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Survey of the quality of antiretroviral medicines circulating in selected African countries

September 2007

Quality Assurance and Safety: Medicines
Medicines Policy and Standards

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Abbreviations

AIDS	Acquired Immune Deficiency Syndrome
AFRO	WHO Regional Office for Africa
API	Active pharmaceutical ingredient
ART	Antiretroviral therapy
ARV	Antiretroviral
BP	British Pharmacopoeia
DRA	Drug regulatory authority
DRC	Democratic Republic of Congo
FDC	Fixed-dose combination
FPP	Finished pharmaceutical product
GMP	Good Manufacturing Practice
HIV	Human Immunodeficiency Virus
INN	International Nonproprietary Names for pharmaceutical substances
IP	Indian Pharmacopoeia
NGO	Nongovernmental Organization
NPO	National Professional Officer
OMCL	Official Medicines Control Laboratory
Ph.Eur.	European Pharmacopoeia
Ph.Int.	The International Pharmacopoeia
RSD	Relative standard deviation
USP	United States Pharmacopeia
WHO	World Health Organization

Summary

Background

Provision of antiretroviral therapy has expanded in Sub-Saharan Africa and quality assurance of antiretrovirals is of crucial importance for the success of treatment programmes. Therefore WHO, in co-operation with national authorities, organized a quality survey of antiretrovirals in selected African countries.

Methods

The survey was performed in Cameroon, the Democratic Republic of Congo, Kenya, Nigeria, United Republic of Tanzania, Uganda and Zambia. Country teams made up of WHO country officers and national authority representatives collected samples at public and private sector antiretroviral procurement organizations and treatment centres around the capital cities. Samples included monocomponent products of didanosine, efavirenz, lamivudine, nevirapine, stavudine and zidovudine, and fixed-dose combinations of lamivudine/zidovudine, stavudine/lamivudine, stavudine/lamivudine/nevirapine. All samples were tested by the Official Medicines Control Laboratory of Switzerland, Swissmedic, for appearance, labelling, identity, related substances, and content of each active ingredient. In addition, capsules and tablets were tested for uniformity of mass and either dissolution or disintegration; oral solutions were tested for pH if appropriate. Methods of the International Pharmacopoeia, United States Pharmacopoeia, Indian Pharmacopoeia or manufacturers' methods with method transfer were used as appropriate. Sampling and testing were carried out over a period of six months from 13 June to 15 December 2005.

Findings

None of the antiretrovirals sampled had any critical quality deficiencies which would pose a serious risk to patients.

In 394 samples collected, the overall failure rate was 1.8%. One sample contained a broken tablet and tablets with chipped coating. Two samples were insufficiently labelled on the immediate packaging. The content of active ingredient of one sample exceeded the upper limit. One of 163 samples tested for disintegration failed to disintegrate completely within 30 minutes, and two of 153 samples tested for dissolution showed lower results than required.

Fifty-three percent of sampled products were WHO-prequalified. Information on registration by National Drug Regulatory Authorities was available for 285 products; of these, 84% were registered. Products not registered at the time of sampling were found in three countries, mostly at private sector facilities, and constituted 12% of the total of 394 sampled products.

Conclusions

The generally good quality and safety of products sampled indicate the positive effect of common efforts of National Drug Regulatory Authorities, WHO and other organizations involved in prequalification and purchase policies. Market control was still incomplete in at least three countries.

Since the survey was limited to official distribution points and treatment centres around the capital cities, these results cannot be generalized to the entire territories of the countries surveyed.

1. Background

In 2006, almost two thirds of all persons infected with HIV were living in Sub-Saharan Africa[1]. Provision of antiretroviral treatment in Sub-Saharan Africa increased tenfold between December 2003 and June 2006, with significant national scale-up efforts in Botswana, Kenya, Namibia, Malawi, Rwanda, South Africa, Uganda and Zambia[1].

Antiretroviral treatment (ART) is provided by both public and private sector facilities. Although public facilities increasingly deliver free or subsidized ART, the engagement of NGOs, health care provided by international and national corporations, faith-based organizations, individual medical providers and pharmacies will continue to be critical in a number of national settings[2]. Of 16 faith-based non-governmental drug supply organizations in Africa surveyed by WHO in 2003, twelve distributed HIV diagnostic tests, four also distributed antiretrovirals[3].

Many issues in the delivery of antiretroviral treatment in resource-poor settings have been identified, including the selection of beneficiaries, strengthening of health systems, clinical management, demand and adherence, community involvement, financing, and monitoring and evaluation[4]. However, the first requirement for any treatment programme is the availability of antiretrovirals of acceptable quality, safety and efficacy.

Quality assurance of antiretrovirals is of crucial importance for the success of treatment programmes. Antiretrovirals manufactured below established standards of quality can lead to therapeutic failure, development of drug resistance and toxic or adverse reactions. The HI virus develops resistance readily, and resistant strains can be transmitted, making sub-standard medicines a public health problem[5].

The problem of sub-standard and counterfeit medicines in developing countries is well documented. A survey on the quality of antimalarials in eight African countries found failure rates at all levels of the distribution chain, including public-sector hospitals and medical stores, with content failure rates ranging from 20-67% for chloroquine tablets and dissolution failure rates of 75-100% for sulfadoxine/pyrimethamine tablets[6]. In quality tests for a mixed sample of tracer medicines in six countries, including Tanzania and Ghana, failure rates above 10% were common, and studies in ten countries found great variation in compliance with Good Manufacturing Practices [7].

Counterfeiting is particularly prevalent where regulatory and legal oversight is weak, where prices of medicines are high, where price differentials between identical products exist, and where the official supply chain fails to reach some communities, especially in rural areas[8].

All these criteria apply to antiretrovirals in Africa. Only 23% of the people in need of ART in sub-Saharan Africa had access to it at the end of 2006[1]. Differential pricing is in place for antiretrovirals, with discounts being offered to eligible countries and organizations[9]. Regulatory capacity is often inadequate: in a WHO survey of regulatory authorities in 38 African countries, 63% stated that they were unable to evaluate the quality, efficacy and safety of new medicines for lack of resources, and about half did not carry out medicines inspections[10]. Laboratories are not adequately equipped to do quality analysis of ARVs, especially of new multi-source products[11].

In November 2003, the WHO issued an alert about the availability of a counterfeit version of a triple antiretroviral combination product, Ginovir 3D, in Côte d'Ivoire. The label stated that the product was manufactured by Selchi Pharmaceuticals, Namibia, and contained zidovudine (200mg), lamivudine (150mg), and indinavir (40mg) per capsule. The recommended dosage of indinavir is 800mg/day, boosted with 100mg ritonavir[12]. Analysis by the Agence Française de Sécurité Sanitaire des Produits de Santé (AFSSAPS) upon request from the Association of AIDS Patients (AIDES) showed that the samples contained zidovudine 201mg, stavudine 40mg, and an unidentified substance[13].

A literature survey on drug quality in USAID-assisted countries from 2001 to 2007, including 16 African countries [14], contains a reference to this incident, and to other reports on counterfeit or substandard antiretrovirals in the Democratic Republic of Congo, Ethiopia, Kenya, Uganda and Zimbabwe. Most of these reports relate to antiretrovirals circulating in the informal market.

The WHO alert on a counterfeit ARV in Côte d'Ivoire raised concerns from various member states on the quality of medicines circulating in the WHO African region. During the 54th session of the WHO Regional Committee for Africa, held in Brazzaville from 30 August to 3 September 2004, delegates from countries echoed this concern.

To facilitate global access to medicines of acceptable quality, the WHO prequalification programme evaluates pharmaceutical products according to WHO-recommended standards of safety, efficacy and quality, and compliance with good manufacturing practices and good clinical practices (GCP). It prequalifies medicines which are acceptable, in principle, for procurement by UN procurement agencies[15]. In 2004, WHO started its programme to prequalify quality control laboratories for the analysis of HIV-, malaria- and tuberculosis-related products in Africa. Three laboratories were prequalified as at January 2007[16], two in South Africa and one in Algeria. The implementation of a harmonized quality assurance system by procurement agencies will be a further step towards assuring the quality, safety and efficacy of medicines.

Although prequalification is an invaluable tool for procurement of quality antiretrovirals, the process does not guarantee the quality of the products procured from the suppliers listed. Neither does the absence of a product from the list mean that it is sub-standard. Ongoing quality control of antiretrovirals remains essential at all stages of the supply cycle.

Aim of this study

The aim of this project was to assess the quality of antiretroviral medicines obtained at accredited public and private sector antiretroviral procurement and treatment sites in selected African countries, using a variety of assessment methods.

The following questions were addressed:

- What proportion of antiretroviral samples collected at approved procurement and treatment centres fails quality testing?
- Are any of the deficiencies critical, i.e. could they affect treatment efficiency and/or cause harm to the patient?
- Which specific quality tests do the samples fail, if any?

The results of this study are expected to assist responsible authorities in the countries surveyed to develop appropriate quality assurance strategies for antiretrovirals. They also provide information for WHO to adapt its prequalification procedures. Finally, they will be of use in awareness and advocacy programmes on quality issues in antiretroviral treatment in general.

2. Methodology

2.1 Participating countries and study period

The survey was performed in Cameroon, the Democratic Republic of Congo, Kenya, Nigeria, United Republic of Tanzania, Uganda and Zambia.

Sampling and testing were carried out over a period of six months from 13 June to 15 December 2005.

A follow-up survey will consider other countries including Chad, Ethiopia, Mali, Rwanda and Senegal.

2.2 Selection of sample collection sites

The survey was undertaken in and around the capital city of each country.

Four separate lists of public and private sector antiretroviral procurement organizations and treatment centres were prepared. Only officially approved treatment centres were considered. Sites were selected from the lists, aiming at the following composition of sites in each country:

a) Two public-sector antiretroviral treatment centres

b) Two private-sector antiretroviral treatment centres

c) One public-sector antiretroviral procurement centre

d) One private-sector antiretroviral procurement centre or distribution outlet

Sample collection sites were selected from the lists in such a manner to cover both urban and sub-urban areas of the capital city, and a variety of facilities at different levels of the health care system, including procurement centres, hospitals, health centres and pharmacies.

The above target composition of sample collection sites was modified in a number of countries, depending on the presence of each type of site on the lists, and the availability of antiretrovirals at the sites. A total of 42 collection sites were included in the final selection. The types of collection sites selected in each country are listed below.

- Nigeria – 7 sites: one public-sector State procurement centre, one private-sector procurement company, two manufacturers, one importer/wholesaler of pharmaceuticals, one public-sector national research institute and one public-sector teaching hospital
- Cameroon – 2 sites: two public-sector procurement centres
- Uganda – 6 sites: one public-sector procurement centre (national medical stores), one private-sector pharmacy, two public-sector treatment centres and two private treatment centres (one hospital, one clinic)
- United Republic of Tanzania – 6 sites: one public-sector procurement centre, one private-sector procurement centre, one public-sector hospital, one public-sector cancer institute, one private-sector hospital and one private-sector maternity home

- Democratic Republic of Congo – 6 sites: One private-sector local manufacturer, one private-sector procurement centre, one private-sector distribution centre, two public-sector hospitals and one private-sector hospital
- Zambia – 8 sites: Five pharmaceutical companies (wholesalers/importers), one university teaching hospital and two public-sector treatment centres
- Kenya – 7 sites: One public-sector procurement agency, one faith-based NGO procurement agency, two public-sector hospitals (one tertiary hospital, one district hospital) and two private-sector hospitals

2.3 Antiretroviral products surveyed

Finished dosage forms of capsules, tablets and oral solutions or suspensions containing the following active ingredients were included in the survey:

Monocomponent products:

- didanosine
- efavirenz
- lamivudine
- nevirapine
- stavudine
- zidovudine

Fixed-dose combinations (FDCs):

- lamivudine/zidovudine
- stavudine/lamivudine
- stavudine/lamivudine/nevirapine

A total of 394 samples were collected and analysed. Of these, 209 were WHO-prequalified products. More details are shown in Chapter 3.

2.4 Sample collection

In each country, a team made up of the Medicines National Professional Officer (NPO), HIV/AIDS-NPO and a senior inspector from the National Drug Regulatory Authority was established to manage the project and collect samples. Where there was no NPO, preferably, the chief analyst of the Drug Quality Control Laboratory joined the team. If there was no analyst, then the head of Drug Registration or an inspector from the drug regulatory authority was invited to join the team.

A Sample Information Collection Form was designed for this survey. The team completed one Sample Information Collection Form for each sample collected. The following details were recorded: Commercial name/brand/trade name, name of active ingredient(s), dosage form, strength per unit dose, packaging material of primary container and description of secondary container, quantity collected, description of the product, date of manufacture, batch number, expiry date, name and country of manufacturer, registration status and country, site and date of sample collection. These details were considered essential not only for final data analysis, but also to identify each sample.

Each sample was given a unique code number, prefixed by the country code as assigned by AFRO. This code number was also marked on the sample pack with indelible ink.

Each Sample Information Collection Form was signed by all the team members.

2.5 Testing laboratory

All samples were sent to the Official Medicines Control Laboratory (OMCL) of Switzerland, Swissmedic, for testing. Each sample was assigned an OMCL number.

2.6 Tests conducted

Depending upon the formulation, each sample was tested for the following:

- Appearance
- Labelling
- Identity
- Uniformity of mass (capsules/tablets)
- Dissolution if appropriate, otherwise disintegration (capsules/tablets)
- pH if appropriate, depending upon the matrix (oral solutions)
- Related substances
- Content of each active ingredient

Uniformity of content was only tested in one case to confirm other results.

2.7 Test methods

Appearance, uniformity of mass and disintegration were tested using procedures of the International Pharmacopoeia [17]. Dissolution tests were performed using either the methods specified in USP monographs or manufacturers' methods with method transfer.

Related substances and content of each active ingredient were tested according to the following methods, depending on the prequalification status of the products:

- For WHO-pre-qualified products, validated in-house Swissmedic methods as described for comparable product compositions were used if available. If not, manufacturers' methods were used. For combination products containing stavudine/ lamivudine/nevirapine without documented manufacturer's methods, Swissmedic methods for the corresponding monocomponent products were used.
- For products not prequalified by WHO with unknown compositions, the use of official Ph.Int., BP, USP or IP methods (in this order) was preferred. If no official method existed for a product, Swissmedic methods with appropriate method validation and transfer were used.

