GENERAL QUALITY STATEMENT

In this statement we, Fermion Oy, confirm that our quality system complies with the requirements of ICHQ7 and European GMP guideline, Part II. We also confirm that the other relevant quality guidelines, as the ones listed in table 2 below, are followed.

This statement includes a list of the confirmations to the most common questions concerning Fermion's GMP and GDP compliance and quality issues.

This document has been signed in validated Documentum application by:

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Fermion Oy

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1. General information

Company Name	Fermion Oy
Headquarters	Fermion Oy Koivu-Mankkaan tie 6 A FI-02200 ESPOO, Finland DUNS: 401656850 DERN/FEI: 3003491490 OMS Organisation Id. / OMS Location Id.: ORG-100011508 / LOC-100020280
Manufacturing sites	
Hanko	Fermion Oy, Orioninkatu 2, FI-10960 Hanko Pohjoinen, Finland DUNS: 537993060 DERN/FEI: 3002807817 OMS Organisation Id. / OMS Location Id.: ORG-100011508 / LOC-100020981
Oulu	Fermion Oy, Lääketehtaantie 2, FI-90660 Oulu, Finland DUNS: 537994803 DERN/FEI: 3003340711 OMS Organisation Id. / OMS Location Id.: ORG-100011508 / LOC-100021038
Phone, all sites	+358 10 4261
Internet address	www.fermion.fi
Parent Company	Orion Corporation
Type of production	Non sterile APIs by chemical synthesis
Raw materials	Chemicals. No animal or human materials are used in the synthesis

Manufacturing steps	Materials management, synthesis, crystallisation, milling, packing, labelling, analysis by QC, release of APIs by QA, storage and distribution
Working schedule	24 h per day, 7 days per week About four weeks annual maintenance break in July-August

2. Guidance, GMP certificates and statements

GMP guidance followed	ICH Q7 Eudralex. The Rules Governing Medicinal Products in the European Union. Volume 4. Good Manufacturing Practice Medicinal Products for Human and Veterinary Use Part II: Basic Requirements for Active Substances used as Starting Materials
GDP guidance followed	Guidelines of 19 March 2015 on principles of Good Distribution Practice of active substances for medicinal products for human use Commission Implementing Regulation (EU) 2021/1280 of 2 August 2021 as regards measures on good distribution practice for active substances used as starting materials in veterinary medicinal products in accordance with Regulation (EU) 2019/6 of the European Parliament and of the Council
Other guidance	ICH, FDA and EMA guidance when applicable
GMP guidance implemented in	Quality Manual Standard Operating Procedures (SOPs)
GMP certificates	Link to EudraGMDP for GMP certificates can be found at: https://www.fermion.fi/who-we-are/quality-management/
Quality statements	General statements are available at: https://www.fermion.fi/who-we-are/quality-management/

3. Quality system

3.1. General controls and documentation
Issuance, approval, revision, superseding and withdrawal of all GXP critical documents are controlled with maintenance of revision histories.
Written procedures are in place for record management, retention and archiving.
SOP documents are periodically reviewed and updated. Procedures are in place to prevent use of invalid or obsolete documents.
When electronic signatures are used they are authenticated and secure.
GXP critical batch related records are retained for at least 3 years after the batches are completely distributed.
Procedures for documentation and evaluation of deviations are in place and critical deviations are investigated.
Procedures for documentation, evaluation and investigation of Out of Specifications are in place.
Procedures for documentation, evaluation and investigation of complaints, returns and recalls are in place.
CAPA system is in place to monitor implementation of Corrective and Preventive actions arising from audit observations, complaints, recalls, deviation and OOS investigations.
Procedures for reprocessing are in place and reprocessing is in accordance with DMF/CEP descriptions.
Reworking is a regulatory change and not allowed if the reworking process is not described in the DMF/CEP.
Annual Product Quality Reviews (PQR) are performed for all commercial APIs.
Quality Risk Management procedures are in place and in accordance with ICH Q9.
3.2. Quality Unit and its responsibilities
Quality Unit is independent of production. Quality Unit covers the responsibilities as follows, in accordance with ICH Q7:
• Maintaining and developing the Quality System and GMP procedures • Establishing a system to release or reject raw materials, intermediates, packaging and labelling materials • Approving SOPs which concern GXP critical matters • Approving specifications and master production instructions • Approving all procedures impacting the quality of intermediates and APIs • Making sure that self inspections (internal audits) are performed • Change Management (approving all changes that potentially impact on API quality) • Reviewing and approving validation protocols and reports

