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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	Ipanema Industria Produtos Veterinarios
Applicant/ Corporate address of manufacturer	Envu, 2022 Environmental Science FR S.A.S Lyon Vaise Business Center, 1 Place Giovanni Da Verrazzano 69009 Lyon, France
Inspected site	
Name & address of inspected manufacturing site(s)	Ipanema Industria Produtos Veterinarios Rodovia Raposo Tavares, Km113 S/N – Bairro: Barreiro CEP: 18190-000, Araçoiaba da Serra – SP, Brazil
Unit/Block/ Workshop	Not applicable
Inspection details	
Dates of inspection	14, 15 and 18 August 2025
Type of inspection	Initial Inspection The inspection was to establish that the applicable requirements to ISO 9001:2015 as well as WHO specific requirements were met.
Introduction	
Brief description of the manufacturing activities	Ipanema Industria Produtos Veterinarios was established in 1990. Ipanema manufactured a wide range of products, including pesticides, therapeutic products (non-restricted products) and Beta-lactams for Veterinary use, rodenticides, and insecticides. Ipanema manufactured Fludora Co-Max on contract for Envu, 2022 Environmental Science FR S.A.S. The manufacture of Fludora Co-Max involved preparation of mixtures, filling, labeling, and packaging.
General information about the company and site	The site did not hold any ISO certifications. It however was a GMP certified site.
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 • 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
Exclusions and Non-applications of requirements in the QMS	None
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	• Fludora Co-Max – (52.5 g/L Transfluthrin; 26.3 g/L Flupyradifurone) EW - P-00164
Abbreviations	**Meaning**
CoA	Certificate of analysis
FMEA	Failure Modes and Effects Analysis
KPI	Key Performance Indicators
PPE	Personal Protective Equipment
MR	Management Review
MRM	Management Review Meeting
QMS	Quality Management System
RPN	Risk Priority Number

Part 2	Summary of the findings and comments

1. Management Review

The manufacturer shared that the review of business operations was done using different approaches. The quality was reviewed through the annual water quality and annual product reviews for certain products and the monthly, quarterly, and annual results of the quality indicators. Other reviews included supply chain and procurement with clients and customers. A presentation was provided on the ongoing project to integrate key systems building from the Enterprise Resource Planning (ERP) and other data sources to build into an all-company performance monitoring and evaluation system.

2. Quality policy and quality objectives

The quality policy and strategic objectives procedure was reviewed. The procedure described the responsibilities of key positions and the company's strategic quality commitment. The procedure also outlined three strategic objectives aimed at enhancing stakeholder satisfaction, fostering continuous improvement, and securing market leadership. The procedure described the communication approaches of the quality policy to internal and external audiences. This was considered adequate for the quality policy.

The procedure for quality indicators was also reviewed. The procedure provided the key quality indicators as doing things right the first time (RFT), avoiding waste and rework, and providing a service with agility, quality, safety, and customer satisfaction. The procedure described the collection and analysis of input data from the respective operational areas. The procedure provided key outputs and targets for different indicators. A quarterly quality monitoring report based on the template was reviewed.

3. Control of documented information

The procedure for document control was reviewed. The procedure described the generation, review, approval, and distribution of approved QMS documents. The procedure described the management of both electronic and printed hard copy documents. Management and access on documents were provided to all employees through an electronic system.

4. Personnel competence and training

The procedure on training was reviewed. The procedure described the process for management of the competence matrix and how it was used in the discussions to develop annual general training programs. The identification of training needs and planning of trainings were done by HR, QA, and heads of sections. The reviewed 2025 training plan and training records were in place.

5. Risk Management

The procedure for risk assessment was reviewed. The defined criteria for prioritization of risks was defined. HAZOP and FMEA methodologies were used for risk assessment and analysis. A risk register was in place. The risk assessment included warehouse, product transportation, operation, quality conformity, raw materials, packaging, facilities, employees, utilities, finance, environment, public relationships, communication, laboratory, IT and software, etc.

6. Internal Audits

The SOP for conducting internal audits was reviewed. It provided for how to develop the annual internal audit program, the qualification process of internal auditors, and the conducting, reporting, and closing out of internal audits. The also procedure provided for the technical requirements to assess during the audits. The 2025 internal audit program and the 2024 internal audit report were also reviewed.

7. Control of nonconforming products

The handling of complaints was described in the procedure for nonconformities. The complaints handling was managed using a customised software system. The software program was used for communication, investigation, analysis, classification, and recording of nonconformities and complaints as well as CAPA and effective assessment when applicable. Employees were responsible for immediately informing their superior when any event occurs that may impact the quality, safety, and effectiveness of the product and process. Nonconformities were categorized as major, minor, or critical. The procedure also defined and categorized deviations into planned and unplanned deviations. Rework was defined as any additional step in the production process of a given product.

