SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY

GUIDELINES ON INSPECTIONS INVOLVING THE GMP INSPECTORS

This document has been prepared to serve as guidance about the GMP Inspectors responsible for performing inspections for compliance with current Good Manufacturing Principles asserted to by Pharmaceutical Medicine Manufacturers as prescribed by South African Health Products Regulatory Authority. SAHPRA is committed to ensure that all medicines that are registered are of the required quality, safety and efficacy.

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Version 1	Date of implementation	August 2006

THE CHIEF EXECUTIVE OFFICER (CEO)

1. INTRODUCTION

South African Health Products Regulatory Authority (SAHPRA) is a statutory body, appointed by the Minister of Health to register medicines, and to ensure that these medicines are of quality, safe and efficacious. Medicines registered by SAHPRA, should, during its entire life cycle, comply with the information that has been evaluated and approved by SAHPRA.

Regular inspections are performed at the applicant/manufacturer of such medicines by inspectors appointed by the Chief Executive Officer in order to ensure compliance with quality control and Manufacturing Principles (GMP) as well as compliance with the registration dossier.

Inspections may be performed as part of a routine GMP schedule, or specifically as a compliance or concise inspection.

All GMP inspections are carried out in accordance with the approved procedure to ensure compliance with the SA Guide to GMP, PIC/S guidelines on GMP and WHO Guide to GMP.

Inspections may be announced or unannounced.

Inspections of each site are carried out every two to three years depending on the risk associated with the products manufactured at the relevant site.

The GMP inspectors have extensive practical experience in the manufacture and quality assurance of medicines. In addition, advisory committee members of South African Health Products Regulatory Authority may be called upon to provide technical assistance during the audits.

Once a site has been found to comply with cGMP, South African Health Products Regulatory Authority l may issue a licence in terms of the provisions of Section 22C(1)(b) of the Medicines and Related Substances Act, 1965 (Act 101 of 1965).

2. ROLE OF THE GMP INSPECTORS

The role of the GMP inspectors includes:

- GMP inspections and licensing of South African manufacturers of medicines;
- GMP inspections and approval of overseas manufacturers supplying medicines to South Africa;
- Special inspections to investigate product complaints, problem reports and recalls of medicine;
- Revision of the SA Guide to GMP to reflect changes in technology, national and international requirements;
- Verification of GMP compliance for certification for medicines to be exported;
- Manage and processing of licences and GMP certificates;
- Performance of pre-registration inspections on any medicine dossier received by SAHPRA to verify compliance prior to product registration.

3. HOW INSPECTION IS CONDUCTED

An inspection is conducted covering the following areas at the manufacturing site.

Applicant Inspection	Plant Inspection
• Assessment of the SMF • Assessment of the Quality Manual • Assessment of the Validation Master Plan, Protocols and Reports • Assessment of Contracts • Master Documents and Specifications • Annual Product Review • Standard Operating Procedure	• Water system • Receiving area • Warehouse • Sampling area • Dispensary areas • Production areas • Quality Control laboratories • HVAC systems • Documentation including SOP's • Validation Master Plan, Protocols and Reports • Assessment of the Quality Manual • Assessment of Contracts • Annual Product Review • Master Documents and Specifications

After completion of the inspection, an inspection report is written and sent to the inspected company within thirty (30) days of the inspections.

The Company should respond in writing to the office of the Chief Executive Officer (CEO) within thirty (30) days from the date of the inspection report. Supportive documentation as proof of corrective action of each negative observation should be submitted. An inspection fee as prescribed by the Regulations to the Medicines and Related Substances Act, 1965 is payable to the Chief Executive Officer (CEO).

4. UPDATE HISTORY

Date	Reason for update	Version & Publication
Nov2019	Authority: "MCC" to "SAHPRA" Authority Logo: "MCC Logo" to "SAHPRA Logo" Council to SAHPRA Registrar of Medicines to the Chief Executive Officer (CEO) Director-General to CEO Timelines amendments/changes	v1.2 November 2019