All methods used were subjected to appropriate method transfer procedures and were verified before use.

2.8 Specifications

The following specifications were used for the different tests.

2.8.1 Appearance

Tablets should be undamaged, smooth, and usually of uniform colour. Capsules should be smooth and undamaged.

Oral solutions should be clear with no visible particulate matter.

Suspensions should be homogenous on shaking.

2.8.2 Labelling

Each label on the immediate container was checked for the following information:

(1) The name of the pharmaceutical product

(2) The name(s) of the active ingredient(s); INNs (International Nonproprietary Names) should be used wherever possible

(3) The amount of the active ingredient(s) in each tablet/capsule and the number of tablets/capsules in the container

(4) The batch (lot) number assigned by the manufacturer

(5) The expiry date

(6) Any special storage conditions or handling precautions that may be necessary

(7) Directions for use, warnings, and precautions that may be necessary

(8) The name and address of the manufacturer or the sponsor responsible for placing the product on the market

2.8.3 Identity

Identity was confirmed by matching the retention time of active peak in the standard and sample HPLC chromatograms obtained in the assay.

2.8.4 Disintegration

Acceptable time for complete disintegration was specified as follows:

Uncoated tablets	≤ 15 minutes
Film-coated tablets	≤ 30 minutes
Capsules	≤ 30 minutes

2.8.5 Dissolution

The USP method[18] was used for dissolution tests. According to this method, dissolution is tested in three stages, with the following acceptance criteria:

Stage	Number of units tested	Acceptance Criteria
S1	6 units	Each unit is not less than Q* + 5%
S2	Another 6 units	Average of 12 units (S1 + S2) is equal to or greater than Q, **and** no unit is less than Q – 15%
S3	Another 12 units	Average of 24 units (S1 + S2 + S3) is equal to or greater than Q, **and** not more than 2 units are less than Q – 15%, **and** no unit is less than Q – 25%

* Q is the amount of dissolved active ingredient specified in the individual monograph, expressed as a percentage of the content stated on the label. The testing is continued through the three stages unless the results conform at either stage 1 or stage 2.

Specifications applied in terms of Q values and testing time limits are shown above the tables of test results in Appendix 1 where applicable.

2.8.6 Content of active ingredient

The limits for content of the active ingredient(s) applied to the individual products are shown above each table of results in Appendix 1. The limits vary, depending on the source of the specifications. The pharmacopoeial limits are typically 90.0-110.0%, but manufacturer's limits may be narrower, e.g. 95.0-105.0%. Non-symmetric limits, like 92.5-105.0%, indicate that the active ingredient is prone to degradation during storage of the product.

2.8.7 pH

Acceptable ranges of pH of oral solutions, where tested, are shown above the respective tables in Appendix 1.

2.8.8 Related substances

Related substances are impurities arising in pharmaceutical products during synthesis of the active ingredient or as a result of degradation. Specifications for testing of related substances applied to the individual products are shown above each table of results in Appendix 1.

2.8.9 Uniformity of mass

Specifications of the International Pharmacopoeia[17] as shown below were applied.

Pharmaceutical form	Average mass	Acceptable deviation in %	Number of units (of 20 units tested)
Tablets (uncoated and film-coated)	less than 80 mg	± 10.0 ± 20.0	minimum 18 maximum 2
	80 mg to 250 mg	± 7.5 ± 15.0	minimum 18 maximum 2
	more than 250 mg	± 5.0 ± 10.0	minimum 18 maximum 2
Capsules	less than 300 mg	± 10.0 ± 20.0	minimum 18 maximum 2
	300mg or over	± 7.5 ± 15.0	minimum 18 maximum 2

2.9 Conformity of samples with standards

The samples were considered to be in conformity with standards if they met the specifications as set out in Section 2.8 above and/or listed above each table of results in Appendix 1.

3. Results

A total of 394 samples from 42 sample collection sites in seven African countries were collected and tested. Details and test results of the samples are listed in Appendix 1, grouped by active ingredients and specifications used. Samples in each table are sorted in ascending order of OMCL numbers, reflecting the sequence in which samples from the seven countries were received and tested at the laboratory.

An overview of the samples tested is given in Section 3.1 below. The main findings of the different quality tests are summarized in Section 3.2. OMCL numbers are used to refer to samples in the text.

3.1 Overview of samples tested

The samples collected in each country are listed in Table 1 according to the APIs contained.

Table 1: Numbers of samples of FPPs/FDCs collected in each country

Active ingredient(s)	Number of samples							**Total**
	Cameroon	DRC	Kenya	Nigeria	Tanzania	Uganda	Zambia	
didanosine	-	-	-	-	-	-	1	**1**
efavirenz	9	3	13	3	7	5	6	**46**
lamivudine	5	7	14	15	15	6	4	**66**
nevirapine		8	21	14	15	7	7	**72**
stavudine	3	5	18	10	12	5	7	**60**
zidovudine	4	7	5	7	9	4	8	**44**
lamivudine / zidovudine	5	4	6	4	8	6	4	**37**
stavudine / lamivudine	-	-	14	-	-	-	2	**16**
stavudine / lamivudine / nevirapine	8	7	18	1	6	4	8	**52**
Total	**34**	**41**	**109**	**54**	**72**	**37**	**47**	**394**

The registration status of the sampled products in each country except Kenya was recorded on the Sample Collection Forms. All samples collected in Cameroon, Tanzania and Uganda were registered in these countries. A more complex situation was found in DRC, Nigeria and Zambia. Tables 2 - 4 show the numbers of registered and non-registered samples in these three countries differentiated according to active ingredients and sites of sample collection.

Table 2: Registration status of products sampled in DRC

DRC		Registered				Not registered			
Active ingredient(s)	**Number of samples**	Manu-facturer	Private procure-ment	Private hospital	Public hospital	Manu-facturer	Private procure-ment	Private hospital	Public hospital
didanosine		-	-	-	-	-	-	-	-
efavirenz	**3**	-	-	-	1	-	1	1	-
lamivudine	**7**	-	2	-	1	1	1	2	-
nevirapine	**8**	-	3	-	3	-	-	2	-
stavudine	**5**	-	1	-	2	1	-	1	-
zidovudine	**7**	-	4	-	1	-	1	1	-
lamivudine / zidovudine	**4**	-	2	1	1	-	-	-	-
stavudine / lamivudine	**-**	-	-	-	-	-	-	-	-
stavudine / lamivudine / nevirapine	**7**	1	3	1	2	-	-	-	-
Total	**41**	**29**				**12**			

In DRC, 10 sampled products which were not registered at the time of sample collection were registered for one year in 2000-2002, but the registration was not renewed. Dossiers of two further non-registered products were submitted to WHO for the prequalification procedure.

Table 3: Registration status of products sampled in Nigeria

Nigeria		Registered				Not registered*			
Active ingredient(s)	**Number of samples**	Manu-facturer	Private procure-ment	Public procure-ment	Public treatment centre	Manufac turer	Private procure-ment	Public procure-ment	Public treatment centre
didanosine		-	-	-	-	-	-	-	-
efavirenz	**3**	-	-	1	-	-	1	-	1
lamivudine	**15**	3	-	5	6	-	1	-	-
nevirapine	**14**	3	-	5	4	-	1	-	1
stavudine	**10**	-	-	3	3	-	2	-	2
zidovudine	**7**	3	-	2	-	-	2	-	-
lamivudine / zidovudine	**4**	2	-	-	1	-	1	-	-
stavudine / lamivudine	**-**	-	-	-	-	-	-	-	-
stavudine / lamivudine / nevirapine	**1**	-	-	-	-	-	-	1	-
Total	**54**	**41**				**13**			

*The registration status in Nigeria was evaluated according to the information on the package label. Although no evidence of registration on the package does not necessarily mean that products are not registered, these products were included in Table 3 as non-registered.

Table 4: Registration status of products sampled in Zambia

Zambia		Registered			Registration pending			Not registered		
Active ingredient(s)	**Number of samples**	Whole-saler	Uni-versity hospital	Public treatment centre	Whole-saler/ importer	Teaching hospital	Public treatment centre	Whole-saler/ importer	Teaching hospital	Public treatment centre
didanosine	**1**	-	-	-	1	-	-	-	-	-
efavirenz	**6**	1	1	2	2	-	-	-	-	-
lamivudine	**4**	-	-	-	2	2	-	-	-	-
nevirapine	**7**	2	1	1	3	-	-	-	-	-
stavudine	**7**	1	2	1	2	-	-	1	-	-
zidovudine	**8**	1	2	2	2	1	-	-	-	-
lamivudine / zidovudine	**4**	2	-	-	1	-	1	-	-	-
stavudine / lamivudine	**2**	-	-	-	1	-	-	1	-	-
stavudine / lamivudine / nevirapine	**8**	4	2	1	1	-	-	-	-	-
Total	**47**	**26**			**19**			**2**		

In the Sample Collection Forms from Zambia the information on pending registration applications was also provided.

Table 5 indicates the number of prequalified and non-prequalified products for the different active ingredients and Table 6 indicates the number for individual countries where samples were collected. The percentage of products prequalified by WHO appears in brackets. WHO-prequalification status reflects the situation at the time of sampling.

Table 5: WHO-prequalification status of samples tested (percentage of products prequalified by WHO in brackets)

Active ingredient(s)	Number of samples		
	WHO-prequalified	Not WHO-prequalified	**Total**
didanosine	-	1	**1**
efavirenz	-	46	**46**
lamivudine	43 (65%)	23	**66**
nevirapine	44 (61%)	28	**72**
stavudine	26 (43%)	34	**60**
zidovudine	36 (81%)	8	**44**
lamivudine / zidovudine	29 (78%)	8	**37**
stavudine / lamivudine	-	16	**16**
stavudine / lamivudine / nevirapine	31 (60%)	21	**52**
Total	**209**	**185**	**394**

Table 6: WHO-prequalification status of samples collected in individual countries (percentage of products prequalified by WHO in brackets)

Active ingredient(s)	Number of samples		
	WHO-prequalified	Not WHO-prequalified	**Total**
Cameroon	23 (68%)	11	**34**
DRC	25 (61%)	16	**41**
Kenya	49 (45%)	60	**109**
Nigeria	18 (33%)	36	**54**
Tanzania	55 (76%)	17	**72**
Uganda	23 (32%)	14	**37**
Zambia	16 (34%)	31	**47**
Total	**209**	**185**	**394**

Table 7 shows number of samples of different dosage forms and strengths collected and tested for each FPP/FDC.

Table 7: Active ingredient(s), dosage forms and strengths of samples tested

Active ingredient(s)	Dosage form	Strength(s) and number(s) of samples	**Total**
didanosine	Tablets	100mg: **1**	**1**
efavirenz	Capsules	50mg: **6**, 200mg: **11**	**17**
	Tablets	600mg: **26**	**26**
	Oral solutions	30mg/ml: **3**	**3**
lamivudine	Tablets	150mg: **43**	**43**
	Oral solutions	50mg/5ml: **23**	**23**
nevirapine	Tablets	200mg: **44**	**44**
	Oral suspensions	50mg/5ml: **28**	**28**
stavudine	Capsules	15mg: **4,** 20mg: **2,** 30mg: **24,** 40mg: **28**	**58**
	Powder for oral solution	200mg: **2**	**2**
zidovudine	Capsules	100mg: **7**	**7**
	Tablets	300mg: **15**	**15**
	Oral solutions	50mg/5ml: **22**	**22**
lamivudine/zidovudine	Tablets	150/300mg: **37**	**37**
stavudine/lamivudine	Tablets	30/150mg: **8,** 40/150mg: **8**	**16**
stavudine/lamivudine/ nevirapine	Tablets	30/150/200mg: **34,** 40/150/200mg: **18**	**52**
Total			**394**

Expiry dates of samples collected in this survey ranged from June 2006 to September 2009. Two samples from Nigeria, the first country to start sampling on 13 June 2005, had the earliest expiry dates. Figure 1 shows percentages of expired samples over time, for samples from each country. Countries are listed in the legend in the order in which their samples were tested at the laboratory.

No expired samples were found in this survey. Some products were close to their expiry dates when they underwent testing.

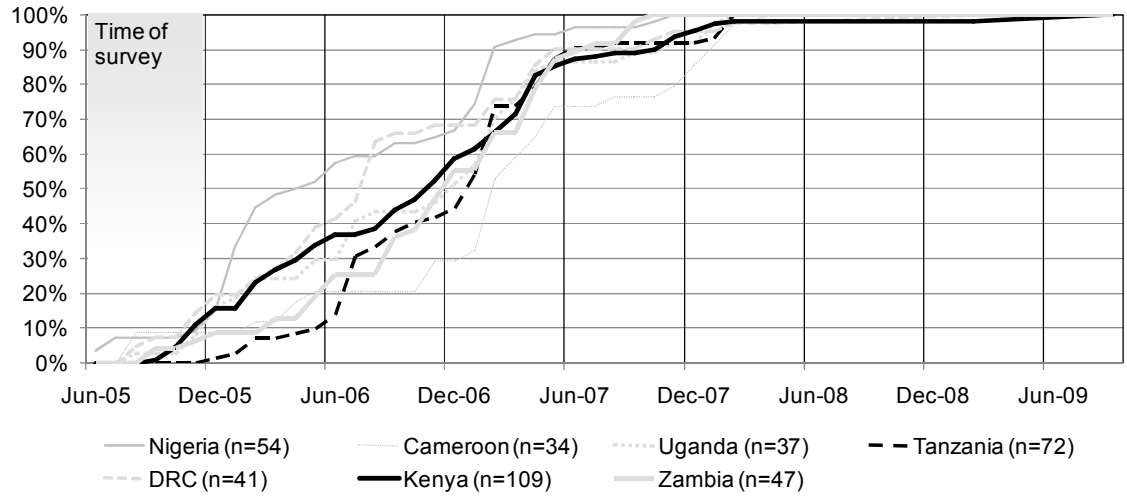

Figure 1: Percentages of expired samples over time, by country

3.2 Compliance with quality standards

Overall, only seven of 394 samples tested failed to comply with specifications of any of the quality tests performed. Several samples were not classified as failures, although they were slightly out-of-specification. Other samples were just inside the acceptable limits, and potential quality problems were noted. The findings of the different tests are summarized in Sections 3.2.1 to 3.2.7 below.

