



## **Drug Quality Control Laboratories**



**World Health Organization  
Regional Office for Africa  
Harare, Zimbabwe**



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# PREFACE

The Essential Drugs Programme of the WHO Regional Office for Africa (WHO/AFRO) aims at assisting Member States in ensuring that the majority of the population has access to good quality essential drugs at affordable cost through the implementation of national drug policies.

The regular supply of effective and good quality drugs at affordable cost is one of the essential components of the Primary Health Care approach for achieving the global goal of Health for All.

To ensure that the drugs being used in the Region are effective, safe and of good quality, it is necessary for the countries to have drug regulatory authorities supported by quality control laboratories. Such a system is rarely found in practice, particularly in the developing countries, as it would require the existence of an adequate number of qualified staff, funds and infrastructure.

In the African Region, not all the countries are able to control the quality of the drugs circulating in their markets. Most countries do not have national quality control laboratories, and where they exist, they often lack the necessary material, financial and human resources, and do not operate independently.

In view of the above and because of the emergence of problems associated with the circulation of substandard drugs in the Region, the WHO Regional Office for Africa, in consultation with Member States of the Region, decided to create regional drug quality control laboratories by supporting, technically and financially, selected national drug control laboratories. As a result, the drug quality control laboratories of Cameroon, Ghana, Niger and Zimbabwe were raised to the status of Regional Drug Quality Control Laboratories (RDQCLs) between 1985 and 1991.

In September 1993, WHO carried out an assessment of the functioning of the four laboratories. In November 1993, it organized a regional meeting in Niamey (Niger) to discuss and examine ways of optimizing the use of the activities carried out by the laboratories with a view to assuring the quality of drugs circulating in the African Region. From the discussions of the meeting

and the results of the assessment carried out and presented at the meeting, it was clear that the RDQCLs were being underutilized considering their status as regional laboratories. The major problems contributing to this situation were identified as:

- absence of a proper legal base and autonomy;
- poor linkage with drug regulatory authorities;
- lack of proper management, technical capacities, and human and material resources; and
- absence of an exchange system for drug quality information.

The participants at the Niamey meeting made recommendations to the RDQCLs, to the national health authorities in the African Region and to WHO with a view to ensuring the optimal utilization of RDQCLs.

In October 1994, a working group of African drug quality control experts met in Brazzaville to examine ways of implementing the Niamey recommendations, in particular those recommendations to WHO, in order to optimize the use of the RDQCLs. The working group came up with four specific activities and detailed implementation plans:

- publication of an information brochure on the RDQCLs;
- publication of a bulletin on drug quality control;
- financial support for quality control of drugs from Member States of the African Region;
- training of drug quality control technicians.

In September 1997, the African Drug Regulatory Authorities Network (AFDRAN) met in Harare, Zimbabwe. One of the objectives of the meeting was to examine the level of implementation of the four activities adopted by the group of experts that met in Brazzaville in October 1994. The participants at the meeting noted the following facts during their discussions:

- the information brochure on the RDQCLs was published by WHO/AFRO in both English and French and the two versions were widely disseminated; a recommendation was made to WHO/AFRO to publish

- a second version of the brochure, adding to the RDQCLs, national drug quality control laboratories (NDQCLs) and the collaborating centres involved in drug quality control;
- no bulletin on quality control of drugs was published by the officials appointed mainly because of communication problems and changes of focal points of the activity. It was recommended to WHO to provide support to AFDRAN in the publication of the bulletin;
  - WHO made 20 000 American dollars available to Member States of the African Region to cover the cost of analysing 400 batches of drugs in the RDQCLs. The funds were not completely utilized. All the samples were analysed by the Niger and Zimbabwe laboratories. WHO was entrusted with the responsibility of finding out, in collaboration with the national authorities, the reasons why the Cameroon and Ghana laboratories did not participate in this initiative;
  - the structured training of technicians in the RDQCLs was not launched, except for specific refresher courses organized at the Niger laboratory. However, the Potchefstroom drug quality assurance collaborating centre in South Africa was able to train technicians from Eritrea. It was recommended to WHO to provide support to the RDQCLs, the NDQCLs and the collaborating centre in the identification of training needs, the design of training modules and the provision of training;
  - after the meeting, the cost of analysing samples under the WHO project was increased from USD50 to USD150 while awaiting the results of a detailed study on the structure of prices of reagents and reference substances.