• Making sure that effective systems are used for maintaining and calibrating critical equipment • Controlling and monitoring all purchased and manufactured materials • Approving the material suppliers and intermediate and API contract manufacturers • Ensuring that materials are appropriately tested and the results are reported • Making decision for confirmed OOS and critical deviation investigations • Releasing or rejecting raw materials, packaging materials, intermediates and APIs • Reviewing completed batch production and laboratory control records of critical process steps before release of the API for distribution • Ensuring that quality related complaints are investigated and resolved • Making sure that there is stability data to support retest dates and storage conditions on APIs and/or intermediates • Making final decision for complaints, returns and recalls • Performing Product Quality Review (PQR) for all commercial APIs in which consistency of the manufacturing process is verified • Evaluating of PQR results and the need for corrective actions and/or revalidation
3.3. Inspections
Last regulatory inspections: Inspection history can be found in: list-of-inspections-at-fermion-oy.pdf
No warning letter has ever been received
Self inspections (Internal audits), covering all GXP critical areas GDP including, are conducted according to annual plans. Audit findings are documented and managed by CAPA system.
3.4. Change management
Change management procedures are in place including all quality related changes including documentation, impact analysis and risk assessment.
Customers are informed about changes that can potentially impact API quality and/or regulatory compliance
3.5. Personnel qualification
GMP training program is in place for all personnel, including temporary and third party workers, and training is documented. GMP training is required prior to participation in GMP regulated areas. Periodic compliance training is conducted for all employees working in GMP function.
Written job descriptions for all personnel working in GMP environment are in place.
Personnel hygiene instructions and protective devices requirements are in place.
Smoking, eating, drinking and chewing is not allowed in production facilities.

4. Facilities and equipment system

4.1. Facilities
Production facilities are multipurpose. Cross-contamination risk is managed by residual limits, equipment cleaning master records and cleaning validations.
Access is controlled to all facilities and unauthorized access to production, final handling and storage areas is prevented.
Facilities have been designed and constructed to facilitate cleaning, maintenance and API production and handling in a way to minimize potential contamination risk.
Production and final handling facilities have been qualified.
Production facilities are routinely maintained.
Computer systems used to control production are validated.
Written procedures are in place for cleaning/sanitation of the facilities including schedules, methods, equipment, cleaning materials and documentation of such activities.
Microbiological environmental controls are in place.
Pest control procedures are in place. They include general procedures to avoid pests and also traps and their controls and reporting.
Contamination risk is controlled.
No highly sensitizing materials, like penicillins, β-lactams, cephalosporins, or pesticides are manufactured in Fermion.
Materials of an infectious nature or pharmacological activity or toxicity, like certain steroids or cytotoxic anti-cancer agents, are produced in dedicated manufacturing areas. Cytotoxic anti-cancer agents are manufactured at Oulu site only.
Dedicated areas or other controls for the following activities in place: • Receipt, identification, sampling, and quarantine of incoming materials • Quarantine areas for unreleased or rejected intermediates and APIs • Sampling of intermediates and APIs • Storage of released materials • Production operations • Packaging and labelling operations • Laboratory operations
Raw materials and APIs are stored at the manufacturing site warehouses
Seasonal temperature mapping studies have been performed for API storage locations. Temperature is monitored continuously in the API warehouses.
There are separate areas for raw material sampling.

Where wooden pallets are used, only ISPM 15 Standard, heat treated wooden pallets are acceptable.
Washing and toilet facilities exist and are separate from production and final handling areas.
Instructions and systems for sewage and waste disposal are in place including sorting and collection of normal and chemical waste separately.
4.2. Utilities and lighting
All utilities that could impact on product quality (steam, gases, compressed air, and HVAC= heating, ventilation and air conditioning) are qualified and appropriately monitored.
Water used in production has been demonstrated to be suitable for its intended use Types of water used in production are: Tap (potable) water Purified water (RO water)
Specifications and analytical methods and written procedures for sampling and testing of water are in place.
Lighting is adequate.
4.3. Process equipment
Equipment qualification procedures are in place and all GXP critical equipment and instruments have been qualified.
Preventive maintenance and calibration for all GXP critical equipment and instruments are in place.
Equipment surfaces in contact with process components are not reactive, additive, or absorptive.
Equipment and processing lines are clearly identified.
Equipment cleaning procedures are in place including cleaning master batch record and documentation as cleaning batch records.
Equipment cleaning is validated.
Status of equipment is clearly indicated.
Equipment status and cleanliness is checked before starting a new batch.
Substances associated with the operation of equipment (heating fluids or coolants) are not in contact with raw materials, intermediates and APIs, so as to alter their quality beyond the established specifications.
Lubricants, which might be in product contact, are food grade.

5. Materials system

5.1. Supplier qualifications
Supplier qualification procedure for materials is in place and list of approved suppliers of materials exists. Materials are allowed to be purchased from qualified sources only.
QA organization is responsible for approval of material suppliers.
5.2. Incoming and other materials controls
Written procedures are in place for receipt, identification, handling, quarantine, storage, sampling, testing and approval or rejection of materials.
Raw material sampling procedures are in place and sampling is documented.
Incoming materials are analysed and released according to specifications before they are used. Or manufacturer's Certificate of Analysis is required for processing aids, hazardous or highly toxic raw materials that are not tested, showing that these raw materials conform to established specifications.
Water used in production has been demonstrated to be suitable for its intended use and systems for purified water have been validated.
Approval or rejection of incoming materials is recorded /documented.
FIFO principle (first-in/first-out) is used for picking materials for manufacturing processes.