3.2.1 Appearance

Not all the products were WHO-prequalified and the manufacturers' specifications for appearance were not available for some products. Therefore the appearance was evaluated against the general specifications for dosage forms only. Of the 394 samples assessed, one was found to be of unsatisfactory appearance in terms of the specifications:

efavirenz 600mg tablets (OMCL No 4.41, page 26):

The sample of a non-WHO-prequalified product, collected at wholesaler/importer in Zambia, contained a broken tablet and a number of tablets with chipped coating.

3.2.2 Labelling

Two of 394 samples failed to comply with labelling requirements:

stavudine 200mg powder for oral solution (OMCL Nos. 1.13 and 1.24, page 35):

These two samples of a non-WHO-prequalified product, collected at a public-sector procurement centre in Cameroon and at a public-sector treatment centre in Tanzania respectively, were produced by the same manufacturer. The following information was missing from the label of the primary container:

– Any special storage conditions or handling precautions that may be necessary

– Directions for use, warnings and precautions that may be necessary

– The name and address of the local sponsor

3.2.3 Disintegration

One of 163 samples tested was unsatisfactory with regard to disintegration:

lamivudine / zidovudine 150/300mg tablets (OMCL No. 7.04, page 41):

This sample of a non-WHO-prequalified product was collected at a manufacturer in Nigeria. In repeated tests, two to four out of six tablets failed to disintegrate completely within 30 minutes.

3.2.4 Dissolution

A total of 153 samples were tested for dissolution. All except two samples complied with specifications. In the samples which complied, the minimum amounts of active ingredient dissolved for monocomponent products, in percent of the label claim, were 93% for lamivudine (number of products tested - n=25), 80% for nevirapine (n=29), 94% for stavudine (n=26), and 80% for zidovudine (n=12, an additional sample did not comply). In fixed-dose combinations, the respective minimum amounts dissolved were 92% and 89% for lamivudine/zidovudine (n=28, an additional sample did not comply), and 85%, 92% and 92% for stavudine/lamivudine/nevirapine (n=31).

Details for the two samples which failed dissolution testing were as follows:

zidovudine 300mg tablets (OMCL No. 5.19, page 37):

This sample of a non-WHO-prequalified product, collected at a public-sector procurement centre in Tanzania, did not meet the USP specification for dissolution (Q value of 75% at 30 minutes). The test was performed according to the USP monograph using apparatus 2 (paddle). At Stage 1, three tablets had results of 69%, 70% and 74%, i.e. below 80% (Q+5%). At Stage 2, the average of the 12 tablets was 76%, which met the specification, but one tablet (58%) was below 65% (Q–15%). At Stage 3, not more than two tablets were less than Q–15%, and none was less than Q–25%, but the average of the 24 tablets was determined to be 74%, which was less than Q (75%). Consequently, the sample was found to be unsatisfactory with respect to dissolution.

lamivudine/zidovudine 150/300mg tablets (OMCL No. 7.24, page 43):

This sample of a WHO-prequalified product, collected at a private-sector hospital in the DRC, failed to meet the USP Stage 3 requirements for dissolution. The lowest amounts of lamivudine and zidovudine dissolved were determined to be 51.6% and 50.6% respectively. These results were below the Stage 3 specification of not less than 55% (Q–25%). This batch was very close to expiry (09/05) at the time of dissolution testing, which took place on 20/09/05.

Another sample of the same product from a different batch (OMCL No. 7.25, expiry 12/05), collected at a private-sector distribution centre in the DRC, was found to be of satisfactory quality with respect to dissolution.

3.2.5 Content of active ingredient

All 289 samples of monocomponent products and 104 of 105 samples of fixed-dose combinations complied with content specifications. Mean content and ranges for the different active ingredients and dosage forms are illustrated in Figures 2 and 3.

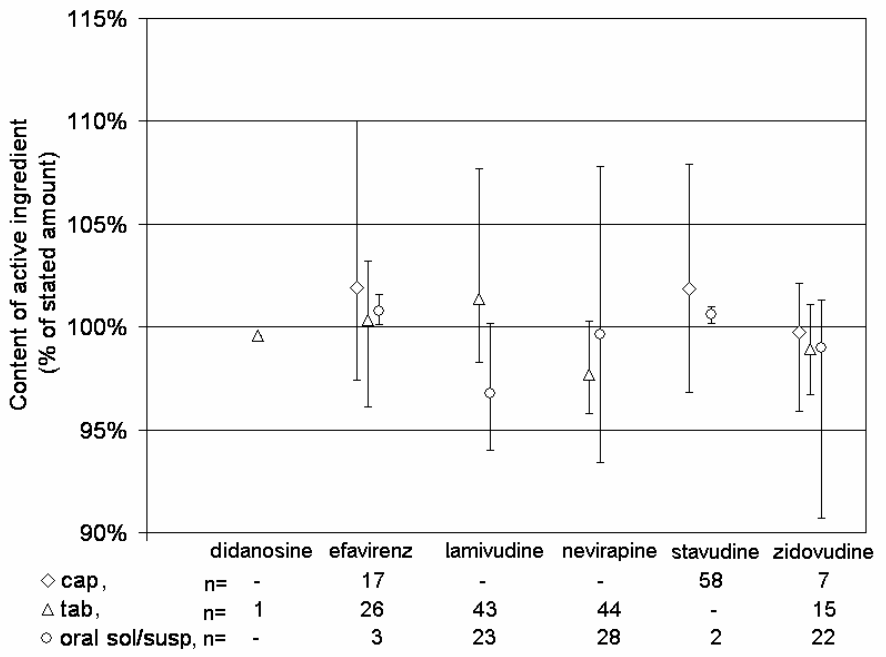

Figure 2: Monocomponent antiretrovirals (n=289): Content of active ingredient (in % of stated amount): average, minimum and maximum

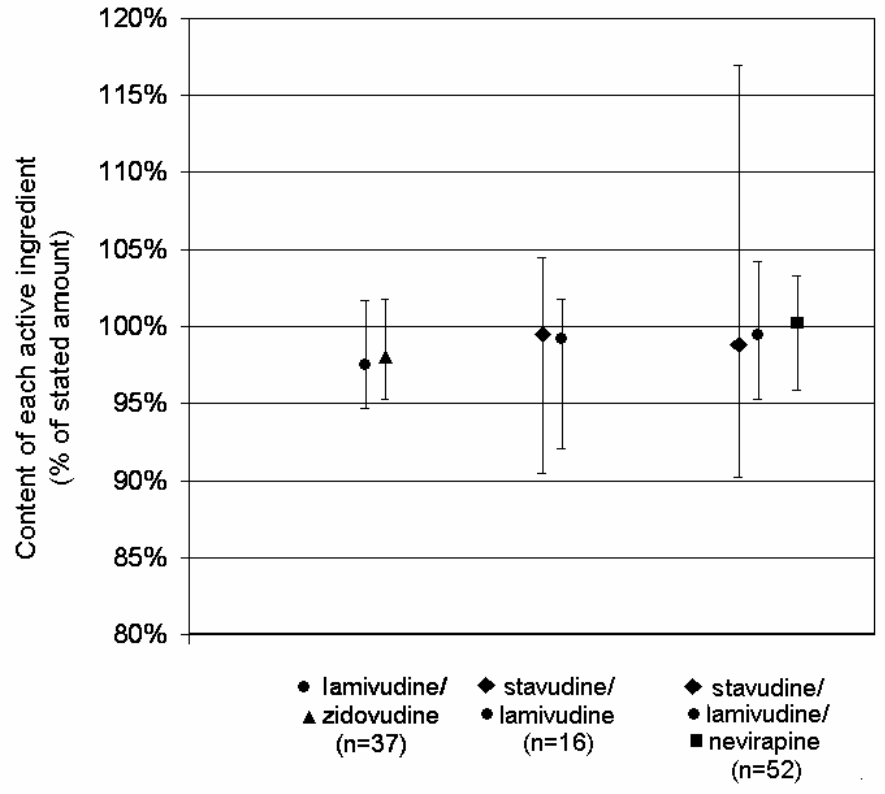

Figure 3: Fixed-dose antiretroviral combination tablets (n=105): Content of active ingredient (in % of stated amount): average, minimum and maximum

The sample which failed the specifications in terms of content was a "high failure", with a content above the acceptance criteria:

stavudine/lamivudine/nevirapine 30/150/200mg tablets (OMCL No. 6.16, page 49):

In this sample of a WHO-prequalified product, collected at a public-sector treatment centre in Tanzania, the content of stavudine was 117%, which was above the specified range of 90.0 to 110.0%.

This result was consistent with the results of dissolution testing, where the amount of stavudine dissolved ranged from 120-135% of the stated amount.

In order to confirm this high result, 20 tablets were tested for uniformity of content of stavudine. For the first set of 10 tablets, the content of stavudine ranged from 101.2 to 138.4% with a mean of 117.5% (RSD=12.7%) and for the second set, it ranged from 95.4-131.7% with a mean of 108.1% (RSD =10.6%).

The three different tests confirmed that this sample did not meet the specification for the content of stavudine.

One sample of non-WHO-prequalified **stavudine** 40mg capsules from a private-sector procurement company in Nigeria (OMCL No. 1.09, page 34) contained 107.9% of the stated amount of active ingredient, which is slightly above the specification of 90.0-105.0%. Given the uncertainty of measurement of the method, this result is considered satisfactory.

In four samples of fixed-dose combination tablets, the content of one or more active ingredients was at the lower limit of the specifications (90.0-110.0%):

- Three samples of WHO-prequalified **stavudine/lamivudine/nevirapine** tablets – two from public procurement centres in Cameroon (OMCL Nos. 6.05 and 6.06) and one from a public treatment centre in Uganda (OMCL No. 6.11), contained 90.2%, 91.3% and 90.3% of the stated amount of **stavudine** respectively (see page 48).
- One sample of **stavudine/lamivudine** 40/150mg from a wholesaler/importer in Zambia (OMCL No. 8.16, page 45, non-WHO-prequalified product) contained 90.5% and 92.1% of the stated amounts. In the remaining 15 samples tested, the content of stavudine ranged from 97.5-104.5% and that of lamivudine from 98.0-101.8%.

One sample of **zidovudine** 50mg/5ml oral solution (OMCL No. 5.07, page 39), not WHO-prequalified, collected at a manufacturer in Nigeria, had a low content of 90.7% of the label claim.

Given that all the above-mentioned samples met the requirements for related substances, the results suggest that correct amounts of active ingredients might have not been added at the time of manufacture.

There was another sample of non-WHO-prequalified oral suspension containing nevirapine (OMCL No. 3.14, from a manufacturer in Nigeria, page 33) with a relatively low content of active ingredient (93.4% of the stated amount of nevirapine). This sample had a lower pH value than all the other nevirapine oral suspensions tested (3.4 compared to 5.5 - 6.0) and also different appearance (orange compared to white to pale off-white). However as this product was not WHO-prequalified and the manufacturers' specifications for pH value and appearance were not available, it was considered to be compliant.

3.2.6 Impurities (related substances)

All 394 samples were tested for related substances. Two samples showed apparent out-of-specification results as discussed below.

zidovudine 300mg tablets (OMCL Nos. 5.05 and 5.36, page 40):

Both samples, collected at a manufacturer in Nigeria and at a public-sector treatment centre in Kenya respectively, were from the same batch. They contained 0.3% of an impurity identified as 3'-chloro-3'-deoxythymidine. This result does not meet the USP specification of ≤0.2% for any other individual unidentified impurity. However, as the acceptable limit for this impurity in the active ingredient is 1.0% according to USP, as well as the European Pharmacopoeia, it has not been concluded as a failure.

In the only sample of didanosine tested, total impurities were determined to be 0.5%. This result is at the upper limit of the specification for this product. At the time of testing (14/12/05), the sample was well within its expiry date (12/06).

3.2.7 Uniformity of mass

316 samples were tested for uniformity of mass and all complied with USP (28) 2005 specifications. In 308 samples, all 20 units were within the required range for at least 18 units. Eight samples had one unit outside this range, but within the limits allowed for the remaining two units.

3.2.8 Samples from identical batches

Two or more samples were tested from each of twenty-nine batches (see Appendix 2), with comparable results. Two samples shared a batch number coincidentally but these samples were manufactured at different manufacturing sites.

3.3 Summary of quality failures

In total, seven samples out of a total of 394 failed to meet specifications of different tests. This represents a failure rate of 1.8%. A summary of failures is shown in Table 8.

Table 8: Overview of failures

Test	Sample description	WHO-pre-qualified	OMCL No.	Page	Country and type of sampling site	Reason
Appearance	**(1)** efavirenz 600mg tablets	No	4.41	26	Zambia, a wholesaler / importer	One broken tablet and chipped coating of other tablets
Label	**(2)** stavudine 200mg powder for oral solution	No	1.13	35	Cameroon, public procurement centre	Information items 6, 7 and 8 missing from immediate container
Label	**(3)** stavudine 200mg powder for oral solution	No	1.24	35	Tanzania, public treatment centre	Information items 6, 7 and 8 missing from immediate container
Disintegration	**(4)** lamivudine/ zidovudine 150/300mg tablets	No	7.04	41	Nigeria, manufacturer	Exceeded 30-minute limit
Dissolution	**(5)** zidovudine 300mg tablets	Yes	5.19	37	Tanzania, public procurement centre	Failed stage 3 specification of the USP
Dissolution	**(6)** lamivudine/ zidovudine 150/300mg tablets	Yes	7.24	43	DRC, private hospital	Failed stage 3 specification of the USP
Content	**(7)** stavudine/ lamivudine/ nevirapine 30/150/200mg tablets	Yes	6.16	49	Tanzania, public treatment centre	Content of stavudine exceeded specification

As Table 8 shows, failures were not particularly frequent for any specific country, type of collection site, product, dosage form or type of test.