This brochure aims to make the RDQCLs, the NDQCLs (those which have sent to us information concerning them) and the collaborating centre for drug quality assurance better known to all Member States of the African Region and to other potential users of their services. For each laboratory, the brochure provides the mailing address, the telephone, fax and telex numbers, a brief background indicating equipment available, tests performed, sampling procedure and time required for carrying out certain tests or group of tests. Information is also given on how to package and dispatch samples.

The WHO Regional Office for Africa is appealing to all Member States to forward to us all information on the laboratories in the countries so that it can be included in the next edition of the brochure.

For further information concerning the content of the brochure, contact the laboratories concerned or:

The Regional Director  
WHO Regional Office for Africa  
Attention: Dr Moses Chisale  
Regional Advisor  
Essential Drugs Programme

Parirenyatwa Hospital, Ward C,  
Box BE 773, Belvedere  
Harare, Zimbabwe  
Tel: 263 4 703684/703580/1 321 733 9355  
Fax: 263 4 791214/1 321 733 9160  
E-mail: [chisalem@whoafr.org](mailto:chisalem@whoafr.org)



# DEFINITIONS

## **NATIONAL DRUG QUALITY CONTROL LABORATORY (NDQCL)**

The main tasks assigned to the NDQCL are:

- assist the National Drug Registration Service and the Drug Inspection Service;
- assist central medical stores in controlling the quality of their supplies;
- develop and implement a plan for the continued training of the technicians of the laboratory;
- develop a quality assurance policy.

## **REGIONAL DRUG QUALITY CONTROL LABORATORY (RDQCL)**

In addition to the tasks assigned to the NDQCL, the RDQCL can serve as:

- reference centre for the NDQCL;
- training centre;
- distribution centre for secondary reference substances.

The RDQCL should be part of an international inter-laboratory collaboration network. It should also have a **QUALITY MANUAL**.

## **WHO COLLABORATING CENTRE**

The WHO Collaborating Centre should assist the NDQCLs and RDQCLs in:

- training specialized staff;
- validating analytical methods;
- training in quality assurance; and
- maintaining equipment.

It should also be able to:

- disseminate technical documentation; and
- organize inter-laboratory collaboration.

## **GENERAL INFORMATION**

The following information is necessary to access the services of the different laboratories:

### **Sampling procedure**

Samples are taken from one and the same batch. A batch is defined as a quantity of raw material, packaging article or product manufactured in an operation or a series of operations in a way that such quantity can be considered as homogenous.

### **Size of samples to be taken from each batch**

Tablets/capsules	:	60-100 pieces
Suppositories/ovules	:	20 pieces
Powders/sachets	:	20 pieces
Injectable ampoules	:	20 pieces
Injectable vials	:	10 pieces
Eye - drops	:	6 pieces
Syrups	:	5 pieces
IV fluids	:	6 pieces

### **Dispatch of samples**

Samples to be analysed should be properly packaged and should each bear:

- international non proprietary name of the product;
- dosage;
- batch number; and
- expiry date.

The samples should be dispatched to the laboratory by the fastest means (EMS, DHL, etc).

For further information, contact the laboratories concerned or:

The WHO Regional Office for Africa

Essential Drugs Programme

Attention: Dr Moses Chisale

Tel: 263 4 70 3684/703580/1 321 733 9355

Fax: 1 321 733 9160

E-mail: [chisalem@whoafr.org](mailto:chisalem@whoafr.org)



# NATIONAL DRUG QUALITY CONTROL LABORATORIES

## ALGERIA

**1. Name:**

National Drug Quality Control Laboratory  
(under the Ministry of Health)

**2. Address:**

Polyclinique AHMED AROUA  
Rond Point SIDI YAHIA HYDRA, ALGIERS  
Telephone: (213) 2.59.10.06 or 2.59.14.97  
Fax: (213) 2.60.54.96  
E-mail:

**3. Head of laboratory:**

Pr Mansouri Mohamed Benslimane,  
Director-General

**4. Date of establishment:**

Decree No.93-140 of 14 June 1993

**5. Legal status:**

The National Drug Quality Control Laboratory is an administrative public establishment, with legal personality and financial autonomy, placed under the supervision of the Ministry of Health and comprising:

- the central administration of the National Drug Quality Control Laboratory, Polyclinique Ahmed Aroua, Rond Point Sidi Yahia Hydra.

