

**TMDA/DMD/MCIE/F/002
REV.#. 01**



**THE UNITED REPUBLIC OF TANZANIA
MINISTRY OF HEALTH**



TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

**INNOTHERA CHOUZY, RUE RENE CHANTEREAU, FRANCE
PUBLIC GMP DESK ASSESSMENT REPORT**

March, 2025



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Part 1: General information about the company

1.1 Manufacturer's details	
Name of manufacturer/ Applicant	Innothera Chouzy – France / Laboratoire Innotech International - France
1.2 Inspected site Details	
Name & physical address of inspected manufacturing site	Name: Innothera Chouzy Physical address of the site: Rue Ren Chantereau, L'Isle Vert-41150 Chouzy Sur Cisse, France Tel: +33 6 22 32 27 43 Email: Valerie.turpin@innothera.com
Name of Unit/ block/ workshop number inspected	The company has three (3) buildings for the production of bulk products; <ul style="list-style-type: none">• Block 6- for manufacturing dry and liquid dosage• Block 9- for soft capsules• A new block M32/18– Dedicated for soft capsule• Unit at Valloire-sur-Cisse, unit number not declared; a clarification will be required
1.3 Inspection details	
Date of desk review	23 rd June, 2023
Date of last inspection by the SRA, WHO-PQ or EAC / SADC for production line applied at TMDA	This facility was inspected on 20-09-2024 by National Agency For The Safety Of Medicine And Health Products by a competent authority of France, GMP Certificate No. 2024_HPF_FR_181 Manufacturing and packaging of General pharmaceuticals for human use non-sterile dosage form (Tablets, soft gelatin capsules, oral liquids and herbal products), quality control testing (Microbiological (non-sterility), chemical and physical) and importation of medicinal products was issued which is valid for three years from date of inspection. These certificates can be



	traced in the EudraGMP database
1.4 Brief report of the activities undertaken at the site	
Summary of the activities performed at the site	<p>The facility is involved in</p> <ul style="list-style-type: none"> • Manufacturing and packaging batch certification of general pharmaceutical products for human use inform of non-sterile solid dosage form (Tablets, capsules (soft gelatin capsules), oral liquids and herbal products). • Quality control testing (physical/chemical and microbiology: non-sterility) of general pharmaceutical products for human use inform of non-sterile solid dosage form (Tablets, soft gelatin capsules, oral liquids and herbal products)
Production lines applied at TMDA	General pharmaceuticals for human use inform of non-sterile solid dosage form (Tablets, capsules and oral liquids)

Part 2: Review of submitted documentary evidence

- 2.1. Site master file (*describe consistency of SMF as per requirements*)
Contents and layout of submitted Site master file presented complied with requirements stipulated in TFDA GMP Regulations, 2018
- 2.2. Provide list of all regulatory inspections carried out in the past three years.

20-09-2024 by National Agency For The Safety Of Medicine And Health Products by a competent authority of France, GMP Certificate No. 2024_HPF_FR_181 Manufacturing and packaging of General pharmaceuticals for human use non-sterile dosage form (Tablets, soft gelatin capsules, oral liquids and herbal products), quality control testing (Microbiological (non-sterility), chemical and physical) and importation of medicinal products was issued which is valid for three years from date of inspection. These certificates can be traced in the EudraGMP database



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- 2.3. Manufacturing license and GMP permit granted by the local National Medicines Regulatory Authority (NMRA).

20-09-2024 by National Agency for The Safety Of Medicine And Health Products by a competent authority of France,
GMP Certificate No. 2024_HPF_FR_181 Manufacturing and packaging of General pharmaceuticals for human use non-sterile dosage form (Tablets, soft gelatin capsules, oral liquids and herbal products), quality control testing (Microbiological (non-sterility), chemical and physical) and importation of medicinal products was issued which is valid for three years from date of inspection. These certificates can be traced in the EudraGMP database

- 2.4. Valid GMP certificate issued by WHO listed authority and/or that from WHO prequalification and Regional Harmonization Initiatives/AMA (whichever is applicable) for inspection carried out within the past three years for production line(s) applied at TMDA.

Not applicable, see section 2.2 of this report

- 2.4.1. Name of SRA/WHO-PQ/RECs

National Agency for The Safety Of Medicine And Health Products

- 2.4.2. Dates of inspection
23rd June, 2023

- 2.4.3. Scope of inspection / List of compliant production line

General pharmaceuticals for human use inform of solid dosage form (tablets, capsules and oral liquids)

- 2.4.4. A confirmation by the senior QA representative that a full WLA audit covering the product(s) has been performed and all matters dealt with and attest to the authenticity of the information

Not provided but this can be waived since the manufacturing facility was inspected by stringent regulatory National Agency for The Safety of Medicine And Health Products and deemed GMP compliant in accordance with Art. 40 of Directive 2001/83/EC



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2.5. Regulatory Actions against the facility that were taken in the past three (3) years.

The facility confirmed that there were no high-risk market complaints for the past three years, it was also noted that there are no complaints received from the Tanzania Market for the products as well for the past three years.

2.6. PQR(s) of the concerned product(s) (If products have not been registered).

This is waived because the product of concern has been registered by TMDA, this implies that PQR was assessed during the dossier assessment

2.7. Real time and Accelerated Stability studies under Zone IVb conditions (*If products have not been registered*).

This is waived because the product of concern has been registered by TMDA, this implies that PQR was assessed during the dossier assessment

2.8. Review of Aseptic processing and filling validation protocols and reports (*for sterile products*).

This is waived because the manufacturing facility applied for and was GMP certified by SRA for manufacturing of hormonal products for human use in the form of tablets

2.9. Review of validation master plan; policy on validation qualification and calibration (If no product has been registered).

This is waived because the product of concern has been registered by TMDA, this implies that PQR was assessed during the dossier assessment

2.10. Market complaints in the last three years for products applied at TMDA

The facility confirmed that there were no high-risk market complaints for the past three years, it was also noted that there are no complaints received from the Tanzania Market for the products as well for the past three years.



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Part 3: Conclusion

Based on the desk assessment and evidence(s) provided Innothera Chouzy, Rue Rene Chantereau, 41150 Valloire-Sur-Cisse, France is considered to be operating at an acceptable level of compliance with the requirements of the Tanzania Food, Drugs and Cosmetics (Good Manufacturing Practice Enforcement) Regulations, 2018 for manufacturing of General pharmaceuticals for human use in form of non-sterile solid dosage form (Tablets, capsules and oral liquids).

This TPIR will remain valid until 22nd June, 2026, provided that the facility will remain compliant following any inspections conducted in the period.