4. Discussion

This extensive survey, which covered seven African countries and used various types of antiretroviral procurement and treatment centres as sampling sites, achieved its objective of determining quality failure rates of antiretroviral products. The antiretrovirals tested were generally of good quality, with a low failure rate of 1.8%, and no serious failures, i.e. no critical deficiencies which would pose a serious risk to patients. The sampling sites were generally fairly large, official treatment centres or wholesalers. No samples were collected from any unofficial sources of antiretrovirals.

The logistic organization of the survey was good. Samples were gathered by the WHO country officers and national authority representatives within a reasonably short period. Packaging and documenting of sampling was generally adequate and consistent. Uniform Sample Information Collection Forms were used, and the samples were sent to the laboratory without delay. Involvement of WHO Medicines National Professional Officers and inspectors or analysts from National Drug Regulatory Authorities in sampling ensured the proper handling and labelling of samples and no deterioration of the quality of samples. In this survey, a single laboratory analysed all the samples. As the number of samples was high, a large laboratory was needed.

In total, 394 samples were collected for testing; 209 (53%) of these were WHO-prequalified at the time of sample collection. The highest percentage of prequalified products was for products containing zidovudine (81%), followed by the fixed-dose combination lamivudine/zidovudine (78%) and lamivudine (65%), whilst no prequalified product was amongst samples containing didanosine, efavirenz and the combination stavudine/lamivudine/nevirapine. This reflected the availability of prequalified products at the time of collecting samples, when no products containing efavirenz or didanosine were prequalified, and the FDC stavudine/lamivudine/ nevirapine had just been added to the prequalification list. With respect to the individual countries, the highest percentages of prequalified products were found among samples collected in Tanzania (76%) and Cameroon (68%), whilst in Uganda, Nigeria and Zambia the percentages of prequalified products were much lower (32%, 33% and 34%, respectively).

Information on the registration status of the sampled products was provided from all selected countries except Kenya. Of the 285 sampled products for which the information was provided, 84% were registered nationally, among them all samples collected in Cameroon, Tanzania and Uganda. A more complex situation was found in DRC, Nigeria and Zambia. In DRC 29% of sampled products were not registered at the time of sample collection, however 83% of these had either been registered previously, or applications had been submitted to WHO for prequalification. In Nigeria, no evidence of registration was found on the package labels of 24% of sampled products, which does however not confirm that products were unregistered. In Zambia, 45% of sampled products were not registered at the time of sample collection; for 90% of these, registration by the National Drug Regulatory Authority was pending. From these results it can be concluded that the majority of sampled products were in principle under the control of National Drug Regulatory Authorities. However, at least 12% of all sampled products were not registered at the time of sampling, indicating that market control was still incomplete in at least three countries. Non-registered products were collected mostly from the private sector. The proportions of WHO-prequalified products were 60% among nationally registered products, and 35% among non-registered products.

The appearance of samples was evaluated against the general specifications for dosage forms and only one of 394 samples did not comply. Only two of 394 samples (collected in two countries but belonging to the identical pharmaceutical product from one manufacturer) were insufficiently labelled. All 316 samples tested for uniformity of mass were compliant with the specifications. 163 samples were tested for disintegration and one only failed to disintegrate completely within 30 minutes.

Two of 153 samples tested for dissolution (one monocomponent product and one FDC) were found non-compliant due to lower dissolution results than required. One of these, a fixed-dose combination of lamivudine/zidovudine, failed in dissolution of both active ingredients.

With regard to related impurities tested for the active ingredients, all 394 samples were found to be compliant with the specifications, indicating that the APIs used in the manufacturing were of acceptable quality and/or stability did not pose a major problem.

Only one of 394 samples did not comply in the terms of active ingredient content. It concerned WHO-prequalified stavudine/lamivudine/nevirapine FDC tablets, with the stavudine content beyond the upper limit. The result was confirmed through repeat analysis and was consistent with the results of dissolution testing. The manufacturer, which was contacted, provided results at the time of release and results of analysis of retention samples, which all were compliant. This will be reviewed during the next inspection of this manufacturer within the prequalification programme.

The low failure rates found in this survey are encouraging, as they indicate that the purchase policies for the antiretrovirals supplied to the distribution points sampled were valid. More than half of the samples were of WHO-prequalified products. Considering that in January 2005, less than a third of all dossiers submitted (85 of 285) were approved for prequalification[19] and that many other manufacturers never sought prequalification for their products, it appears that preference is given to WHO-prequalified products in procurement. Even if non-WHO-prequalified products were procured, they were of acceptable quality. However it should be borne in mind that the quality control methods used were designed for well defined products in the regulated area, where they are used in parallel to the assessment of a dossier and inspections. These methods may have some limitations in a less regulated environment.

Limitations

The survey did not cover any remote treatment sites, or any informal sources of antiretroviral medication. Antiretrovirals in these settings may have higher failure rates than that observed in this survey, for various reasons: Transport, storage and control of medicines are more challenging in remote areas, and the presence of counterfeit products is reported more frequently from informal markets than from the formal, regulated environment[14].

Performing a similar survey in more rural settings would pose significant challenges. Particular care would have to be taken to achieve adequate sampling coverage, coordination of logistics and transport of samples with accompanying information. In terms of sample analysis, the task could be divided among several smaller laboratories, but careful planning of sampling and logistics would again be required.

5. Conclusion and recommendations

The quality of antiretrovirals supplied at official distribution points around the capital cities of seven African countries was found to be good, with only 1.8% failures and no critical deficiencies. It indicates that the efforts made by the WHO and other organizations on prequalification and purchase policies of the antiretrovirals have a positive effect. However, at least 12% of sampled products were not registered at the time of sampling indicating that market control in some countries is still incomplete.

No samples of antiretroviral products were collected at non-official sources, where higher failure rates than observed in this survey, or even counterfeit products, could be expected. Therefore, the positive outcome of this study does not necessarily reflect the quality of all antiretroviral products available to the public in these countries.

The organization of the survey was satisfactory, with no major limitations encountered.

The following recommendations are made:

- The findings of this survey should be made available to medicines regulatory authorities in African countries to assist them to develop appropriate quality assurance strategies.
- The findings of this survey should be used in awareness and advocacy programmes, reinforcing the need for quality assurance in procurement.
- The quality of antiretroviral products at user points should continue to be monitored. Various settings should be included in future surveys.
- The findings are of general public interest and should be published in a suitable journal.

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Appendix 1: Test results

1. Didanosine

Tablets, not prequalified (1 sample)

SPECIFICATIONS:		
Content of didanosine:	92.5-105.0% of stated amount	
Related substances:	Hypoxanthine (Ph.Eur. 5.2, 07/2005:2200 Impurity A):	≤ 2.0%
	Impurities, other (individual):	≤ 0.2%
	Impurities total, other:	≤ 0.5%

OMCL No.	Trade name, strength and dosage form	Batch	Primary pack	Sample and pack size	Expiry date	Country	Label	Ap-pear-ance	Iden-tity	Content (% of stated amount)	Related sub-stances	Dis-integra-tion	Uniformity of mass
9.01	Dinor 100mg tablets	01A05001	HDPE bottle	2 × 60	12/2006	Zambia	✓	✓	✓	99.6	**(a)**	✓	mean: 1195.59mg -1.1% to + 0.8%

(a) Complies; total impurities=0.5% (at the limit of the specification)

✓ = Complies

2. Efavirenz

Test Plan A: Capsules/tablets, not prequalified (43 samples) – methods of the Indian Pharmacopoeia

SPECIFICATIONS:
Content of efavirenz: 90.0-110.0% of stated amount
Related substances: Any individual impurity: ≤ 1.0%
Total impurities: ≤ 2.0%

OMCL No.	Trade name, strength and dosage form	Batch number	Primary Pack	Sample and pack size	Ex-piry date	Country	Label	Ap-pear-ance	Iden-tity	Content (% of stated amount)	Related sub-stances	Dis-integra-tion	Uniformity of mass
4.01	Aviranz 600mg tab	1513769	Plastic bottle	2×30	03/07	Nigeria	✓	✓	✓	96.2	✓	✓	mean: 1212.9mg -0.9% to +0.7%
4.02	Stocrin 600mg tab	NB14210	Plastic bottle	2×30	12/06	Nigeria	✓	✓	✓	100.9	✓	✓	mean: 1231.4mg -0.6% to +0.5%
4.03	Polodipin 200mg cap	G46198	Plastic bottle	2×30	01/06	Nigeria	✓	✓	✓	99.3	✓	✓	mean: 445.9mg -6.1% to +6.3%
4.04	Efavir 200mg cap	G56486	Plastic bottle	2×90	02/07	Cameroon	✓	✓	✓	99.2	✓	✓	mean: 447.0mg -4.6% to +4.0%
4.05	Efavir 600mg tab	G56252	Plastic bottle	4×30	01/07	Cameroon	✓	✓	✓	96.7	✓	✓	mean: 1359.9mg -2.2% to +1.7%
4.06	Efavir 600mg tab	G56499	Plastic bottle	4×30	03/07	Cameroon	✓	✓	✓	96.1	✓	✓	mean: 1363.1mg -3.0% to +2.9%
4.09	Stocrin 200mg cap	NB22820	Plastic bottle	2×90	01/08	Cameroon	✓	✓	✓	102.6	✓	✓	mean: 516.2mg -1.0% to +1.2%
4.10	Stocrin 200mg cap	NB32540	Plastic bottle	2×90	02/08	Cameroon	✓	✓	✓	102.4	✓	✓	mean: 509.5mg -1.3% to +1.5%
4.11	Stocrin 200mg cap	NB35720	Plastic bottle	2×90	02/08	Cameroon	✓	✓	✓	100.1	✓	✓	mean: 514.6mg -1.6% to +1.7%
4.12	Stocrin 600mg tab	NB32530	Plastic bottle	4×30	02/07	Cameroon	✓	✓	✓	102.4	✓	✓	mean: 1226.4mg -0.5% to +0.7%
4.13	Sustivir 600mg tab	Y41684	Plastic bottle	2×30	09/07	Uganda	✓	✓	✓	98.2	✓	✓	mean: 1375.8mg -1.9% to 2.2%
4.14	Efavir 600mg tab	Y42035	Plastic bottle	2×30	11/06	Uganda	✓	✓	✓	96.6	✓	✓	mean: 1370.1mg -1.7% to +2.0%
4.15	Stocrin 600mg tab	NB35330 **As 4.17**	Plastic bottle	2×30	02/07	Uganda	✓	✓	✓	102.5	✓	✓	mean: 1223.3mg -0.6% to +0.9%
4.16	Stocrin 50mg cap	NA24340	Plastic bottle	2×30	05/07	Uganda	✓	✓	✓	103.2	✓	✓	mean: 129.0mg -3.4% to +3.7%
4.17	Stocrin 600mg tab	NB35330 **As 4.15**	Plastic bottle	2×30	02/07	Uganda	✓	✓	✓	101.3	✓	✓	mean: 1223.4mg -1.5% to +2.5%
4.18	Stocrin 600mg tab	NB35320	Plastic bottle	2×30	02/07	Tanzania	✓	✓	✓	102.3	✓	✓	mean: 1223.8mg -1.4% to +0.8%
4.19	Stocrin 600mg tab	NB26700	Plastic bottle	2×30	01/07	Tanzania	✓	✓	✓	101.2	✓	✓	mean: 1228.1mg -0.8% % to0.7%
4.21	Stocrin 600mg tab	HV77220 **As 4.24**	Plastic bottle	2×30	02/06	Tanzania	✓	✓	✓	102.2	✓	✓	mean: 1241.4mg -1.4% to +1.0%
4.22	Stocrin 600mg tab	HV77230	Plastic bottle	2×30	02/06	Tanzania	✓	✓	✓	102.6	✓	✓	mean: 1238.5mg -1.5% to +1.1%
4.23	Stocrin 600mg tab	NB26690	Plastic bottle	2×30	01/07	Tanzania	✓	✓	✓	103.1	✓	✓	mean: 1229.6mg -1.3% to +0.7%
4.24	Stocrin 600mg tab	HV77220 **As 4.21**	Plastic bottle	2×30	02/06	Tanzania	✓	✓	✓	103.1	✓	✓	mean: 1240.5mg -1.1% to 1.2%
4.25	Stocrin 600mg tab	NA30350	Plastic bottle	2×30	08/06	DRC	✓	✓	✓	103.2	✓	✓	mean: 1240.9mg -0.9% to 0.9%
4.20	Efavir 200mg cap	Y41451	Plastic bottle	2×90	01/06	Tanzania	✓	✓	✓	98.4	✓	✓	mean: 442.9mg 19 capsules: -4.7% to +3.7% **1 capsule: +7.6%**
4.26	Estiva 200mg cap	EV40911	Plastic bottle	2×90	08/06	DRC	✓	✓	✓	97.4	✓	✓	mean: 401.9mg -5.7% to +4.5%
4.27	Stocrin 200mg cap	HV60070	Plastic bottle	1×90	02/06	DRC	✓	✓	✓	103.2	✓	✓	mean: 514.9mg -2.3% to +2.5%
4.28	Efariv 600mg tab	050708	Plastic bottle	4×30	04/07	Kenya	✓	✓	✓	97.3	✓	✓	mean: 1139.3mg -2.5% to +3.0%
4.29	Aviranz 600mg tab	1390735	Plastic bottle	4×30	03/06	Kenya	✓	✓	✓	98.1	✓	✓	mean: 1239.0mg -1.4% to +1.9%
4.30	Aviranz 600mg tab	1386917	Plastic bottle	4×30	03/06	Kenya	✓	✓	✓	99.2	✓	✓	mean: 1231.6mg -1.2% to +1.8%

✓ = Complies

2. Efavirenz

Test Plan A: Capsules/tablets, not prequalified (43 samples) – methods of the Indian Pharmacopoeia **(continued)**

SPECIFICATIONS:
Content of efavirenz: 90.0-110.0% of stated amount
Related substances: Any individual impurity: ≤ 1.0%
Total impurities: ≤ 2.0%