**Specialized laboratories:**

- Physico-Chemical Control Laboratory, Chemin El-Dakr El-Biar; and
- Parnet Pharmaco-toxicological Control Laboratory.

**Technical annexes:**

- Algiers technical annex, 08 Mai 1945 Bouzereah (Algiers)
- Oran technical annex, Rue Benaouali El-Houari, Gambetta
- Constantine technical annex, Cité Mantouri Dakssi, Sidi Mabrouk

**6. Organization:**

Interministerial Order No.68 of 20 November 1996 which laid down the organization of the National Drug Quality Control Laboratory.

**It comprises:**

- Department of General Administration
- Technical-Administrative Department
- Specialized Laboratories Department
- Annexes

**Department of General Administration:**

- Support services
- Finance and Accounts Service
- Human Resources Service

**Technical-Administrative Department:**

- Registration Service
- Documentation Service
- Quality Assurance Service

**Specialized Laboratories Department**

This department, which is responsible for controlling pharmaceutical products subject to registration, comprises:

- Chemistry Department
- Microbiology Department
- Pharmaco-toxicology Department

**Annexes**

The annexes are in charge of controlling systematically batches of pharmaceutical products imported or manufactured locally (before they are marketed).

**Each annex comprises:**

- Specialized Controls Service
- Technical-Administrative Service
- Support services

**7. Technical staff:**

- Professor
- Assistant Lecturers
- Specialist Pharmacist
- Specialist Doctor
- Generalist Pharmacist
- State registered Paramedic
- Engineer PhD (Lab and Maintenance)
- Laboratory and Maintenance Engineer
- Senior Laboratory and Maintenance Technician
- Computer Technician
- Senior Computer Technician

**8. Major equipment available:**

- High performance liquid chromatograph (HPLC)
- Gas chromatograph
- UV/Visible spectrophotometer
- Visible spectrophotometer (Turbidimetry)
- Fluorimeter
- Infra-red spectrophotometer with Fourier Transformer
- Simple infra-red spectrophotometer
- Atomic absorption spectrophotometer
- Potentiometer/Titrimeter
- Karl-Fischer (Water assay)
- Viscosimeter
- Polarimeter
- Osmometer
- pH-meter
- Zone reader/Microbiology
- Laminar flow cabinet
- Elisa reader
- Filtration ramp (Bacteriology)

- Device for determining pyrogens
- Dissolutest linked to a spectrophotometer and pat P.C. Pilote (8 posts)
- Dissolutest (6 posts)

**9. Activities:**

9.1 Physico-chemical tests:

- Physico-chemical test of pharmaceutical products (drugs, supplies and reagents) subject to registration before marketing - post-marketing (inspection).

The test comprises several phases:

Electrochemistry-Spectrophotometry-Chromatography-

Pharmacotechnic-Standardization of reference standards

9.2 Microbiological tests:

- Sterility test and microbial titration of pharmaceutical products (drugs-vaccines-serum and sterile supplies).

The test comprises:

- Immuno-assay (drugs against allergy) - purity-activity of antibiotics-sterility.

9.3 Pharmacotoxicological tests:

- toxicological control of all forms of pharmaceuticals (local tolerance of greasy forms, pyrogens, safety, GL50);
- control of pharmacodynamic activity of some active ingredients;
- study of bio-equivalence of low therapeutic index generic drugs;
- animal house: development of a species of standard laboratory animals (mice, rats and rabbits).



