WIL-ZONE CONSULTING

GMP Inspection report

Inspected site(s):
Activities Carried out: ❑ Manufacture of Active Substance ❑ Manufacture of Finished Medicinal Product Packaging ❑ Importing ❑ Laboratory Testing ❑ Batch Control and Batch Release ❑ Other: ……..
Inspection date(s): .
Name of the inspector(s) **Vilmos Berényi** **Organization:** **Name of expert / assessor (if applicable)**
Short description of the company and the activities of the company
❑ **Site master file was available before/during the inspection** o **Date of the site master file:** o **Issued by:** ❑ **SMF assessed, comments:**
GMP-related recalls from the market of any product in the last 2 years.

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):

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:

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.

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.

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

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.

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.

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.

E.12 Product recalls

(a) Procedure, records and investigation.

E.13 Contract production and analysis

(a) Responsibilities of contract giver.
(b) Responsibilities of contract accepter.
(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

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:

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)

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