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GMP Inspection report

Inspected site(s):
Activities Carried out: <ul style="list-style-type: none"><input type="checkbox"/> Manufacture of Active Substance<input type="checkbox"/> Manufacture of Finished Medicinal Product Packaging<input type="checkbox"/> Importing<input type="checkbox"/> Laboratory Testing<input type="checkbox"/> Batch Control and Batch Release<input type="checkbox"/> Other:
Inspection date(s): .
Name of the inspector(s) <p style="text-align: center;">Vilmos Berényi</p> Organization: Name of expert / assessor (if applicable)
Short description of the company and the activities of the company
<input type="checkbox"/> Site master file was available before/during the inspection <ul style="list-style-type: none"><input type="radio"/> Date of the site master file:<input type="radio"/> Issued by: <input type="checkbox"/> SMF assessed, comments:
GMP-related recalls from the market of any product in the last 2 years.

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Date of previous inspection:

Major changes since the previous inspection:

Brief report of the inspection activities undertaken:

Scope of Inspection:

- Product related inspection (..... Active Substance)
- General GMP inspection
- Other:.....

Inspected area(s):

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Personnel met during the inspection:

Inspector's findings and observations:

- Quality Management
- Personnel
- Premises and Equipment
- Documentation
- Production
- Quality Control
- Contract Manufacture and Analysis
- Complaints and Product Recall
- Self Inspection
- Questions from the Assessment of the Application
- Investigation of Product Recall or Product Defect

Comments:

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E.1 Quality assurance

- (a) Quality system and documented quality policy of the manufacturer, e.g. as described in the quality manual.
- (b) Responsibilities are clearly defined
- (c) QP – release and rejection scheme, OOS- and change control or deviation-investigations
- (d) Quality Manual, SMF, regulatory status, certificates, organization, key personnel, complaints, recalls,
- (e) supplier evaluation and purchase

E.2 Organization and personnel

- (a) Organizational chart showing the arrangements for quality assurance, including production and quality control.
- (b) Qualifications, experience and responsibilities of key personnel.
- (c) Outline of arrangements for basic and in-service training and method of keeping records.
- (d) Health requirements for personnel engaged in production.
- (e) Personnel hygiene requirements, including clothing.

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E.3 Premises

- (a) Manufacturing areas (design, location etc.) used e.g. for storage and manufacturing (e.g. weighing, production, packaging) and flow of personnel and material.
- (b) Special areas for the handling of highly toxic, hazardous and sensitizing materials.
- (c) Nature of construction and finishes.
- (d) Systems such as drainage, ventilation, air conditioning, and supply of steam and gas. Detailed description of critical areas with potential risks of contamination and cross-contamination.
- (e) Classification of the rooms used for the manufacture of products, including clean rooms.
- (f) Water systems.
- (g) Planned preventative maintenance programme.
- (h) Qualification of premises and systems as appropriate.

E.4 Equipment

- (a) Design, location and adaptation of equipment used in production and control laboratories.
- (b) Planned preventative maintenance programmes for equipment and records.
- (c) Qualification and calibration, including records.

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E.5 Materials

- (a) Sourcing of materials.
- (b) Control, storage and handling of materials, including:
 - starting materials;
 - packaging materials;
 - intermediate and bulk products;
 - finished products;
 - returned and rejected materials;
 - reagents and culture media;
 - reference standards;
 - waste material.

E.6 Good practices in production

- (a) Transport, handling and use of starting materials, packaging materials, and bulk and finished products.
- (b) Production operations and important parameters (e.g. sampling, quarantine, weighing, process operations and conditions, acceptance limits, IPC).
- (c) Validation (e.g. process).
- (d) Change control and deviation reporting.
- (e) Dedicated or multi-purpose production line

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E.7 Quality control

- (a) Activities of quality control (including quarantine control, sampling, chemical and microbial analysis).
- (b) Organization and personnel.
- (c) Premises.
- (d) Equipment and instrumentation.
- (e) Materials.
- (f) Documentation (e.g. specifications, procedures, reports, records)
- (g) Path for samples in laboratory, sampling, storage of samples, measuring devices, measuring and records, standards, control samples

E.8 Sanitation and hygiene

- (a) Procedures for sanitation and/or cleaning (e.g. of premises and equipment) and records.
- (b) Personal hygiene.

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E.9 Validation

- (a) Validation master plan.
- (b) Validation and qualification protocols and reports for qualification and validation (e.g. of premises, systems, equipment, process, computer, cleaning, analytical methods).
- (c) Stages of validation.
- (d) Types of validation.

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E.10 Documentation

- (a) Documentation (e.g. specifications, procedures, records, protocols, reports).
- (b) Preparation, revision and distribution of documentation.
- (c) Reports on production, quality control (including environmental control), engineering and other relevant areas.
- (d) Computerised systems, records and data handling
- (e) PRODUCT-related specific documentation (BMR, records, analytical specs, SOPs, stability tests, validation and DMF for API)
- (f) DMF – change control / last upgrading/ stability data refreshment
- (g) CEP application?

E.11 Complaints

- (a) Procedure, records and investigation.

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E.12 Product recalls

- (a) Procedure, records and investigation.

E.13 Contract production and analysis

- (a) Responsibilities of contract giver.
- (b) Responsibilities of contract acceptor.
- (c) Contract (containing clearly defined responsibilities).
- (d) GMP compliance of the contract acceptor (initial assessment and continued compliance audited at regular intervals).

Marketing contract, declaration for registered synthesis route

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E.14 Self-inspection and quality audits

- (a) Procedure, programme and compliance.
- (b) Items for self-inspection.
- (c) Self-inspection team.
- (d) Frequency of self-inspection.
- (e) Self-inspection report.
- (f) Follow-up action.
- (g) Quality audit.
- (h) Suppliers' audits.

Annexes attached:

Comments:

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Summary of Deficiencies:

Definition of Significant Deficiencies

1. **CRITICAL DEFICIENCY:** A deficiency which has produced, or leads to a significant risk of producing either a product which is harmful to the human or veterinary patient or a product which could result in a harmful residue in a food producing animal.
2. **OTHER SIGNIFICANT DEFICIENCY:** A non-critical deficiency, which has produced or may produce a product, which does not comply with its marketing authorisation.
 - or which indicates a significant deviation from EU Good Manufacturing Practice.
 - or which indicates a significant deviation from the terms of the manufacturing authorisation.
 - or which indicates a failure to carry out satisfactory procedures for release of batches
 - or a failure of the Qualified Person to fulfil his legal duties.

Note: Several smaller related deficiencies, none of which on their own may be significant, may together represent a significant deficiency and should be reported as such

Summary and conclusions:

Inspected company operates in accordance with the EU GMP Rules.

Name(s) **Vilmos Berényi** **inspector** **company**

Signatures(s)

Organisation(s)

Date:

Name(s) **inspector** **company**

Signatures(s)

Organisation(s)

Date:

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