VMD TEMPLATE

GMP Inspection Report

Inspected site: **[Name of business]**

[Address line 1]
Address line 2
Address line 3
County
Post Code]

Tel:
Fax:

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:

Inspectors: Inspector A
Inspector B
Veterinary Medicines Directorate

References: ManA No.
(enter appropriate manufacturing classification: AVA, NFFABA, ESCC, Cascade, Schedule 6)

Introduction

As per deficiency report.

Brief report of the inspection activities undertaken

Scope of inspection: As per deficiency report

Inspected facilities: As per deficiency report

Inspected systems and documentation: As per deficiency report

Specific areas and topics which were not inspected: As per deficiency report

Key personnel met during the inspection

As per deficiency report.

Follow up of inspection findings from the last inspection: As per deficiency report.

Inspectors' findings and observations

A/ Pharmaceutical quality system

Describe the pharmaceutical quality system structure and functionality.
Describe the rationale behind cited deficiencies and recommendations.

B/ Personnel

Describe personnel organisation, experience and approach to training.
Describe the rationale behind cited deficiencies and recommendations.

C/ Premises and equipment

Describe setting, condition and fabric of premises.
Describe equipment used and cleanliness, fit for purposeness and validation/calibration
Describe security, pest control and other product impact processes.
Describe the rationale behind cited deficiencies and recommendations.

D/ Documentation

Describe organisation and functionality and documentation reviewed
Describe the rationale behind cited deficiencies and recommendations.

E/ Production

Describe production processes and controls.
Describe the rationale behind cited deficiencies and recommendations.

F/ Quality control

Describe QC area and key processes.
Describe starting material controls and finished product release processes.
Describe the rationale behind cited deficiencies and recommendations.

G/ Outsourced activities

Describe associated outsourced activities.
Describe the rationale behind cited deficiencies and recommendations.

H/ Complaints and recall

Describe complaints and recall processes.
Describe the rationale behind cited deficiencies and recommendations.

I/ Self Inspection

Describe self-inspection process.
Confirm schedule is in place and current.
Describe the rationale behind cited deficiencies and recommendations.

J/ Distribution and Shipment

e.g. Compliance with GDP. Shipping validation

K/ Questions raised relating to the assessment of a MA

e.g. Pre-authorisation inspections.

L/ Other specific issues identified

e.g. Relevant future changes announced by company.

M/ Site master file

Assessment of SMF if any; date of SMF.

N/ Miscellaneous

Samples taken.

Annexes attached: *List of any annexes attached.*

Note: References in parentheses refer to the relevant points in "*Eudralex Volume 4: Medicinal Products for Human and Veterinary Use: Good Manufacturing Practice".*

Summary of deficiencies

1 Critical deficiencies

As per deficiency report.

Company response to each deficiency should be inserted in the report under the deficiency.

2 Major deficiencies

As per deficiency report.

Company response to each deficiency should be inserted in the report under the deficiency.

.3 Other deficiencies

As per deficiency report.

Company response to each deficiency should be inserted in the report under the deficiency.

4 Observations and Comments

As per deficiency report.

Company response to each deficiency should be inserted in the report under the deficiency.

Recommendation:

The company have submitted satisfactory responses to the deficiencies raised above; thus the facilities, systems and procedures in place are considered to be in compliance with the requirements of GMP. The inspection frequency detailed below will be subject to review should there be any change in the circumstances of the company or the veterinary products manufactured.

Inspection Findings	**GMP Compliance Rating** *Poor = 1 critical/ ≥ 6 Major* *Acceptable = <6 major* *Good = 0 major*	**Maximum Inspection Interval** *Poor = 12 month* *Acceptable = 24 month* *Good = 33 month*	**Comments**
? Critical ? Major ? Other	Poor/Acceptable/Good (*delete as appropriate)*	12/24/33 *(delete as appropriate)*	Insert 'None' or rationale for bespoke frequency

Conclusions:

The facilities, systems and procedures in place at this site continue to be in compliance with the requirements of GMP. The Manufacturing Authorisation continues to be supported and the inspection is closed out. *(omit for overseas sites and reword for new sites).*

Inspector A
GMP Inspector
Veterinary Medicines Directorate

Reviewed by
Inspector B

Distribution: Name of business, VMD