## ANGOLA

1. **Name:**  
Drug Quality Control Laboratory  
(under ANGOMEDICA, Ministry of Health)
2. **Address:**  
P.O. Box 2.698 - Luanda  
Tel: (244) 09501293/09501618/363771/362336  
Fax: (244) 363771  
E-mail:
3. **Head of laboratory:**  
Dr Fatima Saiundo
4. **Date of establishment:**  
1991
5. **Legal status:**  
Public establishment
6. **Technical staff:**  
2 Pharmacists  
2 Chemists  
6 Laboratory technicians
7. **Major equipment available:**
  - pH-meter
  - Centrifuge
  - Conductimeter
  - High performance liquid chromatograph
  - Dissolution test equipment
  - Hardness tester
  - Ban Kofler
  - Muffle furnace
  - Polarimeter
  - Vertical autoclave
  - UV/VIS spectrophotometer
  - Friability tester

**8. Activities:**

Control of locally manufactured and/or imported drugs:

- Physico-chemical and galenic tests
- Microbial test
- Sterility test
- Pyrogen test
- Physico-chemical test and microbial assay of water.

## CONGO

1. **Name:**  
Quality Control Laboratory  
(Department of Pharmacy and Laboratory Services, Ministry of Health).
2. **Address:**  
P.O. Box 1.635, Brazzaville  
Telephone: (242) 83.22.98  
Fax: (242) 83.50.13
3. **Head of laboratory:**  
Jean-Bruneau Mokoko
4. **Date of establishment:**
5. **Legal status:**  
Public institution
6. **Technical staff:**
7. **Major equipment available:**
  - Melting-point apparatus
  - Water-bath
  - Volumetric kit
8. **Activities:**
  - Identification and assaying of drugs.

## **KENYA**

- 1. Name:**  
National Quality Control Laboratory  
(under the Ministry of Health)
- 2. Address:**  
P.O. Box 29726, Nairobi  
Telephone: +254-726963 or 254-2-728398  
Fax: +254-2-718083  
E-mail: Afdran-nqcl@cken.healthnet.org  
natqclab@form-net.com
- 3. Head of laboratory:**  
Dr Elizabeth Ominde-ogaja
- 4. Date of establishment:**  
1995
- 5. Legal status:**  
Public establishment
- 6. Technical staff:**
- 7. Major equipment available:**
  - UV/VIS spectrophotometer
  - FT-IR spectrophotometer
  - Karl-Fischer
  - Digital polarimeter
  - High performance liquid chromatograph
  - Dissolutest
  - Disintegration equipment
  - Friability tester
  - TLC (Thin Layer Chromatography) kit
  - Muffle furnace
  - pH-meters
  - Laminar flow cabinet
  - Incubators
  - Equipment for condom testing

**8. Activities:**

8.1 Drug quality control:

- Physico-chemical and galenic tests
- Sterility test
- Microbial titration.

8.2 Condom quality testing.

## **MALAWI**

- 1. Name:**  
National Drug Quality Control Laboratory  
(under the Pharmacy, Medicines and Poisons Board)
- 2. Address:**  
P.O. Box 55, Lilongwe  
Telephone: (265) 741027/741028  
Fax: (265) 741027  
E-mail: ndqcl@eo.wn.apc.org
- 3. Head of laboratory:**  
Mr Steve Chapima
- 4. Date of establishment:**  
September 1993
- 5. Legal status:**  
Public establishment
- 6. Technical staff:**  
2 Laboratory technicians
- 7. Major equipment available:**
  - UV/VIS BECKAMN 600 spectrophotometer
  - IR PERKIN-ELMER spectrophotometer
  - Analytical balances
  - ERWEKA DT 60 dissolutest
  - pH-meters
  - ERWEKA ZT31 disintegration test equipment
  - Hardness tester
  - Drying ovens
  - ERWEKA TA 20 friability tester
  - METROHM 682 potentiometer
  - Thin-layer chromatography kit
  - GALLEN KAMP melting-point apparatus
  - Water distillation apparatus
  - GALLEN KAMP CNW 325 colony counter

- GALLEN KAMP incubators
- Laminar flow cabinet
- HAWKSLEYE centrifuge
- Autoclave
- WILL WETZLER 355 microscope

**8. Activities:**

- 8.1 Drug quality control.
- 8.2 Participation in the National Quality Assurance System (under the Pharmaceutical Inspection Service and the Registration Service).
- 8.3 Analysis of seized narcotics.
- 8.4 Training in quality assurance.
- 8.5 Participation in inter-laboratory studies on quality control.

