

TMDA/DMD/MCIE/F/002

REV.#. 01



THE UNITED REPUBLIC OF TANZANIA
MINISTRY OF HEALTH



TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

FERRER INTERNACIONAL, S.A
TMDA PUBLIC GMP DESK ASSESSMENT REPORT

7th March, 2025



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Part 1: General information about the company

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| 1.1 Manufacturer's details | |
| Name of manufacturer/ Applicant | Ferrer Internacional, S.A. |
| 1.2 Inspected Site Details | |
| Name & physical address of inspected manufacturing site | Ferrer Internacional, S.A. C/Joan Buscallà, 1-9 08173, Sant Cugat del Vallès Spain Tel: + 34 935 044 000 Fax: + 34 93 674 20 72 Email: cdelared@ferrer.com |
| Name of Unit/ block/ workshop number inspected | Manufacturing, Packaging and Quality Control block for Human pharmaceutical Products |
| 1.3 Inspection details | |
| Date of desk assessment | 7 th March, 2025 |
| Date of last inspection by the WLA, WHO-PQ or EAC / SADC/AMA for production line applied at TMDA | The facility has been inspected by Health Authority of Russia-12-15 th February 2024 and Health Authority of Spain- 17-20/07/2023 |
| 1.4 Brief report of the activities undertaken at the site | |
| Summary of the activities performed at the site | Manufacturing, Packaging and Quality Control of medicinal products for human use and investigational medicinal products including: i. Sterile products in the form of Lyophilizates and small-volume liquids ii. Non-sterile products in the form of Hard gelatin capsules, tablets, powder, liquids for external and internal use, |



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| | semi-solids and suppositories |
| Production lines applied at TMDA | Tablets Capsules Solution for Injection (SVP) |

Part 2: Review of submitted documentary evidence

2.1. Site master file

The information provided conforms with the TMDA Regulations, Contents of the SMF were as follows: Cover page, general information, Quality management system, Personnel, Equipment, Documentation, Production, Quality control, distribution, complaint, defects and recall; Self-inspection.

2.2. Provide list of all regulatory inspections carried out in the past three (3) years.

This facility was inspected on 2023-07-17 by Generalitat De Catalunya by a competent authority of **Spain**, GMP Certificate No. ST-01-GMP-2024-0027 was issued which is valid for three years from date of inspection. This certificate can be traced in the EudraGMP database

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

The facility had valid manufacturing license issued by The Spanish Agency of Medicines and Medical Devices (AEMPS) for the manufacturing of human medicines and investigational medicinal products.

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.



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GMP Certificate number NCF/2361/001/CAT was issued by the competent authority of the Government of Catalonia (competent authority of Spain) on 22nd December 2023 and is valid for 3 years.

2.4.1. Name of WLA /WHO-PQ/RECs

Generalitat De Catalunya

2.4.2. Dates of inspection

Health Authority of Russia 12-15th February 2024 (Tablets and non-sterile liquid dosage forms) and 23rd to 25th October, 2023 (creams) and Health Authority of Spain- 17-20/07/2023

2.4.3. Scope of GMP certificates/ List of compliant production line

The scope of inspection included manufacturing, packaging and Quality control testing of:

- i. Sterile products (lyophilizes and small-volume liquids)
- ii. Non-sterile products including Hard gelatin capsules and tablets, liquids for external and internal use, semi-solids and suppositories

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.

The facility has registered several products in Tanzania. Considering that before a product is registered, a detailed assessment of the manufacturing and control processes is conducted this section can be waived. The documents submitted along with the GMP inspection report provided the evidence needed and thus it was accepted.



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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)*.

Reviewed reports have shown that the applicant has submitted sufficient information to assure that the manufacturing processes are capable of producing quality, safe and effective products consistently

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)*.

Since the products manufactured by this facility have been registered, this section was previously accessed during dossier evaluation and thus to avoid duplication of work, its assessment is waived

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

Since the products manufactured by this facility have been registered, this section was previously accessed during dossier evaluation and thus to avoid duplication of work, its assessment is waived

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

Ferrer Internacional S.A confirmed that no complaints have been received in the last 3 years from references included in the GMP renewal



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Part 3: Conclusion

Based on the desk assessment and evidence(s) provided by **Ferrer Internacional, S.A. C/Joan Buscallà, 1-9 08173, Sant Cugat del Vallès, Spain** 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 Pharmaceutical Formulations in form of tablets, capsules, oral solution and sterile solution for injection and Corticosteroids in form of cream**

This TPIR will remain valid until 6th March, 2027 provided that the facility will remain compliant following any inspections conducted in the period.