OMCL No.	Trade name, strength and dosage form	Batch number	Primary Pack	Sample and pack size	Ex-piry date	Country	Label	Ap-pear-ance	Iden-tity	Content (% of stated amount)	Related sub-stances	Dis-integra-tion	Uniformity of mass
4.31	Aviranz 600mg tab	1390752	Plastic bottle	4×30	03/06	Kenya	✓	✓	✓	96.6	✓	✓	mean: 1195.4mg -2.5% to +1.6%
4.33	Stocrin 50mg cap	NA37970	Plastic bottle	4×30	05/07	Kenya	✓	✓	✓	99.9	✓	✓	mean: 127.4mg -6.8% to +5.3%
4.34	Stocrin 50mg cap	NB00350	Plastic bottle	4×30	07/07	Kenya	✓	✓	✓	110.0	✓	✓	mean: 132.2mg -1.6% to +1.5%
4.35	Stocrin 50mg cap	NA42780	Plastic bottle	4×30	08/07	Kenya	✓	✓	✓	102.6	✓	✓	mean: 127.3mg -5.9% to +6.4%
4.36	Stocrin 200mg cap	NA17240	Plastic bottle	2×90	05/07	Kenya	✓	✓	✓	102.7	✓	✓	mean: 516.9mg -1.9% to +0.9%
4.37	Stocrin 200mg cap	NB10760	Plastic bottle	2×90	12/07	Kenya	✓	✓	✓	106.3	✓	✓	mean: 517.4mg -2.3% to +2.7%
4.41	Efcure 600mg tab	01A04003	Plastic bottle	2×30	10/06	Zambia	✓	**(1)**	✓	101.3	✓	✓	mean: 1228.7mg -1.2% to +1.1%
4.42	Aviranz 600mg tab	1520830	Plastic bottle	2×30	04/07	Zambia	✓	✓	✓	100.5	✓	✓	mean: 1228.6mg -1.1% to +0.9%
4.43	Efavir 200mg cap	G47289	Plastic bottle	2×30	09/06	Zambia	✓	✓	✓	99.8	✓	✓	mean: 441.0mg -6.5% to +4.9%
4.44	Stocrin 50mg cap	L030600	Plastic bottle	3×30	06/07	Zambia	✓	✓	✓	99.9	✓	✓	mean: 129.7mg -3.4% to +3.6%
4.45	Stocrin 50mg cap	L030420	Plastic bottle	1×30	05/07	Zambia	✓	✓	✓	105.3	✓	✓	mean: 131.2mg -2.6% to +4.1%
4.38	Stocrin 600mg tab	HV31700	Plastic bottle	4×30	12/05	Kenya	✓	✓	✓	99.9	✓	✓	mean: 1234.5mg -1.5% to 1.0%
4.39	Stocrin 600mg tab	NB52450	Plastic bottle	4×30	02/07	Kenya	✓	✓	✓	102.3	✓	✓	mean: 1222.2mg -0.8% to 0.9%
4.40	Stocrin 600mg tab	NB02550	Plastic bottle	4×30	11/06	Kenya	✓	✓	✓	102.1	✓	✓	mean: 1228.1mg -0.9% to 0.7%
4.46	Stocrin 600mg tab	NB14200	Plastic bottle	2×30	12/06	Zambia	✓	✓	✓	102.2	✓	✓	mean: 1228.0mg -1.4% to 0.8%

(1) Does not comply: Sample contained one broken tablet and several with chipped coating. (WHO sampling number: PW/PI/010/004)

✓ = Complies

2. Efavirenz

Test Plan B: Oral solutions, not prequalified (3 samples) – Swissmedic methods

SPECIFICATIONS:

Related substances:	Impurity 1 (potential impurity from synthesis of efavirenz):	≤ 0.25%
	Any other individual impurity:	≤ 0.2%
	Sum of all impurities:	≤ 0.5%

OMCL No.	Trade name, strength and dosage form	Batch number	Pri-mary pack	Sample size	Ex-piry date	Country	Label	Ap-pear-ance	Iden-tity	Content (% of stated amount)	Related substances
4.07	Stocrin 30mg/ml oral solution	NB17260 **As 4.32**	Plastic bottle	2×180ml	12/07	Cameroon	✓	✓	✓	100.1	✓
4.08	Stocrin 30mg/ml oral solution	NB17250	Plastic bottle	2×180ml	12/07	Cameroon	✓	✓	✓	101.6	✓
4.32	Stocrin 30mg/ml oral solution	NB17260 **As 4.07**	Plastic bottle	2×180ml	12/07	Kenya	✓	✓	✓	100.6	✓

✓ = Complies

3. Lamivudine

Test Plan A: Tablets, not prequalified (18 samples) – methods of the Indian Pharmacopoeia

SPECIFICATIONS:
Content of lamivudine: 90.0-110.0% of stated amount
Related substances: Any individual impurity: ≤1.0%
Sum of all impurities: ≤2.0%

OMCL No.	Trade name, strength and dosage form	Batch	Primary pack	Sample & pack size	Expiry date	Country	Label	Appearance	Identity	Disintegration	Content (% of stated amount)	Related substances	Uniformity of mass
2.01	Heptavir 150mg tab	HD50215	Plastic bottle	2 × 60	01/07	Nigeria	✓	✓	✓	✓	100.9	✓	mean: 286.5mg -2.9% to +1.7%
2.05	Avolam 150mg tab	1375882 **As 2.06**	Blister strips	2 × 6 × 10	01/06	Nigeria	✓	✓	✓	✓	104.8	✓	mean: 309.4mg -1.1% to +0.8%
2.06	Avolam 150mg tab	1375882 **As 2.05**	Blister strips	2 × 6 × 10	01/06	Nigeria	✓	✓	✓	✓	104.8	✓	mean: 309.3mg -1.3% to +0.8%
2.08	Avolam 150mg tab	1369991	Blister strips	2 × 6 × 10	01/06	Nigeria	✓	✓	✓	✓	104.9	✓	mean: 309.4mg -1.7% to +1.1%
2.09	Avolam 150mg tab	1365896	Blister strips	2 × 6 × 10	12/05	Nigeria	✓	✓	✓	✓	106.4	✓	mean: 309.1mg -0.8% to +1.0%
2.10	Avolam 150mg tab	1369945	Blister strips	2 × 6 × 10	01/06	Nigeria	✓	✓	✓	✓	106.5	✓	mean: 309.4mg -1.0% to +0.9%
2.11	Avolam 150mg Tab	1365906	Blister strips	2 × 6 × 10	12/05	Nigeria	✓	✓	✓	✓	107.7	✓	mean: 310.1mg -1.2% to +0.9%
2.40	Lavir 150mg tab	01A05002 **As 2.63**	Plastic bottle	2 × 60	02/07	Tanzania	✓	✓	✓	✓	102.7	✓	mean: 291.4mg -1.8% to +1.2%
2.41	Lavir 150mg tab	01A05001	Plastic bottle	2 × 60	02/07	Tanzania	✓	✓	✓	✓	100.4	✓	mean: 292.0mg -1.9% to +2.5%
2.42	Lamivudine 150mg, tab	AL05-L9001	Plastic bottle	2 × 14	05/07	DRC	✓	✓	✓	✓	99.5	✓	mean: 313.0mg -1.7% to +1.6%
2.43	Avolam 150mg tab	1358116	Blister strips	2 × 60	11/05	DRC	✓	✓	✓	✓	100.5	✓	mean: 310.2mg -2.0% to +2.0%
2.49	Heptavir 150mg tab	HD41010	Plastic bottle	2 × 60	09/06	Kenya	✓	✓	✓	✓	99.4	✓	mean: 285.6mg -2.8% to +2.2%
2.50	Lamiriv 150mg tab	031673	Blister strips	2 × 60	11/05	Kenya	✓	✓	✓	✓	100.1	✓	mean: 336.4mg -2.2% to +2.3%
2.51	Lamiriv 150mg tab	031674 **As 2.62**	Blister strips	2 × 60	11/05	Kenya	✓	✓	✓	✓	98.8	✓	mean: 334.5mg -2.0% to +2.3%
2.52	Lamiriv 150mg tab	040341	Blister strips	2 × 60	12/05	Kenya	✓	✓	✓	✓	100.6	✓	mean: 335.8mg -3.3% to +4.7%
2.62	Lamiriv 150mg tab	031674 **As 2.51**	Blister strips	2 × 60	11/05	Kenya	✓	✓	✓	✓	99.4	✓	mean: 337.1mg -2.7% to +4.7%
2.63	Lavir 150mg tab	01A05002 **As 2.40**	Plastic bottle	2 × 60	02/07	Zambia	✓	✓	✓	✓	98.8	✓	mean: 290.6mg 19 tablets: -2.4% to +2.4% **1 tablet: + 5.1%**
2.64	Avolam 150mg tab	1499688	Blister strips	2 × 60	02/07	Zambia	✓	✓	✓	✓	101.6	✓	mean: 308.3mg -2.9% to +1.7%

✓ = Complies

3. Lamivudine

Test Plan B: Tablets, prequalified (25 samples) – Swissmedic methods

SPECIFICATIONS:

Content of lamivudine: 95.0-105.0% of stated amount

Related substances:	Impurity A - Ph.Eur. 5.3, 01/2006:2217:	≤ 0.3%
	Impurity B - Ph.Eur. 5.3, 01/2006:2217:	≤ 0.2%
	Any other impurity:	≤ 0.1%
	Total impurities:	≤ 1.0%
Dissolution:	Not less than 80% (Q) of the stated amount of lamivudine dissolved in 30 minutes	

OMCL No.	Trade name, strength and dosage form	Batch	Primary pack	Sample & pack size	Expiry date	Country	Label	Appearance	Identity	Content (% of stated amount)	Related substances	Dissolution (% of stated amount)	Uniformity of mass
2.02*	Lamivudine 150mg tab	7200227	Plastic bottle	2 × 60	02/07	Nigeria	✓	✓	✓	102.5	✓	94.8-100.7	mean: 279.2mg -1.9% to +2.7%
2.07*	Epivir 150mg tab	B144178 **As 2.13**	Plastic bottle	2 × 60	09/06	Nigeria	✓	✓	✓	100.3	✓	94.4-101.4	mean: 304.5mg -1.1% to +1.3%
2.13*	Epivir 150mg Tab	B144178 **As 2.07**	Plastic bottle	2 × 60	09/06	Nigeria	✓	✓	✓	102.4	✓	96.4-103.0	mean: 305.9mg -1.0% to +1.0%
2.20*	Lamivir 150mg tab	G32074	Plastic bottle	2 × 60	02/06	Cameroon	✓	✓	✓	100.1	✓	96.5-99.7	mean: 307.7mg 19 tablets: -3.5% to + 1.8% **1 tablet: - 5.1%**
2.22*	Epivir 150mg tab	R169400 **As 2.26 and 2.57**	Plastic bottle	2 × 60	03/07	Uganda	✓	✓	✓	102.1	✓	97.1-101.5	mean: 304.9mg -2.3% to +3.2%
2.23*	Epivir 150mg tab	R171437	Plastic bottle	2 × 60	04/07	Uganda	✓	✓	✓	102.6	✓	95.4-98.7	mean: 307.2mg -1.2% to +1.6%
2.24*	Lamivir 150mg tab	G54349	Plastic bottle	2 × 60	02/08	Uganda	✓	✓	✓	101.5	✓	97.9-100.7	mean: 301.6mg -1.8% to +2.1%
2.26*	Epivir 150mg tab	R169400 **As 2.22 and 2.57**	Plastic bottle	2 × 60	03/07	Uganda	✓	✓	✓	100.1	✓	93.8-102.8	mean: 306.0mg -2.5% to +2.5%
2.27*	Lamivir 150mg tab	Y50645	Plastic bottle	2 × 60	02/08	Tanzania	✓	✓	✓	103.0	✓	99.8-102.8	mean: 303.0mg -1.6% to +1.7%
2.29*	Lamivir 150mg tab	Y41272 **As 2.35**	Plastic bottle	2 × 60	05/07	Tanzania	✓	✓	✓	102.0	✓	98.6-100.0	mean: 309.3mg -1.7% to +2.5%
2.30*	Lamivir 150mg tab	G54328	Plastic bottle	2 × 60	02/08	Tanzania	✓	✓	✓	101.6	✓	97.3-100.2	mean: 296.5mg -1.9% to +3.1%
2.31*	Lamivir 150mg tab	Y50743	Plastic bottle	2 × 60	02/08	Tanzania	✓	✓	✓	102.7	✓	97.6-98.8	mean: 300.6mg -1.4% to +1.8%
2.32*	Lamivir 150mg tab	G54177	Plastic bottle	2 × 60	01/08	Tanzania	✓	✓	✓	98.3	✓	94.5-98.6	mean: 300.9mg - 2.4% to +3.1%
2.35*	Lamivir 150mg tab	Y41272 **As 2.29**	Plastic bottle	2 × 60	05/07	Tanzania	✓	✓	✓	98.9	✓	93.3-97.4	mean: 305.9mg - 1.9% to +1.7%
2.37*	Lamivir 150mg tab	G54329 **As 2.39**	Plastic bottle	2 × 60	02/08	Tanzania	✓	✓	✓	100.6	✓	99.3-100.1	mean: 300.8mg -2.8% to +1.5%
2.39*	Lamivir 150mg tab	G54329 **As 2.37**	Plastic bottle	2 × 60	02/08	Tanzania	✓	✓	✓	100.2	✓	96.3-101.5	mean: 300.5mg -3.3% to +2.1%
2.46*	Lamivir 150mg tab	G54268	Plastic bottle	2 × 60	02/08	DRC	✓	✓	✓	99.5	✓	98.0-102.1	mean: 303.3mg -2.0% to +3.3%
2.47*	Epivir 150mg tab	B128377	Plastic bottle	1 × 60	03/06	DRC	✓	✓	✓	100.5	✓	95.8-99.1	mean: 307.1mg -1.0% to +1.1%
2.56*	Epivir 150mg tab	B145845	Plastic bottle	2 × 60	09/06	Kenya	✓	✓	✓	100.4	✓	95.1-97.0	mean: 302.5mg -1.5% to +1.4%
2.57*	Epivir 150mg tab	R169400	Plastic bottle	2 × 60	03/07	Kenya	✓	✓	✓	100.5	✓	93.0-102.4	mean: 303.5mg -2.2% to +2.3%
2.58*	Epivir 150mg tab	B132605	Plastic bottle	2 × 60	05/06	Kenya	✓	✓	✓	100.0	✓	96.5-103.3	mean: 305.2mg -1.4% to +1.1%
2.59*	Epivir 150mg tab	R154285	Plastic bottle	2 × 60	12/06	Kenya	✓	✓	✓	99.2	✓	94.8-99.7	mean: 302.3mg -1.6% to +2.0%
2.60*	Epivir 150mg tab	B143470	Plastic bottle	2 × 60	09/06	Kenya	✓	✓	✓	101.1	✓	96.9-101.5	mean: 304.7mg -1.2% to +1.7%
2.61*	Epivir 150mg tab	R152020	Plastic bottle	2 × 60	11/06	Kenya	✓	✓	✓	102.4	✓	95.4-99.1	mean: 304.5mg -1.7% to +1.5%
2.65*	Lamivir 150mg tab	Y50435	Plastic bottle	2 × 60	12/06	Zambia	✓	✓	✓	98.6	✓	101.5-103.0	mean: 299.6mg -1.2% to +1.4%

