager.
The roles and responsibilities are documented in the manual with appropriate descriptions.

2. Quality policy and quality objectives

The quality policy was reviewed. The quality policy was appropriate to the purpose and context of the organization. The quality policy and objectives met the requirements of the standard.

3. Management review

The relevant procedure for management reviews and minutes were reviewed. Management review meetings were held twice a year. Management review was performed in accordance with the established procedure and met the requirements of the standard.

4. Leadership

Leadership commitment to implementation and maintenance of a quality management system that was functional was described in the Quality Manual. These met the requirements of the ISO 9001:2015 standard. No issues were raised.

5. Control of documented information and changes

The relevant procedure was reviewed, and it adequately described the approval, distribution and review of documents. Document control practices were generally compliant with the document and data control manual and requirements of the standard. Both electronic and hard copies of documents were available. The hard copies of batch processing records were destroyed after three months and only electronic copies maintained. Electronic copies were maintained for a period longer than the shelf life of the bed nets. Changes to documentation and processes were reviewed. Impact of the change on the quality management system was assessed prior to implementation of a change. Change from the 400 L mixing tank to the Cistern tank was reviewed and found satisfactory. The issues raised related to this section were satisfactorily addressed by the manufacturer.

6. Personnel competence and training

The relevant procedure was in place. Training was determined for each department. The departmental plans/requests are then combined into the annual training plan. Training plan for 2018 was reviewed. The annual training plan showed induction training which included training on quality policy, fire, health and safety. Department specific training requirements were also indicated. Training records and evaluation forms were reviewed. Effectiveness of trainings was evaluated.

7. Risks and opportunities

The relevant procedure for risk management was reviewed. The requirements of the procedure were followed. A SWOT analysis had been conducted. Risk registers was in place. These were reviewed and showed a risk assessment had been carried out with scoring applied for each entry as per the procedure. There was mitigation provided for each risk and an assessment of the effectiveness of the mitigation was also recorded.

8. Internal Audits

Internal audits were conducted twice a year according to the established procedure for internal audits. The previous internal report and audit plan for 2018 were reviewed. Internal audit findings were reviewed in management review meetings. The corrective action report detailed the observations, a root cause, corrective action and review of the effectiveness of the implemented corrective action.

The internal auditors had all undergone external training in July 2017. Training records were reviewed and were present for all internal audit staff members; the effectiveness of the training was measured by examination at the end of the course.

9. Control of non-conforming products

The manufacturer inspected bed nets to ensure that defective bed nets were identified and controlled. The manufacturer had documented criteria for assessment of nonconformities such as holes, tears, etc. Repairable defects such as holes were repaired by stitching. The repaired bed nets were inspected again to ensure that they conform to the specified requirements. All nonconformities were documented.

10. Performance evaluation

Key performance indicators had been identified for all the different work areas such as cutting section, laboratory etc throughout the facility. The review of the key Performance indicators for the different work areas was done as part of internal audits and reported in the management review meetings.

11. Complaint handling

The relevant procedure was reviewed. Complaints were reviewed. Complaints were handled in accordance with the established procedure. No issues were raised.

12. Design and development of products

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

13. Support

Infrastructure and work environment

The work environment was found adequate with personnel wearing suitable PPE. MSDS and firefighting equipment were available in warehouse, laboratory and other production areas. Issues raised related to this section were satisfactorily addressed by the manufacturer.

Monitoring and measuring resources

The calibration schedule for the year 2018 was reviewed. The calibration reports for the Gas Chromatograph and bursting strength tester were reviewed.

14. Production and service provisions

Control of Production

Polyester fabric sourced from approved vendors was inspected for defects such as holes, tears, presence of extraneous material. All the fabric (100%) was inspected. Records on defects were maintained.

The manufacture of Interceptor involved chemical treatment (coating), stentering, cutting, sewing, stitching, labeling, packaging and baling. The coating solution was prepared by mixing of Alphacypermethrin with deionized water. The pH and hardness of the water was monitored.

The temperatures of the drying chambers were monitored and controlled. The temperature indicators were calibrated. The monitored in-process parameters included pressure of the pads, speed of the pressure pads and wet pick up, bursting strength, GSM etc. At the time of inspection, the manufacture of Interceptor bednets was ongoing. Production records were maintained.

The laboratory equipment was uniquely identified and calibrated. Laboratory test records for analysis of Alphacypermethrin content were reviewed. The report on the precision, accuracy of method of analysis of Alphacypermethrin and chlofenapyr was reviewed.

The manufacturer was still in the process of manufacturing trial batches of Interceptor G2 (Alphacypermethrin; chlorfenapyr). Registration of Interceptor G2 with the Food and Drug Authority of Thailand was still underway. The issues raised in relation to control of production were satisfactorily addressed by the manufacturer.

Identification and traceability

Materials were uniquely identified, and the status clearly indicated. Records were maintained to enable traceability.

Release of products and services

Completed batch manufacturing records for Interceptor bed nets were reviewed by the Production Manager and Director prior to release of the batch to BASF.

15. Preservation

The temperatures in both the chemical raw material and finished product warehouses were ambient. Records of the inventory were maintained.

16. Post-delivery Activities

Storage stability

Stability studies were conducted and submitted to WHOPES for approval several years back. The report was not available on site. No other stability studies had been conducted since.

17. Control of externally provided processes and products

The relevant procedure and approved vendor list were in place. A vendor with 3 rejected deliveries would be delisted. The criteria for evaluation of the suppliers were described. Vendor performance evaluation report for supplier of fabric was reviewed.

The key chemicals and active ingredient required for production were provided by BASF and these suppliers were managed directly by them, as such the manufacturer has no records relating to these supplier selections or evaluations. The key chemicals and active ingredients were procured by BASF.

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 ***Sunshine World Net 2003 Co. Ltd*** located at ***91 Moo 9 Donsai Photharam Ratchaburi 70120, Thailand*** 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/>