VMD Template
Deficiency Report

Inspected site:

Any business Ltd
Unit 1
Industrial Estate,
Woodbridge,
Boxshire,
BO3 1AT

Tel: 0123 123 1234
Fax: 0123 123 1235

Activities carried out: *(Select appropriate activities from those listed below)*

Manufacture of finished products
Sterile
Non-sterile
Biologicals
Sterilisation of excipient, active substance or medicinal product
Primary packaging
Secondary packaging
Quality control testing
Importing
Batch certification
Storage and distribution
Manufacture of active substance
Other _____

Inspection date: *25th December 2009*

Inspectors:

Inspector A & B
Veterinary Medicines Directorate
United Kingdom

References: ManA 12345
(enter appropriate manufacturing classification: AVA, NFFABA, ESCC, Cascade, Schedule 6)

Introduction:

For the company and facility under inspection add:

- *Brief company and site history*
- *List or summarise authorised products*
- *List products manufactured under contract*
- *Major changes since the last inspection*

For inspections in non-EEA countries, it should be stated whether the national Competent Authority of the country took part.

Brief report of the inspection activities undertaken:

Scope of inspection:

This was a scheduled inspection in line with the VMD's risk based inspection programme to ensure that manufacture of VMPs at company name, location was compliant with the requirements defined in Eudralex Volume 4: Good Manufacturing Practice (GMP) Guidelines.

Inspected facilities:

Warehouse
Production Building
QC laboratory

Inspected systems and documentation:

- Manufacturing Authorisation
- Site Master File (SMF)
- Quality Management System (QMS) and documentation hierarchy
- Product Quality Review (PQR)
- Change Management, Deviations, (Non Conformance) reporting
- Batch Manufacturing and Packaging Records
- Equipment validation and calibration
- Warehouse and Storage
- Technical Agreements/Contracts
- Complaints and Recall
- Self-inspection

Specific areas and topics which were not inspected:

(List issues which require detailed attention at next inspection)

Key personnel met during the inspection:

John Smith	Site Director
Alan Smith	Qualified Person
Colin Smith	QC Manager

Follow up of inspection findings from the last inspection:

The inspection report from the previous inspection was available. A number of deficiencies were raised during the course of the last inspection and the company had responded with action plans to address these issues. During the course of the current inspection it was noted that issues raised previously had largely been addressed. Repeat observations are highlighted in the text below.

Inspectors' findings and observations:

Note: References in parentheses refer to the relevant points in *"Eudralex Volume 4: Good Manufacturing Practice"*.

Summary of deficiencies: *List all deficiencies even if corrective action has taken place straight away.*

1. Critical deficiencies:

'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. Major deficiencies:

'A non-critical deficiency which has produced or may produce a product:

- which does not comply with its MA
- which indicates a major deviation from EU Good Manufacturing Practice
- which indicates a major deviation from the terms of the manufacturing authorisation
- which indicates a failure to carry out satisfactory procedures for release of batches or (within EU) a failure of the QP to fulfil his legal duties
- a combination of several "other" deficiencies, none of which on their own may be major, but which may together represent a major deficiency and should be explained and reported as such.'

Pharmaceutical quality system

2.1 The PQS was deficient in that (*GMP reference* Chapter 1 – 1.1):

2.2.1 (*Enter deficiency details)*
2.2.2 (*Enter deficiency details)*

3. Other deficiencies:

'A deficiency, which cannot be classified as either critical or major, but which indicates a departure from Good Manufacturing Practice. (A deficiency may be "other" either because it is judged as minor or because there is insufficient information to classify it as a major or critical).'

Personnel

3.1 Personnel practices were unsatisfactory in that (Chapter 2 – 2.8);

3.1.1 (*Enter deficiency details*).

Premises and Equipment

3.2 Premises and equipment were unsatisfactory in that (Chapter 3 - 3.4);

3.2.1 (*Enter deficiency details*).

(Enter other deficiencies under the appropriate remaining section 4 to 9 headings)

4. Observations and Comments

4.1 *(Enter issues that cannot be classified as deficiencies)*

Reviewed by
Inspector B

Inspector A
GMP Inspector
Veterinary Medicines Directorate

Distribution: Any business Ltd., VMD