✓ = Complies

*=WHO-prequalified

3. Lamivudine

Test Plan C: Oral solutions (23 samples) – Swissmedic methods

SPECIFICATIONS:

Content of lamivudine:	90.0-105.0% of stated amount	
Related substances:	Cytosine (Ph.Eur. 5.3, 01/2006:2217 Impurity E):	≤ 0.3%
	Impurity G - Ph.Eur. 5.3, 01/2006:2217:	≤ 0.3%
	Impurity H - Ph.Eur. 5.3, 01/2006:2217:	≤ 0.7%
	Impurity J - Ph.Eur. 5.3, 01/2006:2217:	≤ 1.2%
	Other known single impurity:	≤ 0.3%
	Other single impurity (known):	≤ 0.2%
	Total impurities:	≤ 2.7%
pH:	5.7 to 6.3	

OMCL No.	Trade name, strength and dosage form	Primary pack	Sample & pack size	Expiry date	Country	Appearance	Content (% of stated amount)	Related substances	pH
2.03	Avolam 50mg/5ml oral sol.	Glass bottle	2 × 100	01/2006	Nigeria	✓	95.3	✓	6.0
2.04	Avolam 50mg/5ml oral sol.	Glass bottle	1 × 200	02/2007	Nigeria	✓	97.1	✓	5.7
2.12*	Lavudine 50mg/5ml oral sol.	Plastic bottle	2 × 100	01/2007	Nigeria	✓	96.8	✓	5.8
2.14*	Epivir 10mg/ml oral sol.	Plastic bottle	2 × 240	07/2005	Nigeria	✓	94.4	✓	6.1
2.15	Virex-L 50mg/5ml oral sol.	Glass bottle	2 × 100	02/2007	Nigeria	✓	99.0	✓	**5.0**
2.16*	Lamivir 50mg/5ml oral sol.	Glass bottle	2 × 100	11/2006	Cameroon	✓	97.8	✓	5.9
2.17*	Lamivir 50mg/5ml oral sol.	Plastic bottle	2 × 100	11/2006	Cameroon	✓	96.4	✓	6.0
2.18*	Lamivir 50mg/5ml oral sol.	Plastic bottle	2 × 100	03/2007	Cameroon	✓	97.0	✓	6.0
2.19*	Lamivir 50mg/5ml oral sol.	Plastic bottle	2 × 100	02/2007	Cameroon	✓	97.5	✓	6.1
2.21*	Lamivir 50mg/5ml oral sol.	Plastic bottle	2 × 240	02/2007	Uganda	✓	95.6	✓	6.0
2.25	Okavir 50mg/5ml oral sol.	Glass bottle	2 × 100	07/2006	Uganda	✓	94.3	✓	6.0
2.28*	Lamivir 50mg/5ml oral sol.	Plastic bottle	2 × 100	01/2007	Tanzania	✓	95.0	✓	6.1
2.33*	Lamivir 50mg/5ml oral sol.	Plastic bottle	2 × 100	07/2006	Tanzania	✓	94.0	✓	6.0
2.34	Lamivir 50mg/5ml oral sol.	Plastic bottle	2 × 100	07/2006	Tanzania	✓	96.4	✓	6.0
2.36*	Lamivir 50mg/5ml oral sol.	Plastic bottle	2 × 100	02/2007	Tanzania	✓	96.3	✓	5.9
2.38*	Lamivir 50mg/5ml oral sol.	Plastic bottle	2 × 100	02/2007	Tanzania	✓	98.9	✓	6.0
2.44*	Lamivir 50mg/5ml oral sol.	Plastic flacon	2 × 100	08/2006	DRC	✓	99.9	✓	6.0
2.45*	Lamivir 50mg/5ml oral sol.	Plastic bottle	2 × 100	05/2006	DRC	✓	95.6	✓	5.9
2.48*	Epivir 10mg/ml oral sol.	Plastic bottle	2 × 140	11/2005	DRC	✓	96.8	✓	6.1
2.53*	Epivir 10mg/ml oral sol.	Plastic bottle	2 × 240	02/2007	Kenya	✓	100.2	✓	6.1
2.54*	Epivir 10mg/ml oral sol.	Plastic bottle	2 × 240	11/2006	Kenya	✓	98.3	✓	6.1
2.55*	Epivir 10mg/ml oral sol.	Plastic bottle	2 × 240	10/2006	Kenya	✓	98.4	✓	6.1
2.66*	Lamivir 50mg/5ml oral sol.	Plastic bottle	2 × 100	09/2006	Zambia	✓	95.1	✓	6.1

✓ = Complies
*=WHO-prequalified

4. Nevirapine

Test Plan A: Tablets, not prequalified (15 samples) – methods of the Indian Pharmacopoeia

SPECIFICATIONS:
Content of nevirapine: 90.0-110.0% of stated amount;
Related substances: Any individual impurity: ≤ 1.0%
Total impurities: ≤ 2.0%

OMCL No.	Trade name, strength and dosage form	Batch	Pri-mary pack	Sample & pack size	Expiry date	Country	Label	Ap-pear-ance	Iden-tity	Dis-integra-tion	Content (% of stated amount)	Related substances	Uniformity of mass
3.02	Nevran 200mg tab	1397711	Paper carton	2 × 5 × 12	04/06	Nigeria	✓	✓	✓	✓	97.7	✓	mean: 805.6mg -1.7% to +1.3%
3.07	Nevran 200mg tab	1394027	Blister strips	2 × 5 × 12	03/06	Nigeria	✓	✓	✓	✓	98.5	✓	mean: 802.7mg -3.6% to +1.9%
3.08	Nevran 200mg tab	1386313	Blister strips	2 × 5 × 12	02/06	Nigeria	✓	✓	✓	✓	97.4	✓	mean: 804.9mg -2.9% to +2.9%
3.09	Nevran 200mg tab	1386311	Blister strips	2 × 5 × 12	02/06	Nigeria	✓	✓	✓	✓	97.6	✓	mean: 805.4mg -1.8% to +1.8%
3.10	Nevran 200mg tab	1386265	Blister strips	2 × 5 × 12	02/06	Nigeria	✓	✓	✓	✓	97.9	✓	mean: 805.3mg -0.9% to +1.9%
3.25	Nevir 200mg tab	OIA05007	Plastic bottle	2 × 60	02/07	Tanzania	✓	✓	✓	✓	98.5	✓	mean: 370.4mg -1.3% to +1.4%
3.49	Neviriv 200mg tab	040343	Blister strips	8 × 15	12/05	Kenya	✓	✓	✓	✓	97.1	✓	mean: 932.6mg -1.2% to +1.1%
3.50	Neviriv 200mg tab	040344	Blister strips	2 × 60	12/05	Kenya	✓	✓	✓	✓	96.1	✓	mean: 935.8mg -1.3% to +1.4%
3.51	Neviriv 200mg tab	031678	Blister strips	2 × 60	11/05	Kenya	✓	✓	✓	✓	96.7	✓	mean: 930.2mg -1.0% to +0.8%
3.52	Nevipan 200mg tab	1397709	Blister strips	2 × 60	04/06	Kenya	✓	✓	✓	✓	97.2	✓	mean: 803.9mg -1.3% to +2.2%
3.53	Nevir 200mg tab	LNL0406	Plastic bottle	2 × 60	05/06	Kenya	✓	✓	✓	✓	96.1	✓	mean: 367.8mg -1.5% to +1.8%
3.54	Nevir 200mg tab	LNL0405	Plastic bottle	2 × 60	05/06	Kenya	✓	✓	✓	✓	95.8	✓	mean: 369.3mg -1.7% to +1.2%
3.67	Okamune 200mg tab	S50063	Plastic bottle	2 × 60	03/06	Zambia	✓	✓	✓	✓	96.1	✓	mean: 845.3mg -1.9% to +1.1%
3.68	Nevipan 200mg tab	1497485	Blister strips	2 × 60	02/07	Zambia	✓	✓	✓	✓	99.5	✓	mean: 811.4mg -1.7% to +1.8%
3.70	Nevir 200mg	LNL0407	Plastic bottle	2 × 60	05/06	Zambia	✓	✓	✓	✓	96.1	✓	mean: 370.4mg -1.2% to +3.0%

✓ = Complies

4. Nevirapine

Test Plan B: Tablets, prequalified (29 samples) – Swissmedic methods

SPECIFICATIONS:
Content of nevirapine: 95.0-105.0% of stated amount
Related substances: Any individual impurity: ≤ 0.1%; Total impurities:≤ 0.2%
Dissolution: Not less than 75% (Q) of the stated amount of nevirapine dissolved in 60 minutes

OMCL No.	Trade name, strength and dosage form	Batch	Primary pack	Sample and pack size	Expiry date	Country	Label	Appearance	Identity	Content (% of stated amount)	Related substances	Dissolution (% of stated amount)	Uniformity of mass
3.01*	Nevirapine 200mg tab	ZEG 4003	Plastic bottle	2 × 60	11/06	Nigeria	✓	✓	✓	98.9	✓	85.2-88.2 ξ= 86.9	mean: 453.4mg -0.8% to +1.0%
3.05*	Nevivir 200mg tab	NV 50213	Plastic bottle	2 × 60	01/07	Nigeria	✓	✓	✓	96.3	✓	94.5-98.1 ξ= 96.4	mean: 360.5mg -1.7% to +2.4%
3.06*	Viramune 200mg tab	407734 **As 3.61**	Blister strips	2 × 6 × 10	10/07	Nigeria	✓	✓	✓	97.3	✓	88.4-92.9 ξ= 90.0	mean: 807.4mg -2.1% to +1.2%
3.12*	Viramune 200mg tab	405312A	Blister strips	2 × 6 × 10	06/07	Nigeria	✓	✓	✓	97.6	✓	94.9-97.4 ξ= 96.0	mean: 808.5mg -0.8% to +0.8%
3.15*	Nevivir 200mg tab	NV40101	Plastic bottle	2 × 60	12/05	Uganda	✓	✓	✓	96.0	✓	81.0-84.0 ξ= 82.8	mean: 358.9mg -2.3% to +1.1%
3.16*	Viramune 200mg tab	409335B	Plastic bottle	2 × 60	01/08	Uganda	✓	✓	✓	97.8	✓	90.7-95.4 ξ= 93.9	mean: 805.0mg -1.4% to +1.3%
3.19*	Nevivir 200mg tab	NV40101	Plastic bottle	2 × 60	12/05	Uganda	✓	✓	✓	95.9	✓	83.2-85.1 ξ= 84.0	mean: 360.7mg -2.2% to +1.1%
3.21*	Nevivir 200mg tab	NV40101	Plastic bottle	2 × 60	12/05	Uganda	✓	✓	✓	96.0	✓	83.3-86.4 ξ= 84.6	mean: 362.9mg -1.9% to +2.5%
3.23*	Nevimune 200mg tab	C50046	Plastic bottle	2 × 60	12/06	Tanzania	✓	✓	✓	97.2	✓	86.0-93.3 ξ= 89.3	mean: 855.6mg -1.6% to +1.5%
3.24*	Viramune 200mg tab	3086588	Blister strips	2 × 60	11/06	Tanzania	✓	✓	✓	96.8	✓	81.7-85.3 ξ= 84.2	mean: 807.5mg -1.3% to +0.9%
3.27*	Nevimune 200mg tab	C40464	Plastic bottle	2 × 60	07/06	Tanzania	✓	✓	✓	98.5	✓	82.8-92.3 ξ= 86.9	mean: 849.7mg -1.2% to +2.0%
3.29*	Nevimune 200mg tab	C40467 **As 3.36**	Plastic bottle	1 × 60	07/06	Tanzania	✓	✓	✓	99.4	✓	84.0-90.4 ξ= 87.3	mean: 852.2mg -2.3% to +2.0%
3.30*	Nevimune 200mg tab	G54198	Plastic bottle	1 × 60	01/07	Tanzania	✓	✓	✓	97.4	✓	92.7-97.9 ξ= 95.1	mean: 845.6mg -1.1% to +1.3%
3.32*	Nevimune 200mg tab	C40463	Plastic bottle	2 × 60	07/06	Tanzania	✓	✓	✓	96.0	✓	80.0-86.4 ξ= 83.2	mean: 846.2mg -2.2% to +1.2%
3.34*	Nevimune 200mg tab	C40339	Plastic bottle	2 × 60	05/06	Tanzania	✓	✓	✓	98.0	✓	91.3-93.3 ξ= 92.4	mean: 847.7mg -2.5% to +2.9%
3.36*	Nevimune 200mg tab	C40467 **As 3.29**	Plastic bottle	2 × 60	07/06	Tanzania	✓	✓	✓	98.4	✓	94.4-97.7 ξ= 96.2	mean: 846.0mg 19 tablets: -1.8% to +1.1% **1 tablet: + 7.5%**
3.37*	Nevivir 200mg tab	NV41009	Glass bottle	2 × 60	09/06	DRC	✓	✓	✓	97.3	✓	89.9-94.7 ξ= 93.4	mean: 358.3mg -1.3% to +1.0%
3.40*	Nevimune 200mg tab	G54351	Plastic bottle	2 × 60	02/07	DRC	✓	✓	✓	96.5	✓	87.3-90.9 ξ= 89.1	mean: 851.0mg -1.9% to +1.5%
3.42*	Nevimune 200mg tab	G44044	Plastic bottle	2 × 60	12/05	DRC	✓	✓	✓	98.6	✓	81.5-86.0 ξ= 84.4	mean: 849.5mg -1.9% to +1.3%
3.44*	Viramune 200mg tab	502809	Blister strips	2 × 60	02/07	DRC	✓	✓	✓	97.6	✓	91.0-94.2 ξ= 93.1	mean: 808.3mg -2.1% to +1.2%
3.45*	Nevivir 200mg tab	NV31109	Plastic bottle	2 × 60	10/05	Kenya	✓	✓	✓	100.2	✓	92.6-96.4 ξ= 94.5	mean: 360.5mg -0.9% to +3.1%
3.46*	Nevimune 200mg tab	G44559	Plastic bottle	2 × 60	05/06	Kenya	✓	✓	✓	98.1	✓	82.7-85.2 ξ= 84.1	mean: 847.6mg -4.2% to +3.10%
3.47*	Nevimune 200mg tab	C50261	Plastic bottle	8 × 15	04/07	Kenya	✓	✓	✓	98.8	✓	85.2-89.9 ξ= 88.6	mean: 854.4mg -0.8% to +1.4%
3.48*	Nevimune 200mg tab	C50085	Plastic bottle	8 × 15	01/07	Kenya	✓	✓	✓	100.3	✓	81.7-98.6 ξ= 92.1	mean: 859.1mg -1.3% to +2.0%
3.57*	Viramune 200mg tab	502154A	Blister strips	2 × 60	01/08	Kenya	✓	✓	✓	98.4	✓	102.6- 108.8 ξ= 106.0	mean: 804.6mg -1.1% to +1.4%
3.58*	Viramune 200mg tab	409351	Blister strips	2 × 60	01/08	Kenya	✓	✓	✓	99.8	✓	90.5-93.5 ξ= 92.1	mean: 819.4mg -2.0% to +1.7%
3.59*	Viramune 200mg tab	408826	Blister strips	2 × 60	11/07	Kenya	✓	✓	✓	99.2	✓	91.6-94.7 ξ= 93.2	mean: 807.4mg -1.8% to +2.5%
3.60*	Viramune 200mg tab	408827	Blister strips	2 × 60	11/07	Kenya	✓	✓	✓	99.8	✓	93.6-97.2 ξ= 95.8	mean: 812.7mg -1.6% to +1.4%
3.61*	Viramune 200mg tab	407734 **As 3.06**	Blister strips	2 × 60	10/07	Kenya	✓	✓	✓	98.5	✓	87.2-90.9 ξ= 89.3	mean: 809.5mg -1.0% to +1.2%