Out of specifications (OOS) were handled in accordance with SOP for investigation of analytical results for physicochemical analyses and the SOP for investigation of analytical results for microbiological analyses. It was required that QA be notified of all nonconformities. The root cause was determined using the 5W2H tool. Selected nonconformities were reviewed.

8. Control of Changes

The relevant change control procedure was reviewed. Changes were requested using customized software. The quality assurance department performed an initial assessment of the change request, and a change control number was assigned to the change request. Impact assessment was performed by all departments. All changes were recorded and only implemented after approval by the responsible personnel depending on the nature of the change together with the quality assurance manager within 30 days from the opening of the change request. Changes were categorized into 3, namely: Level 1, 2 and 3. Selected changes were reviewed.

9. Design and development of products

Fludora Co-Max was not designed and developed at this site. This was there not included in the scope of this inspection.

10. Support

Infrastructure and work environment

The facility was well maintained. The facility was equipped with fire extinguishers, eye shower stations, and rodent traps. The material safety data sheets were in place. The temperatures and relative humidity of the warehouses were monitored. Spill/containment kits were also available in the warehouses.

Monitoring and measuring resources

Calibration records of selected equipment were reviewed. Equipment maintenance was managed using a software system to help manage the maintenance process and CAPA. Preventive actions to be taken were documented. The frequency of maintenance depended on the period defined by the manufacturer and the frequency of corrective maintenance. The preventive maintenance record for the selected equipment were reviewed.

11. Production and service provisions

Control of Production

The manufacture of Fludora Co-Max involved preparation of the premix, filling, packaging, and labeling. The dispensing/weighing area was inspected. Batch records for Fludora Co-Max were reviewed. Instructions for preparation of Fludora Co-max with defined mixing times were in place. The identification and calibration statuses of the balances were in place.

The quality control laboratory was well equipped. The laboratory carried out both physicochemical and microbial tests. The tests carried out on Fludora Co-Max were defined. An electronic sample register was in place. Samples were adequately labelled. The procedure for determination of Flupyradifurone and Transfluthrin in Fludora Co-Max was reviewed. The raw data and test reports of selected batches of Fludora Co-Max were verified. Audit trails were activated. The date and time on the computers used for HPLC analysis were locked. Primary standards were appropriately stored. The certificates of analysis of the primary standards were in place.

Analytical method validation

The analytical method validation procedure was reviewed. The procedure defined the major and minor deviations. The analytical method verification report from Ipanema was also reviewed. The following analytical validation parameters were defined. The validation was done in accordance with the procedure and requirements of the European Commission guidance SANCO/3030/99 Revision 5.

Equipment qualification

Primary standards were stored in a refrigerator. The qualification protocol and report for the refrigerator was checked. The objective of the study was to demonstrate that results obtained in the study show that uniform refrigeration distribution temperatures are within the required temperature range of 2-8°C as defined in the performance protocol. The descriptions of the sensor locations and distribution loads were provided.

Batch release

The release of batches was described in the procedure for Control of verification of production and disposition orders of finished products. The certificates of analysis were approved by the Quality Assurance manager or delegated person. It was required that when approving the CoA (Certificate of Analysis) or CoC (Certificate of Conformity), the quality manager or designated person check that the analytical results described in the CoA have been transcribed exactly as in the analytical report approved by the quality control manager and that the analyses performed must comply with the current product specification. Following the approval of the CoA by the quality assurance manager or designated person, the batch was then released.

Waste management

Waste was collected centrally by the manufacturer. The waste was then collected by certified third-party companies for treatment. The manufacturer tracked and received notifications on the status of the waste collected.

12. Preservation

The procedure for management of raw material and packaging and the procedure for receiving materials were reviewed. Inventory in the warehouse was managed using ERP. The materials receipt checklist used for verification of received materials was checked. The manufacturer used the FIFO/FEFO principle for issuance of materials.

13. Retention samples

Retention samples were stored in a dedicated area within the warehouse. Entrance to the retention sample storage area was controlled. Retention samples were adequately labelled. The retention samples were kept at ambient conditions. The procedure for control of retention samples was discussed. Samples were retained for a period equivalent to the shelf life of the product plus one year. A retention sample register was in place.

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

The manufacturer was not responsible for the selection of suppliers of the raw materials used in the manufacture of Fludora Co-Max. The applicant (Envu) was responsible for the selection of suppliers of the raw materials. Due to time constraints this area was not audited any further.

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 by **Ipanema Industria Produtos Veterinarios** located at **Rodovia Raposo Tavares, Km113 S/N – Bairro: Barreiro CEP: 18190-000, Araçoiaba da Serra – SP, Brazil** 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.

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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. 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/