## **MALI**

- 1. Name:**  
National Health Laboratory  
(under the Ministry of Health)
- 2. Address:**  
P.O. Box 232, Bamako (Mali)  
Tel: (232) 224770  
Fax: (232) 232281
- 3. Head of laboratory:**  
Pr Ousmane Doumbia
- 4. Date of establishment:**  
June 1990 by Ordinance No.90-34/PRM and Decree No. 90-269/PRM of 5 June 1990 to organize and lay down the conditions of functioning of the laboratory.
- 5. Legal status:**  
Public institution
- 6. Technical staff:**
  - 1 Pharmacist (Therapeutic chemistry)
  - 1 Pharmacist (specialized in pharmacology)
  - 2 State-registered pharmacists
  - 1 Engineer (sacchariferous substances technology)
  - 1 Chemical engineer
  - 1 Veterinarian and livestock engineer
  - 2 Health technicians
  - 3 Chemical technicians
- 7. Major equipment available:**
  - Analytical precision balances
  - Karl-fischer
  - 1 Digestlhal for mineralization
  - 1 HPLC with apex autochrom station software linked to a microcomputer
  - 1 DANI/FID/EDCD gas chromatograph



1 Dissolutest  
1 Tropicalized drying oven for drug stability studies  
4 Drying ovens  
1 Oven  
1 Disintegration test equipment  
2 Laminar flow cabinets  
Suction cabinet  
1 Calorimeter  
1 Polarimeter  
1 Atomic absorption spectrophotometer  
1 Infra-red spectrophotometer  
UV-visible spectrophotometers  
1 HACH DR 2000 spectrophotometer  
1 Automatic titrimer  
1 Ban Kofler type melting-point apparatus  
1 Melting-point apparatus using the capillary tubes method  
1 DCO equipment  
1 BDO equipment  
pH-meters  
1 apparatus for dosage of dissolved oxygen  
1 AUTOS TILL water bidistillator  
1 cartridge water demineralizator  
1 refrigerated cupboard

**8. Activities:**

- 8.1 Surveillance of the quality of imported or locally manufactured pharmaceutical products.
- 8.2 Identification and analysis of seized narcotics, including drugs.
- 8.3 Evaluation of analytical files of drugs for registration.
- 8.4 Issuing of import licences for drugs.
- 8.5 Control of water quality.
- 8.6 Control of industrial waste.
- 8.7 Control of food quality.
- 8.8 Issuing of marketing licences for industrial production of foods and beverages.

## **SIERRA LEONE**

- 1. Name:**  
Drug Quality Control Laboratory  
(under the Ministry of Health)
- 2. Address:**  
Central Medical Stores  
New England Ville  
Jomo Kenyatta Road, Freetown  
Telephone: (232-22) 240298/240587  
Fax: (232-22) 242253  
E-mail:  
Tel:
- 3. Head of laboratory:**  
Mr Hudson H. Lawson
- 4. Date of establishment:**  
August 1996
- 5. Legal status:**  
Public establishment
- 6. Technical staff:**
- 7. Major equipment available:**
  - UV/VIS spectrophotometer
  - Gas chromatograph
  - Disintegration test equipment
  - Dissolution test equipment
  - Hardness tester
  - Friability tester
  - Melting-point apparatus
  - Viscosimeter
  - pH-meter
  - Refractometer
- 8. Activities:**  
Physico-chemical and galenic control of drugs.

## ZAMBIA

1. **Name:**  
Drug and Food Control Laboratory  
(under the Ministry of Health)
2. **Address:**  
University Teaching Hospital Complex  
P.O. Box 30138, Lusaka  
Telephone: (260-1) 25 28 55/252873  
Fax: (260-1) 2234
3. **Head of laboratory:**  
Ms Margaret Sakala
4. **Date of establishment:**  
1972
5. **Legal status:**  
Public establishment
6. **Technical staff:**
7. **Major equipment available:**
  - VARIAN 3300/FID gas chromatograph
  - CHROMPACK/FID/ECD gas chromatograph
  - PYE UNICAM 204/NDP/ECD gas chromatograph
  - GALLENKAMP FGA-350L flame photometer
  - IR PYE UNICAM 5P3-200 spectrophotometer
  - UV/VIS PYE UNICAM 5P8-400 spectrophotometer
  - ERWEKA disintegration test equipment
  - ERWEKA dissolution test equipment
  - Melting-point apparatus
  - Ultrasonic vat
  - Balances
  - Centrifuges
  - Drying ovens

**8. Activities:**

- 8.1 Drug quality control.
- 8.2 Participation in the National Quality Assurance System (under the Pharmaceutical Inspection Service and the Registration Service).
- 8.3 Analysis of seized narcotics.
- 8.4 Training in quality assurance.
- 8.5 Participation in inter-laboratory studies on quality control.