✓ = Complies; *=WHO-prequalified

4. Nevirapine

Test Plan C: Oral suspensions (28 samples) – Swissmedic methods

SPECIFICATIONS:
Content of nevirapine: 95.0-105.0% of stated amount
Related substances: Any individual impurity (unknown): ≤ 0.1%
Total impurities (degradation): ≤ 0.2%
pH: 5.4 to 6.0

OMCL No.	Trade name, strength and dosage form	Batch	Primary pack	Sample & pack size	Expiry date	Country	Label	Ap-pear-ance	Iden-tity	Content (% of stated amount)	Related sub-stances	pH
3.03	Nevran 50mg/5ml oral suspension	00105	Glass bottle	1 × 200	02/07	Nigeria	✓	✓	✓	99.3	✓	6.0
3.04	Nevran 50mg/5ml oral suspension	00104	Glass bottle	2 × 100	01/06	Nigeria	✓	✓	✓	98.3	✓	5.9
3.11	Evadine 50mg/5ml oral suspension	G30454	Plastic bottle	2 × 100	06/05	Nigeria	✓	✓	✓	104.7	✓	5.7
3.13*	Viramune 50mg/5ml oral suspension	L457744A **As 3.64**	Plastic bottle	2 × 240-	04/07	Nigeria	✓	✓	✓	95.8	✓	5.7
3.14	Virex-N 50mg/5ml oral suspension	LA8500N	Glass bottle	2 × 100	02/07	Nigeria	✓	✓	✓	**93.4**	✓	**3.4**
3.17	Nevirapine 50mg/5ml oral suspension	G40667	Plastic bottle	2 × 100	07/06	Uganda	✓	✓	✓	98.5	✓	5.9
3.18	Nevirapine 50mg/5ml oral suspension	G40661	Plastic bottle	3 × 100	07/06	Uganda	✓	✓	✓	106.5	✓	5.9
3.20	Okamune 50mg/5ml oral suspension	C40556	Glass bottle	5 × 100	08/06	Uganda	✓	✓	✓	107.8	✓	5.8
3.22*	Viramune 50mg/5ml oral suspension	L457823A	Plastic bottle	2 × 240	06/07	Tanzania	✓	✓	✓	97.2	✓	5.7
3.26*	Viramune 50mg/5ml oral suspension	L457826A	Plastic bottle	2 × 240	06/07	Tanzania	✓	✓	✓	96.9	✓	5.7
3.28*	Viramune 50mg/5ml oral suspension	L457647A **As 3.31**	Plastic bottle	2 × 240	05/07	Tanzania	✓	✓	✓	97.5	✓	5.7
3.31*	Viramune 50mg/5ml oral suspension	L457647A **As 3.28**	Plastic bottle	2 × 240	05/07	Tanzania	✓	✓	✓	98.0	✓	5.7
3.33*	Viramune 50mg/5ml oral suspension	L457646A **As 3.35**	Plastic bottle	2 × 240	05/07	Tanzania	✓	✓	✓	99.6	✓	5.7
3.35*	Viramune 50mg/5ml oral suspension	L457646A **As 3.33**	Plastic bottle	2 × 240	05/07	Tanzania	✓	✓	✓	99.1	✓	5.7
3.38	Nevimune 50mg/5ml oral suspension	G40748	Plastic bottle	2 × 100	08/06	DRC	✓	✓	✓	104.8	✓	5.8
3.39	Nevimune 50mg/5ml oral suspension	G30533	Plastic bottle	2 × 100	08/05	DRC	✓	✓	✓	105.6	✓	5.8
3.41	Nevimune 50mg/5ml oral suspension	G40186	Glass bottle	2 × 25	02/06	DRC	✓	✓	✓	101.3	✓	6.0
3.43*	Viramune 50mg/5ml oral suspension	L357428C	Plastic bottle	1 × 240	08/05	DRC	✓	✓	✓	95.9	✓	5.7
3.55*	Viramune 50mg/5ml oral suspension	K456586J	Plastic bottle	10 × 20	04/06	Kenya	✓	✓	✓	97.3	✓	5.7
3.56*	Viramune 10mg/ml oral suspension	K456586H	Plastic bottle	10 × 20	04/06	Kenya	✓	✓	✓	98.3	✓	5.7
3.62*	Viramune 50mg/5ml oral suspension	L457822A	Plastic bottle	2 × 240	06/07	Kenya	✓	✓	✓	96.5	✓	5.7
3.63*	Viramune 10mg/ml oral suspension	L456090B	Plastic bottle	2 × 240	08/06	Kenya	✓	✓	✓	98.3	✓	5.7
3.64*	Viramune 50mg/5ml oral suspension	L457744A **As 3.13**	Plastic bottle	2 × 240	04/07	Kenya	✓	✓	✓	96.7	✓	5.7
3.65*	Viramune 50mg/5ml oral suspension	L457643A	Plastic bottle	2 × 240	04/07	Kenya	✓	✓	✓	96.9	✓	5.7
3.66	Nevimune 50mg/5ml oral suspension	G41065	Plastic bottle	2 × 100	11/06	Zambia	✓	✓	✓	107.5	✓	5.6
3.69	Nevir 50mg/5ml oral suspension	RNS0401	Plastic bottle	2 × 100	12/05	Zambia	✓	✓	✓	104.3	✓	5.5
3.71	Viramune 50mg/5ml oral suspension	456588°	Plastic bottle	2 × 240	05/07	Zambia	✓	✓	✓	97.1	✓	5.7
3.72*	Viramune 50mg/5ml oral suspension	456585A	Plastic bottle	2 × 240	04/07	Zambia	✓	✓	✓	96.8	✓	5.7

✓ = Complies; *=WHO-prequalified

5. Stavudine

Test Plan A: Capsules, not prequalified (32 samples) – USP methods

SPECIFICATIONS:
Content of stavudine: 90.0-105.0% of stated amount
Related substances: Thymine: ≤ 1.0%; Any individual impurity: ≤ 0.2%; Total impurities: ≤ 2.0%

OMCL No.	Trade name, strength and dosage form	Batch	Primary pack	Sample & pack size	Expiry date	Country	Label	Appearance	Identity	Disintegration	Content (% of stated amount)	Related substances	Uniformity of mass
1.02	Stag 40mg cap	SV 50227	Plastic bottle	2 × 60	01/07	Nigeria	✓	✓	✓	✓	96.8	✓	mean: 354.9mg -5.2% to +3.7%
1.03	Avostav 40mg cap	1393469	Blister strips	2 × 60	03/06	Nigeria	✓	✓	✓	✓	101.2	✓	mean: 451.6mg -1.2% to +1.1%
1.04	Stavir 40mg cap	G33558	Plastic bottle	2 × 60	06/05	Nigeria	✓	✓	✓	✓	104.8	✓	mean: 274.6mg -3.4% to +5.1%
1.06	Avostav 40mg cap	1383989	Blister strips	2 × 60	02/06	Nigeria	✓	✓	✓	✓	101.5	✓	mean: 450.0mg -1.4% to +1.7%
1.07	Avostav 40mg cap	1384320	Blister strips	2 × 60	02/06	Nigeria	✓	✓	✓	✓	101.9	✓	mean: 452.8mg -1.1% to +1.4%
1.08	Avostav 40mg cap	1385790	Blister strips	2 × 60	02/06	Nigeria	✓	✓	✓	✓	102.5	✓	mean: 453.4mg -2.0% to +1.3%
1.09	Melxicap 40mg cap	G46175	Plastic bottle	2 × 60	01/06	Nigeria	✓	✓	✓	✓	**107.9 (a)**	✓	mean: 275.2mg -1.3% to +1.8%
1.10	Melxicap 30mg cap	G46174	Plastic bottle	2 × 60	01/06	Nigeria	✓	✓	✓	✓	102.9	✓	mean: 274.2mg -1.6% to +2.3%
1.14	Stavin 40mg cap	C40326	Plastic bottle	2 × 60	05/06	Uganda	✓	✓	✓	✓	104.7	✓	mean: 269.1mg -4.9% to +4.5%
1.15	Stavir 30mg cap	G56074	Plastic bottle	2 × 60	12/06	Uganda	✓	✓	✓	✓	104.3	✓	mean: 276.2mg -2.8% to +3.7%
1.16	Stavir 30mg cap	SG31202	Plastic bottle	2 × 60	11/05	Uganda	✓	✓	✓	✓	101.7	✓	mean: 361.7mg -4.5% to +3.0%
1.17	Stag 40mg cap	SV40201	Plastic bottle	2 × 60	01/06	Uganda	✓	✓	✓	✓	101.6	✓	mean: 362.3mg -3.4% to +4.6%
1.18	Stavin 30mg cap	C40341 **As 1.32**	Plastic bottle	2 × 60	05/06	Uganda	✓	✓	✓	✓	103.3	✓	mean: 272.6mg -2.4% to +2.4%
1.19	Stadine 40mg cap	LGA 05002	Plastic bottle	2 × 60	02/07	Tanzania	✓	✓	✓	✓	102.8	✓	mean: 300.7mg -5.1% to +7.8%
1.20	Stadine 40mg cap	LGA 05005	Plastic bottle	2 × 60	02/07	Tanzania	✓	✓	✓	✓	103.9	✓	mean: 307.6mg -1.6% to +1.5%
1.21	Stavex 30mg cap	SX 3005001	Plastic bottle	2 × 60	04/07	Tanzania	✓	✓	✓	✓	101.5	✓	mean: 456.4mg -3.4% to +2.6%
1.22	Stavex 30mg cap	SX 3005002	Plastic bottle	2 × 30	04/07	Tanzania	✓	✓	✓	✓	99.7	✓	mean: 452.4mg -2.8% to +3.3%
1.31	Stavudine 30mg cap	AS05-L9001	Plastic bottle	2 × 14	05/07	DRC	✓	✓	✓	✓	103.5	✓	mean: 271.7mg -5.1% to +4.1%
1.32	Stavir 30mg cap	C40341 **As 1.18**	Plastic bottle	2 × 60	05/06	DRC	✓	✓	✓	✓	104.0	✓	mean: 271.0mg -3.8% to +3.1%
1.33	Stag 30mg cap	S.G40917	Plastic bottle	2 × 60	08/06	DRC	✓	✓	✓	✓	104.3	✓	mean: 370.2mg -4.5% to +4.2%
1.34	Stag 40mg cap	S.V40915	Plastic bottle	2 × 60	08/06	DRC	✓	✓	✓	✓	101.8	✓	mean: 362.1mg -6.4% to +6.8%
1.48	Stag 40mg cap	SV41016	Plastic bottle	2 × 60	09/06	Kenya	✓	✓	✓	✓	100.0	✓	mean: 362.4mg -2.5% to +5.1%
1.49	Stag 30mg cap	SG40916	Plastic bottle	2 × 60	08/06	Kenya	✓	✓	✓	✓	102.9	✓	mean: 365.3mg -6.9% to +5.6%
1.50	Stariv 30mg cap	040340	Blister strips	2 × 60	12/05	Kenya	✓	✓	✓	✓	102.0	✓	mean: 288.2mg -3.6% to +7.2%
1.51	Stariv 30mg cap	031680	Blister strips	2 × 60	11/05	Kenya	✓	✓	✓	✓	99.4	✓	mean: 287.3mg -4.6% to +6.7%
1.52	Stariv 40mg cap	041692	Blister strips	2 × 60	09/06	Kenya	✓	✓	✓	✓	102.0	✓	mean: 289.2mg -3.6% to +6.2%
1.53	Stariv 40mg cap	031682	Blister strips	2 × 60	11/05	Kenya	✓	✓	✓	✓	101.3	✓	mean: 291.1mg -4.3% to +6.7%
1.54	Avostav 30mg cap	1465726	Plastic bottle	2 × 60	11/06	Zambia	✓	✓	✓	✓	103.3	✓	mean: 350.2mg -1.8% to +1.8%
1.55	Stadine 40mg cap	OST0301	Plastic bottle	2 × 60	11/05	Zambia	✓	✓	✓	✓	103.1	✓	mean: 311.4mg -2.7% to +5.4%
1.56	Stavudine 30mg cap	7200497	Plastic bottle	2 × 60	04/07	Zambia	✓	✓	✓	✓	102.6	✓	mean: 318.3mg -3.3% to +2.1%
1.57	Stag 40mg cap	SV41217	Plastic bottle	2 × 60	11/06	Zambia	✓	✓	✓	✓	101.7	✓	mean: 369.0mg -4.3% to +7.0%
1.58	Stag 40mg cap	SV40607	Plastic bottle	2 × 60	05/06	Zambia	✓	✓	✓	✓	99.0	✓	mean: 358.8mg -5.9% to +5.0%