6. Production system

6.1. Manufacturing procedures
A unique batch numbering system is in place (sequential seven digit number generated by the IT system) and all batches are fully traceable.
Critical manufacturing process steps are validated prospectively or in rare cases concurrently
Written and approved Master Batch Records are in place and properly controlled.
Production activities are recorded in Batch Records at the time of their performance.
All Batch related information is traceable and controlled.
Written procedures for control and monitoring of production processes are in place to ensure product quality and meeting the specifications.
Weight / quantity control is performed and documented.
Actual yield of product is compared to theoretical yield.
Critical steps are verified by other person or by barcode reader, and documented in batch records.
Failures and deviations in production processes are documented and critical ones investigated.
Computerized systems used in production are validated.

Data generated by computerized systems is protected and backed up.
Individual user identification codes and passwords are required for computerized systems.
Data Integrity requirements have been defined in the SOPs.
6.2. Recovered solvents
Written procedures and risk assessments for recycling of solvents are in place. Release specifications for recycled (distilled after recovery) solvents have been set. Recycling solvents are not used in the last API crystallization steps.

7. Packaging and labelling system

7.1. Container / Closures / Packaging components
Container / closures / packaging components have been specified.
Primary packaging material is certified to be food grade.
Containers are closed and tamper evidently sealed.
7.2. Labelling operations
Written instructions for labelling are in place including reconciling quantities of labels issued, used, returned and destroyed.
Standard information on API shipment containers is as follows: • Material number and name • Manufacturing site • Batch number • Manufacturing date • Retest date • Container / Number of package • Safety labels according to international safety regulations • Information concerning storage conditions, in case it is required by the nature of the API and/ or national regulations
Procedures are in place to check correctness of API delivery labels.

8. Laboratory control system

8.1. General controls
Written test procedures, specifications, and sampling plans for raw materials, reagents, solvents, starting materials, intermediates and APIs are in place.
Written procedures and protocols are in place to address laboratory operations including sample handling, data generation and control.
Laboratory facilities are separate from production facilities.
All analytical methods and standard procedures and controls are in place.
There is adequate number and type of equipment for intended use.
All pieces of laboratory equipment have been identified.
Calibration and maintenance programs for analytical instruments and equipment are in place and instruments are calibrated and maintained according to them. Calibrations are traceable to certified standards.
Computerized systems related for testing of materials are validated.
Data generated from computerized systems is protected and backed up.
Individual user identification codes and passwords are required for computerized systems.
Data Integrity requirements have been defined in SOPs.
Compendial reference standards are obtained from an officially recognized source.
Quality Unit is responsible for sampling procedures.
Retain samples are kept for all API batches one year after the retest period or for three years after distribution of the batch whichever is longer.
8.2. Testing of APIs
Impurity profile for each API has been defined, including on studies for potential DNA reactive impurities, nitrosamines impurities including, and control strategy has been developed.
All API batches are fully analyzed against the product specification.
All analytical methods used for testing are validated in accordance with ICH Q2(R1)
Analytical result and raw data for each batch are traceable and confirmed by complete analytical records of all tests
Chromatographic analytical raw data is restored.
System suitability test is included in chromatographic testing.
Stability testing programs and specifications for all APIs are in place.
Stability testing methods are stability indicating.
Stability testing is carried out according to ICH Q1 including packaging, storage conditions, and analysis points. Each year at least one API batch is taken into long-term stability study.
Stability chambers are qualified, calibrated and maintained per written procedures.
Out of Specification results are investigated and root causes and CAPAs are defined in case of confirmed critical OOS.

9. Good Distribution Practices (GDP)

Fermion has been granted Known Consignor (KC) status.
Qualified logistics partners having Known Consignor (KC) status are used and agreements with them are in place.
Vehicles for transportation are checked before loading and/or unloading to ensure that they are suitable for the intended purpose.
Distribution records are kept for each shipment and each API delivery supply chain is identifiable and fully traceable.
GDP procedures have been defined in SOPs and trained to personnel.
GDP risks have been formally evaluated for all commercial APIs and risks mitigited as needed.
If stability studies and stress testing shows a need for transportation in controlled conditions, such conditions are provided and monitored.
API packages are closed tamper evidently.
In API deliveries to customers, the principle is to choose safe and the shortest routes available and in accordance with the incoterms.

10. Data integrity

Fermion has procedures in place to ensure quality-relevant data is attributable, legible, contemporaneously recorded, original or a true copy, accurate, complete, consistent, enduring and available (ALCOA+); that it can be traced to its source and that it is readily available during regulatory inspections.
SOPs are in place for data integrity principles and policies, documentation and control of raw data, validity of computerized systems, computerized systems maintenance and upkeeping, and data protection.
All GMP documents have a version control, approval process and all changes are traceable.
All electronic systems used for data management are validated systems and changes managed through change management process.
Data generated by computerized systems is protected and backed up.
Procedures are in place for disaster recovery and restoring of data archieves.
When electronic signatures are used they are authenticated and secure.
Individual user identification codes and passwords are required for computerized systems.
Self inspection (internal audit) program have data integrity elements to be reviewed as part of the procedure.

General Quality Statement

Written by: Lindman Anneli

Date dd.mm.yyyy (UTC)	Justification	Electronically signed by
02.02.2026 14:37:43	Approved	Vartiainen Satu (satkat)