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Prequalification Team Inspection Services
WHO PUBLIC INSPECTION REPORT
(WHOPIR)
Desk Assessment of Vector Control Product Manufacturer

Part 1	General information
Company information	
Name of manufacturer	Onomichi Kumika Industry Co. Ltd
Corporate address of manufacturer	Onomichi Kumika Industry Co. Ltd 160, Chojabara 2-chome, Onomichi, Hiroshima 722-0221 Japan
Manufacturing site(s) under assessment	
Name & address of inspected manufacturing site(s) if different from that given above	Same as above
Unit/Block/ Workshop	Not applicable
Desk assessment details	
Dates of review	15-22 February 2023
Products covered by this desk assessment	Vectron T500 - P-03226
List of documents submitted	1) Site Master File 2) Site floor plans 3) Full address of manufacturing site 4) Quality Manual – only cover page in English. 5) Quality Manual – In Japanese 6) Staff Organogram 7) List of current Quality Management Procedures 8) Complaint handling, vigilance and recalls procedure 9) Control of non-conforming products procedure 10) Procedure for control of changes/change notifications 11) Supplier evaluation 12) Risk Management 13) List of ISO 9001:2015 certifications and surveillance. 14) Audit planning 15) QMS certification of conformity 16) Renewal audit report Issued 22 September 2022 17) Minor defect report and CAPA 2018 18) Minor defect report and CAPA 2022 19) List of products and formulation types at this site

	20) Name and contact details of the responsible person at the manufacturing facility 21) Process flow chart 22) Most recent Management review minutes 23) Completed batch record of WHO product 24) Master batch record for the WHO product of interest 25) List of recall/returns at Onomichi Kumika
Abbreviations	**Meaning**
NC	Non-conformity
NCR	Non-conformity Report
OOS	Out-of-specification
QC	Quality Control
QMS	Quality Management System
Part 2	**Summary of the assessment of ISO audits**

Name of ISO certification body

Japan Chemical Quality Assurance Ltd (JCQA)

Dates of Audit	Report Issued - 22 September 2022
Type of Audit	Renewal Audit (Recertification audit)
Inspected areas/documents	Change of QMS, facilities, Overview of internal and external challenges, needs of interested parties, overview of interview with Top Management, organizational strength to develop the commitment of Top Management, determination of risks and opportunities, monitoring measuring and evaluating key performance indicators, records of complaints and internal nonconformities, internal audits, management review
Product covered	Product names redacted.

Japan Chemical Quality Assurance Ltd (JCQA)

Date of Audit	Report Issued - 20 July 2020.
Type of Audit	Surveillance audit
Inspected areas/documents	Overview of internal and external challenges, needs of interested parties, information from Top Management or QC manager, organizational strength to develop the commitment of Top Management, determination of risks

		and opportunities, monitoring measuring and evaluating key performance indicators, records of complaints and internal nonconformities, internal audits, management review, implementation status of main processes
	Products covered	Not indicated in the report.
Part 3	**Summary of the last WHO inspection**	
	The site has not been inspected by WHO before.	

Part 4	**Summary of the assessment of supporting documentation**

1. Quality Manual:
Only the cover page was translated to English was provided.

2. List of current quality management procedures:
A list of the current quality management procedures was provided.

3. Standard operating procedures for:

i. Complaint handling, vigilance and recalls:
The procedure titled 'Complaint handling, Vigilance and Recalls' was reviewed. The procedure described the receipt and handling of complaints. The procedure included root cause investigation, corrective and preventive actions and verification of preventive measures.

ii. Control of nonconforming goods/processes:
The translated procedure for control of nonconforming products/processes described the measures in place for handling nonconforming products and defined the persons responsible for handling the nonconformities. Records of nonconformities were to be maintained and identified as such. The procedure also allowed for impact assessment, root cause investigation, and CAPA.

iii. Change control/change notifications (product and processes):
A procedure for change control described the management of changes related production equipment, manufacturing methods, prices, quality of raw materials, changes to transaction conditions. The impact of changes was reviewed.

iv. Risk management:
An excerpt of the quality manual describing risk management was provided. Each manager determined the risks in their respective departments. Risk and opportunities were reviewed twice a year. The Quality Control Committee discussed the appropriateness of risks and opportunities.

v. Supplier evaluation and control, verification of purchased product:
The procedure described criteria for the selection of supplier of production equipment, measuring equipment, storage/transport consignment, external calibration, maintenance and packaging materials, measuring instruments, reagents, external analysis, external calibration, maintenance, and raw materials. Records were maintained.

4. Site Master File (SMF) and site floor plan
The Site Master File provided an overview of the quality management system, personnel, premises, equipment, documentation, production, quality control complaints distribution, product defects and internal audits. The layout of the buildings on site was provided.

5. Quality management system certificate(s) and scope of certification: (e.g., ISO 13485/ISO 9001):
A valid ISO 9001:2015 certificate was provided.

6. List of notifications of upcoming inspections by the regulatory authorities or ISO 9001:2015 certification bodies in the next 6 months:
No inspections were planned in the next 6 months.

7. Process flowchart including in-process control points:
The process flow chart for the manufacture of Vectron T500 was provided.

8. List of all the products and formulation types manufactured at this site:
A list of products manufactured on site was provided.

9. Most recent management review report/minutes:
The most recent management review minutes were reviewed.

10. Master batch manufacturing, and/or packaging records of the WHO product of interest:
Templates of the manufacturing records were provided and reviewed.

11. Completed batch manufacturing and/or packaging records:
Batch manufacturing and packaging records were provided and reviewed.

12. List of any recalls/returns:
Manufacturer declared that no recalls had been performed.

13. List of equipment that is shared and measures in place to ensure that this sharing of equipment is managed appropriately:
No information was provided.

14. Name and address of sites to which any related activities are outsourced:
No information was provided.

15. Additional documents submitted:
None.

Part 5	Desk assessment conclusion

Based on the inspection by the Japan Chemical Quality Assurance Ltd (JCQA) and on the QMS evidence received and reviewed; it is considered that a desk assessment is acceptable in lieu of a WHO onsite inspection. The site **Onomichi Kumika Industry Co. Ltd** located at **160, Chojabaru 2-chome, Onomichi, Hiroshima 722-0221 Japan** is considered to be operating at an acceptable level of compliance with ISO 9001:2015 standard and WHO guidelines as per Overview of the WHO Prequalification Assessment of Vector Control Products, June 2021. This compliance status shall be valid until **8th November 2025** or when another inspection is conducted by WHO or by a reliable certification body.

Part 6	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. 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/

3. Overview of the WHO Prequalification Assessment of Vector Control Products, June 2021
   https://extranet.who.int/prequal/sites/default/files/document_files/WHO_PQT_VectorControlProducts_June2021.pdf