Annex 6
Guidance on Good Manufacturing Practices (GMP): inspection report

When a site at which pharmaceutical products are manufactured is inspected, the inspector(s) responsible must draw up a report containing the items listed below. Where relevant, the appropriate section of the WHO GMP (Annex 4) is indicated.

A. Manufacturer
   (a) Name of inspected manufacturer.
   (b) Address of inspected manufacturer (including telephone, fax, email and 24-hour telephone numbers).
   (c) Address of manufacturing site if different from that given above.
   (d) Site number (e.g. site master file or number allocated by the responsible authority).
   (e) Manufacturing licence number, if applicable.
   (f) Activities.
   (g) Pharmaceutical products manufactured.
   (h) Key personnel.
   (i) Key persons met.

B. Inspection details
   (a) Date(s) of inspection(s).
   (b) Previous inspection date.
   (c) Type of inspection.
   (d) Scope of inspection.
   (e) The regulatory authority.
   (f) GMP guidelines used for assessing compliance.
   (g) For foreign inspections state whether, the national regulatory authority (NRA) of the country where the inspection took place was informed and whether it took part in the inspection.
   (h) Brief report of inspection activities undertaken.
   (i) Samples taken and results obtained.
   (j) Assessment of the site master file.
   (k) GMP-related recalls from the market of any product in the last 2 years.

C. Inspector(s)
   (a) Name(s) of inspector(s) and accompanying experts.
D. **Introduction**

(a) Brief summary of the manufacturing activities.
(b) Other manufacturing activities carried out on the site (e.g. manufacture of cosmetics, research and development).
(c) Use of outside scientific, analytical, or other technical assistance in manufacture and quality control.
(d) Brief description of the quality management system of the firm responsible for manufacture. Reference can be made to a site master file if one is available.

E. **Observations**

*The observations made during the inspection that are considered to be non-compliant with GMP should be listed. Where positive observations are included in the report, clear distinction should be made between “positive” and “non-compliant”. Non-compliant observations can be classified, e.g. as “critical”, “major” and “minor” if the Member State concerned has defined these terms. The date by which corrective action and completion are requested in accordance with the policy of the national regulatory authority should be given.*

E.1 **Quality assurance (see WHO GMP, section 1)**

(a) Quality system and documented quality policy of the manufacturer, e.g. as described in the quality manual.

E.2 **Organization and personnel (see WHO GMP, section 9)**

(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 (see WHO GMP, section 12)**

(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 (see WHO GMP, section 13)**

(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 (see WHO GMP, section 14)**

(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 (see WHO GMP, section 16)**

(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).

(c) Validation (e.g. process).

(d) Change control and deviation reporting.

E.7 **Quality control (see WHO GMP, section 17)**

(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).
E.8 **Sanitation and hygiene (see WHO GMP, section 3)**
(a) Procedures for sanitation and/or cleaning (e.g. of premises and equipment) and records.
(b) Personal hygiene.

E.9 **Validation (see WHO GMP, section 4)**
(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 (see WHO GMP, section 15)**
(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.

E.11 **Complaints (see WHO GMP, section 5)**
(a) Procedure, records and investigation.

E.12 **Product recalls (see WHO GMP, section 6)**
(a) Procedure, records and investigation.

E.13 **Contract production and analysis (see WHO GMP, section 7)**
(a) Responsibilities of contract giver.
(b) Responsibilities of contract accepter.
(c) Contract (containing clearly defined responsibilities).
(d) GMP compliance of the contract accepter (initial assessment and continued compliance audited at regular intervals).

E.14 **Self-inspection and quality audits (see WHO GMP, section 8)**
(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.
F. **Summary**
   Brief summary of the findings, and recommendations (where applicable).

G. **Conclusions**
   A statement regarding the GMP status.
   
   Name: ___________  Signature:___________  Date: __________