# REGIONAL DRUG QUALITY CONTROL LABORATORIES

## CAMEROON

1. **Name:**  
Regional Drug Quality Control Laboratory (RDQCL)
2. **Address:**  
P. O. Box 12216
3. **Head of laboratory:**  
Dr Thomas Lapnet Moustapha, Director-General
4. **Date of establishment**  
Presidential Decree No.96/55 of 12 March 1996 to set up and organize the laboratory
5. **Legal status:**  
Public establishment
6. **Technical staff:**  
1 Pharmacist  
3 Specialized technicians  
2 Technicians
7. **Major equipment available:**
  - ERWEKA DT6 dissolution test equipment
  - ERWEKA ZT3 disintegration test equipment
  - ERWEKA TA friability tester
  - ERWEKA TDM apparatus for measuring the thickness of tablets
  - ERWEKA TBH28 apparatus for measuring the hardness of tablets
  - SR 2000 100EC and 200EC Thermosi drying oven
  - Vacuum drier and vacuum pump
  - 220EC Memmert drying oven
  - SEQUOIA-TURNER340 spectrophotometer
  - BUCHI530 melting-point apparatus

- (CPG) VARIAN gas chromatograph + integrator + 9200 hydrogen generator
- CARL ZEISS binocular microscope
- METTLER PM 2000 balance
- XL 300 DENVER Instrument Company balance
- METTLER PM 400 balance + Terminal Pharmalac-M + printer
- METTLER GA 44
- METTLER AE 240 balance
- BOSCH SAE 200 balance
- PATH pressure pump
- Hydraulic test apparatus
- Micrometer
- Mandrel
- PATH vacuum pump + vacuum cabinet
- GAST compressor
- AQUATRON A 4S distillator
- 1000EC CARBOLITE muffle furnace
- R-F water-bath
- SONOREX ultra-sound bath
- ROTAVAPOR BUCHI 4611
- GFL 3009 8-handle mixer-shaker
- BUCHI FON TAVAPORT 210 distillator
- Electromagnetic hotplate stirrer
- IEC Centra-3E centrifuge
- VORTEX GENIR ETM
- UV lamp
- GFL 3015 stirrer
- KNF compressor/vacuum pump + drier
- SAVIS 6-position water-bath
- CAPTAIR ERLAB mobile cabinet
- E536 METROHM HERISAN potentiometer + 665 DOSIMAT
- DU-62 BECHMAN spectrophotometer
- KARL-FISCHER 231 automatic titrator
- DASIS EBCO 1600 automatic dehumidifier
- SA JOBIN YVON JY101 spectrophotometer

- Suction cabinet
- Suppo melting-point apparatus
- Glass drying oven

**8. Activities:**

- 8.1 Drug quality control:  
Physico-chemical and galenic tests.
- 8.2 Condom quality testing.
- 8.3 Training of laboratory technicians.

## **GHANA**

- 1. Name:**  
Regional Drug Quality Control Laboratory  
(under the Ghana Standards Board)
- 2. Address:**  
P.O. Box M 245, Accra  
Telephone: (223) 21.776191 Fax: (223) 21.776092
- 3. Head of laboratory:**  
Mrs Charlotte Afi Ohene-Manu
- 4. Date of establishment:**  
1991
- 5. Legal status:**  
Public establishment
- 6. Technical staff:**
- 7. Major equipment available:**
  - High performance liquid chromatograph
  - Gas chromatograph
  - Atomic absorption spectrophotometer
  - Infra-red spectrophotometer
  - Refractometer
  - Dissolution test equipment
  - Disintegration test equipment
  - Friability tester
  - Turbidimeter
  - pH-meter
  - Conductimeter
  - Melting-point apparatus
- 8. Activities:**
  - 8.1 Drug quality control:
    - physico-chemical analyses
    - sterility test
    - pyrogen test.
  - 8.2. Analysis of narcotics.
  - 8.3. Training.



