

CERTIFICATE OF ACCREDITATION

In terms of section 22(2) (b) of the Accreditation for Conformity Assessment, Calibration and Good Laboratory Practice Act, 2006 (Act 19 of 2006), read with sections 23(1), (2) and (3) of the said Act, I hereby certify that:-

MEDICINES CONTROL AUTHORITY OF ZIMBABWE

Facility Accreditation Number: **P0004**

is a South African National Accreditation System accredited Testing Laboratory provided that all SANAS conditions and requirements are complied with

This certificate is valid as per the scope on the accompanying schedule of accreditation Annexure "A", bearing the above accreditation number for

CHEMICAL ANALYSIS AND MEDICAL DEVICES

The facility is accredited in accordance with the recognised International Standard

ISO/IEC 17025:2005

The accreditation demonstrates technical competency for a defined scope and the operation of a quality management system

While this certificate remains valid, the Accredited Facility named above is authorised to use the relevant SANAS accreditation symbol to issue facility reports and/or certificates

Mr R Josias
Acting Chief Executive Officer

Effective Date: 30 April 2010
Certificate Expires: 29 April 2015

ANNEXURE A

SCHEDULE OF ACCREDITATION

Testing Laboratory Number: P0004

Permanent Address of Laboratory: Medicines Control Authority of Zimbabwe 106 Baines Avenue Harare Zimbabwe		Management Signatory: : Ms G N Mahlangu	
Postal Address: P O Box 10559 Harare Zimbabwe		Technical Signatories: : Mr T A Gonho (Medical Devices) : Ms N Matshitse (Medical Devices) : Mr A Maqolo (Medical Devices) : Mr B Mudyawabikwa (HPLC) : Mrs B Dube (HPLC)	
Tel : 263-4-736981-5 Fax : 263-4-736980 E-mail : mcaz@mcaz.co.zw web : www.mcaz.co.zw		Nominated Representative : Mr PN Ndanga Issue No. : 01 Date of Issue : 30 April 2010 Expiry Date : 29 April 2015	
Sample Type/ Materials/ Products Tested	Types of Tests / Properties Measured, Range of Measurement	Standard Specifications, Equipment/Technique Used	
LABORATORY SERVICES UNIT: Medicines (pharmaceutical raw materials and finished products)	TECHNIQUE Quantitative and Qualitative Analysis of Pharmaceutical Formulations by High Performance liquid Chromatography (HPLC UV-Vis detection). <u>Tests:</u> <ol style="list-style-type: none"> i. Identification ii. Assay iii. Dissolution iv. Uniformity of Content v. Decomposition products and related substances 	<ol style="list-style-type: none"> 1. Customer Methods 2. International Compendia, such as: <ul style="list-style-type: none"> - United States Pharmacopoeia - British Pharmacopoeia - European Pharmacopoeia - International Pharmacopoeia 3. Documented in-house Standard Operating Procedure 	
MEDICAL DEVICES UNIT: Male rubber latex condoms	Airburst Testing of Condoms Package Seal Integrity on condom pieces Determination of pinhole and other defects Measurement of condom length, thickness and width	SOP: MD-MT 001 SOP: MD-MT 002 SOP: MD-MT 003 SOP: MD-MT 004 SOP: MD-MT 005 SOP: MD-MT 006	

Original date of accreditation: 30 April 2010

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ISSUED BY THE SOUTH AFRICAN NATIONAL ACCREDITATION SYSTEM

Field Manager