## **NIGER**

**1. Name:**

National Public Health Laboratory  
(under the Ministry of Public Health)

It comprises;

- a regional drug control laboratory; and
- a UNIDCP regional centre for training in the analysis of seized narcotics.

**2. Address:**

P.O. Box 10.465, Niamey

Tel: (227) 74.28.29

Fax: (227) 74.26.34

**3. Head of laboratory:**

Dr Jean-Marie Trapsida

**4. Date of establishment:**

1980 (The laboratory is attached to the National Pharmaceutical and Chemical Products Office)

**5. Legal status:**

Public establishment since December 1996

**6. Technical staff:**

- 1 Pharmacist-Pharmacotoxicologist
- 1 Pharmacist-Biologist
- 1 Pharmacist-Chemist
- 3 Assistant engineers
- 1 Chemist
- 3 Senior technicians
- 3 Laboratory technicians

**7. Major equipment available:**

- SPECTRA PHYSICS high performance liquid chromatograph
- SHIMADZU high performance liquid chromatograph
- VARIAN STAR 3400 CX gas chromatograph linked to a PC/ECD/NDP

- VARIAN 3400/ECD/NDP gas chromatograph
- 6800 DANI/FID gas chromatograph
- VARIAN 3300/FID DBO gas chromatograph
- UV/VISIBLE LAMBDA 3B spectrophotometer
- UV/VISIBLE PERKIN-ELMER 5515 spectrophotometer
- UV/VIS SHIMADZU 2101 spectrophotometer linked to a PC
- PC01 JENWAY colorimeter
- ZEISS polarimeter
- ATAGO refractometer
- pH-meters
- RE 120 rotavapors
- Mettler DL 40 RC memotitrator
- Precision balances
- GALLENKAMP melting-point apparatus
- Milli Q water purification system
- Laminar flow cabinet
- Millipore steritest
- PBI autoclaves
- ZEISS microscopes
- 88752 BIOBLOCK Colony counter
- Memmert drying ovens
- TLC kit
- ALED 2000 photometer
- LABINCO 680 humidity balance
- Corning 250 ionometer
- Micro CM 2100 conductimeter
- CORNING 410 flame photometer
- METTLER chain for uniformity of mass
- AT7 0S1 dissolution test equipment
- PTB 301 PROLABO hardness tester
- PTZ IH PROLABO disintegration test equipment
- Six-channel ionometer
- FT/IR spectrophotometer linked to a PC
- Atomic absorption spectrophotometer
- Viscosimeter
- PTF IE PROLABO friability tester
- AXIA Microreader BIOMERIEUX chain

**8. Activities:**

- 8.1 Drug quality control.
- 8.2 Analysis of drinking water.
- 8.3 Analysis of swimming pool water.
- 8.4 Analysis of waste water.
- 8.5 Analysis of foods.
- 8.6 Medico-legal toxicology.
- 8.7 Identification and analysis of seized narcotics.
- 8.8 Control of pesticides.
- 8.9 Analysis of pesticide residue.
- 8.10 Assay of hormones.
- 8.11 Training in:
  - drug quality control
  - analysis of seized narcotics
  - microbial assay of water and foods.
- 8.12 Participation in inter-laboratory collaboration.

**11. Drug control tests performed:**

- Examination of organoleptic characteristics
- Average weight and uniformity of mass
- Extractable volume
- Measurement of pH
- Identification and testing of related and/or degradation substances
- Loss on drying
- Melting point
- Disintegration test
- Dissolution test
- Friability test
- Sterility test
- Pyrogen assay
- Microbial test of antibiotics
- Determination of content of active ingredient

**9. Time required to perform the tests:**

- Physico-chemical test : 1 to 2 days
- Sterility test : 14 days
- Pyrogen assay : 1 day
- Microbial test : 5 days

NB: The time required depends on the number of batches.

**10. Dispatch of samples:**

Samples to be analysed should be properly packed and should each bear the following information:

- international nonproprietary name of the product:
- dosage
- batch number
- date of expiry

Samples should be dispatched to the laboratory by the fastest means (EMS, DHL, etc).

## ZIMBABWE

1. **Name:**  
Regional Drug Control Laboratory  
(under the Medicines Control Authority of Zimbabwe)
2. **Address:**  
106 Baines Avenue  
P.O. Box UA 319  
Union Avenue, Harare  
Tel: (263-4) 736981-5  
Fax: (263-4) 736980
3. **Head of laboratory:**  
Ms Gugu Mahlangu
4. **Date of establishment:**  
1986
5. **Legal status:**  
Public establishment
6. **Technical staff:**
7. **Major equipment available:**
  - UV/VIS spectrophotometer
  - IR spectrophotometer
  - High performance liquid chromatograph
  - Gas chromatograph
  - Atomic absorption spectrophotometer
  - Potentiometer
  - Gas chromatograph linked to a mass spectrophotometer
  - Equipment for condom testing
8. **Activities:**
  - 8.1 Drug quality control.
  - 8.2 Condom testing.
  - 8.3 Training.
  - 8.4 Participation in inter-laboratory collaboration.
  - 8.5 Preparation of working standards based on reference substances.

**9. Drug control tests performed:**

- Uniformity of mass
- Extractable volume
- Disintegration test
- Dissolution test
- Uniformity of content
- Identification
- Test for impurities
- Heavy metals
- Loss on drying
- Water content determination
- pH measurement
- Refractive index
- Relative density
- Viscosity
- Melting point
- Solubility
- Determination of content of active ingredient
- Sterility test
- Microbial test
- Contamination test
- Pyrogen assay
- Identification of germ isolate
- Identification of fungal isolate
- Determination of the quality of condoms

**10. Time required to perform the tests:**

- Physico-chemical tests : 1 to 2 days
- Sterility test : 17 to 45 days
- Microbial test : 1 to 5 days
- Microbial contamination : 7 to 14 days
- Quality of condoms : 28 days
- Pyrogen assay : 1 day

**11. Dispatch of samples:**

Samples should be properly packed and should be accompanied by a request stating the type of analysis to be performed and the specifications of the samples to be analysed which should include.

- name of the product;
- dosage;
- batch number;
- expiry date; and
- name of manufacturer.





# WHO COLLABORATING CENTRE

## SOUTH AFRICA

1. **Name:**  
Centre for the Quality Assurance of Medicines  
(under the Faculty of Pharmacy of the University of Potchefstroom)
2. **Address:**  
Faculty of Pharmacy  
University of Potchefstroom  
Private Bag X 6001 Potchefstroom  
Tel: 27-148-2992280  
Fax: 27-148-2992284  
E-mail: fmsbb@puknet.puk.ac.za  
HOME PAGE:<http://www.puk.ac.za/cenqam/index/html>
3. **Head of laboratory:**  
Prof. Bannie Boneschans
4. **Date of establishment:**  
1988
5. **Legal status:**  
Public institution
6. **Technical staff:**
  - Director D.Sc. (Pharmaceutics)
  - Lab Manager M.Sc. (Pharmaceutics)
  - PA/Secretary:- Nas. Dipl. Business Administration  
Dipl. Bookkeeping Practice
  - Lab Technician B.Sc. (Hon.)
  - Lab Technician 2nd year B.Sc.
  - Lab Technician Trainee B. Pharm.
  - Lab Technician Trainee B. Pharm.
7. **Major equipment available:**
  - High performance liquid chromatograph linked to a mass spectrophotometer

- Gas chromatograph linked to a mass spectrophotometer
- UV/VIS spectrophotometer
- Atomic absorption spectrophotometer
- IR spectrophotometer
- Dissolution test equipment
- Particle counter
- X-ray diffractometer
- Electron microscope

**8. Activities:**

- 8.1 Drug quality control:
  - Physico-chemical tests
  - Sterility test
  - Microbial test of antibiotics.
- 8.2 Antimicrobial control:
  - Test of the quality of condoms
  - Control of disinfectants and antiseptics
- 8.3 Counselling on the validation of analytical methods.
- 8.4 Counselling on equipment maintenance.
- 8.5 Verification of data stability.
- 8.6 Training in preparation of expert reports.
- 8.7 Documentation services.
- 8.8 Training in analytical techniques.
- 8.9 Training in quality assurance.
- 8.10 Organization of inter-laboratory collaboration.
- 8.11 Participation in verification programmes.