(a) Acceptable considering the uncertainty of the test method
✓ = Complies

5. Stavudine

Test Plan B: Oral solutions, not prequalified (2 samples) – USP methods

SPECIFICATIONS:

Content of stavudine:	90.0-110.0% of stated amount	
Related substances:	Thymine:	≤ 1.0%
	Unknown impurities each:	≤ 0.2%
	Total impurities:	≤ 1.5%

OMCL No.	Trade name, strength and dosage form	Batch	Primary pack	Sample and pack size	Expiry date	Country	Label	Appearance	Content (% of stated amount)	Related substances
1.13	Zerit 200mg, powder for oral solution	0170	Plastic bottle	2 × 200	11/06	Cameroon	**(2)**	✓	100.2	✓
1.24	Zerit 200mg, powder for oral solution	0175	Plastic bottle	2 × 200	01/07	Tanzania	**(3)**	✓	101.0	✓

(2) Information items (6), (7) and (8) missing on immediate container (WHO sampling number CAE/STV/Susp/01)

(3) Information items (6), (7) and (8) missing on immediate container (WHO sampling number TAN PUT1 S/01/1)

✓ = Complies

5. Stavudine

Test Plan C: Capsules, prequalified (26 samples) – Swissmedic methods

SPECIFICATIONS:
Content of stavudine: 90.0-105.0 of stated amount
Related substances: Thymine: ≤ 2.0%
Dissolution: Not less than 80%(Q) of the stated amount of stavudine dissolved in 30 minutes

OMCL No.	Trade name, strength and dosage form	Batch	Primary pack	Sample and pack size	Expiry date	Country	Label	Appearance	Identity	Content (% of stated amount)	Related substances	Dissolution (% of stated amount)	Uniformity of mass
1.01*	Stavudine 40mg cap	7200258	Plastic bottle	2 × 60	02/07	Nigeria	✓	✓	✓	102.0	✓	94-104	mean: 314.6mg -3.8% to +3.6%
1.05*	Zerit 30mg cap	0019	Blister strips	2 × 56	06/06	Nigeria	✓	✓	✓	100.5	✓	97-100	mean: 347.3mg -1.4% to +1.2%
1.11*	Zerit 30mg cap	0008	Blister strips	3 × 56	08/05	Cameroon	✓	✓	✓	101.0	✓	97-100	mean: 348.9mg -2.9% to +2.0%
1.12*	Zerit 40mg cap	0012	Blister strips	3 × 56	08/05	Cameroon	✓	✓	✓	100.0	✓	98-99	mean: 455.6mg -1.2% to +1.5%
1.23*	Zerit 15mg cap	4K93177 **As 1.46**	Plastic bottle	2 × 60	10/06	Tanzania	✓	✓	✓	100.1	✓	98-104	mean: 237.2mg -2.6% to +2.1%
1.25*	Zerit 20mg cap	0017	Plastic bottle	2 × 60	02/07	Tanzania	✓	✓	✓	97.4	✓	97-101	mean: 331.3mg -4.2% to +2.6%
1.26*	Zerit 40mg cap	0023 **As 1.28**	Plastic bottle	2 × 60	06/06	Tanzania	✓	✓	✓	101.2	✓	99-101	mean: 452.0mg -0.8% to +0.9%
1.27*	Zerit 30mg cap	0023 **As 1.37**	Plastic bottle	2 × 60	12/06	Tanzania	✓	✓	✓	101.0	✓	100-103	mean: 344.9mg -1.1% to +1.1%
1.28*	Zerit 40mg cap	0023 **As 1.26**	Plastic bottle	2 × 60	06/06	Tanzania	✓	✓	✓	102.1	✓	99-101	mean: 451.5mg -0.9% to +1.2%
1.29*	Zerit 30mg cap	0033 **As 1.23**	Plastic bottle	2 × 60	04/07	Tanzania	✓	✓	✓	101.6	✓	99-102	mean: 344.9mg -1.2% to +0.9%
1.30*	Zerit 30mg cap	0033	Plastic bottle	2 × 60	04/07	Tanzania	✓	✓	✓	101.5	✓	100-101	mean: 344.6mg -1.1% to +0.8%
1.35*	Zerit 40mg cap	0017	Blister strips	1 × 56	11/05	DRC	✓	✓	✓	100.8	✓	99-100	mean: 452.9mg -1.0% to +1.2%
1.36*	Zerit 20mg cap	0009	Plastic bottle	2 × 60	12/06	Kenya	✓	✓	✓	101.5	✓	99-100	mean: 334.0mg -1.9% to +0.9%
1.37*	Zerit 30mg cap	0023	Plastic bottle	2 × 60	12/06	Kenya	✓	✓	✓	101.8	✓	100-101	mean: 344.8mg -1.0% to +1.5%
1.38*	Zerit 30mg cap	0034	Plastic bottle	2 × 60	04/07	Kenya	✓	✓	✓	100.6	✓	98-102	mean: 342.6mg -3.2% to +1.3%
1.39*	Zerit 30mg cap	0033	Plastic bottle	2 × 60	04/07	Kenya	✓	✓	✓	101.5	✓	99-101	mean: 344.8mg -0.6% to +0.8%
1.40*	Zerit 40mg cap	0029	Plastic bottle	2 × 60	11/06	Kenya	✓	✓	✓	102.9	✓	100-101	mean: 452.2mg -2.5% to +2.7%
1.41*	Zerit 40mg cap	0031	Plastic bottle	2 × 60	12/06	Kenya	✓	✓	✓	102.0	✓	100-101	mean: 447.6mg -0.8% to +0.7%
1.42*	Zerit 40mg cap	0037	Plastic bottle	2 × 60	04/07	Kenya	✓	✓	✓	102.0	✓	100-102	mean: 450.6mg -1.9% to +2.1%
1.43*	Zerit 40mg cap	0039	Plastic bottle	2 × 60	04/07	Kenya	✓	✓	✓	102.1	✓	99-101	mean: 454.5mg -1.6% to +1.7%
1.44*	Zerit 30mg cap	4A80354	Plastic bottle	2 × 60	10/05	Kenya	✓	✓	✓	103.5	✓	102-104	mean: 347.0mg -2.2% to +1.7%
1.45*	Zerit 15mg cap	5C07315 B	Plastic bottle	2 × 60	02/08	Kenya	✓	✓	✓	101.0	✓	102-105	mean: 231.3mg -2.6% to +1.9%
1.46*	Zerit 15mg cap	4K93177	Plastic bottle	2 × 60	10/06	Kenya	✓	✓	✓	101.1	✓	100-104	mean: 234.2mg -3.1% to +2.3%
1.47*	Zerit 15mg cap	4A73491	Plastic bottle	2 × 60	10/05	Kenya	✓	✓	✓	99.0	✓	96-102	mean: 232.1mg -3.1% to +2.0%
1.59*	Zerit 30mg cap	0039	Blister strips	2 × 56	04/07	Zambia	✓	✓	✓	101.3	✓	98-100	mean: 345.2mg -1.1% to +0.8%
1.60*	Zerit 40mg cap	0038	Blister strips	2 × 56	04/07	Zambia	✓	✓	✓	103.5	✓	99-101	mean: 455.7mg -1.8% to +1.8%

✓ = Complies
*=WHO-prequalified

6. Zidovudine

Test Plan A: Capsules/tablets, prequalified (17 samples) – Swissmedic methods

SPECIFICATIONS:

Content of zidovudine:	*Tablets*:	95.0-105.0% of the stated amount	
	Capsules:	90.0-110.0% of the stated amount	
Related substances:	*Tablets:*	Thymine:	≤ 3.0%
		Unknown impurities each:	≤ 0.5%
		Sum of unidentified impurities:	≤ 1.0%
		Sum of total related substances:	≤ 4.0% (w/w)
	Capsules:	Sum of total impurities:	≤ 3.0% (w/w)
Dissolution:	*Tablets*:	Not less than 80% at 30 minutes (Q value 75%)	
	Capsules:	Not less than 80% at 45 minutes (Q value of 75% at 45 minutes)	

OMCL No.	Trade name, strength and dosage form	Batch	Pri-mary pack	Sample and pack size	Expiry date	Country	Label	Ap-pear-ance	Iden-tity	Content (% of stated amount)	Related sub-stances	Dis-solution (% of stated amount)	Uniformity of mass
5.04*	Xilec 300mg tab	G33616 **As 5.26**	Plastic bottle	2 × 60	07/06	Nigeria	✓	✓	✓	98.1	✓	80-90	mean: 347.0mg -2.1% to +4.0%
5.10*	Zidovir 300mg tab	G54603	Plastic bottle	2 × 60	04/08	Cameroon	✓	✓	✓	97.0	✓	95-98	mean: 350.2mg -1.7% to + 2.4%
5.11*	Zidovir 300mg tab	G54134	Plastic bottle	2 × 60	01/08	Cameroon	✓	✓	✓	98.5	✓	90-99	mean: 350.8mg -2.1% to +2.4%
5.13*	Zidovir 300mg tab	H54133	Plastic bottle	2 × 60	01/08	Uganda	✓	✓	✓	98.7	✓	92-97	mean: 350.1mg -2.5% to +2.7%
5.14*	Zidovir 300mg tab	G45205	Plastic bottle	2 × 60	11/07	Uganda	✓	✓	✓	99.7	✓	91-99	mean: 356.4mg -1.2% to +0.9%
5.17*	Zidovir 100mg cap	C50074	Blister strips	2 × 200	01/07	Tanzania	✓	✓	✓	101.3	✓	95-106	mean: 236.3mg -6.2% to +7.4%
5.18*	Zidovir 100mg cap	C40618	Blister strips	2 × 200	10/06	Tanzania	✓	✓	✓	99.1	✓	86-94	mean : 236.0mg -9.7% to +7.0%
5.19*	Zidovir 300mg tab	G47056	Plastic bottle	2 × 60	08/07	Tanzania	✓	✓	✓	100.3	✓	**(5)**	mean: 354.2mg -2.0% to +4.3%
5.26*	Zidovir 300mg tab	G33616 **As 5.04**	Plastic bottle	1 × 60	07/06	DRC	✓	✓	✓	96.7	✓	89-98	mean: 344.8mg 19 tablets: -2.5% to +2.2% **1 tablet : - 6.0%**
5.27*	Zidovir 300mg tab	G46743	Plastic bottle	2 × 60	04/07	DRC	✓	✓	✓	99.4	✓	98-101	mean: 353.8mg -1.5% to +3.8%
5.28*	Zidovir 100mg cap	G56295	Plastic bottle	2 × 60	02/07	DRC	✓	✓	✓	95.9	✓	90-97	mean : 223.3mg 19 capsules : -9.6% to +8.2% **1 capsule: +10.2%**
5.30*	Zidovir 300mg tab	G46529	Plastic bottle	2 × 60	04/07	DRC	✓	✓	✓	99.2	✓	87-102	mean: 351.3mg -3.6% to +3.4%
5.31*	Retrovir 100mg cap	X3958	Blister strips	2 × 100	02/09	DRC	✓	✓	✓	101.1	✓	**(a)**	mean: 232.2mg -3.5% to +5.3%
5.32*	Retrovir 100mg cap	X2421	Plastic bottle	1 × 100	09/09	Kenya	✓	✓	✓	99.8	✓	**(a)**	mean: 228.7mg -2.1% to +1.3%
5.33*	Retrovir 100mg cap	X2679	Plastic bottle	1 × 100	09/09	Kenya	✓	✓	✓	102.1	✓	**(a)**	mean: 234.4mg -1.2% to +1.4%
5.38*	Retrovir 100mg cap	X6627	Plastic bottle	2 × 60	10/07	Zambia	✓	✓	✓	98.7	✓	**(a)**	mean : 228.2mg 19 capsules : - 0.9% to +2.6% **1 capsule: -11.3%**
5.41*	Zidovir 300mg tab	C40559	Blister strips	2 × 60	09/06	Zambia	✓	✓	✓	96.8	✓	94- 104	mean: 354.1mg -1.6% to +1.6%

(5) Does not comply (WHO sampling number TAN PUP Z01/1)
Stage 1: min. 1: **69**%, min. 2: **70**%, min. 3: **74**%; max.:87%
Stage 2: mean: 76%, min.: **58**%, max.: 88%
Stage 3: mean: **74**%, min. 1: 55%, min. 2: 58%, min. 3: 64%, max: 88%

(a) Dissolution not performed (not part of prequalified specifications) – disintegration complies

✓ = Complies; *=WHO-prequalified

6. Zidovudine

Test Plan A: Oral solutions, prequalified (3 samples) – Swissmedic methods

SPECIFICATIONS:
Related substances: Thymine ≤ 4.5%
pH: 3.0 to 5.0

OMCL No.	Trade name, strength and dosage form	Batch	Primary pack	Sample and pack size	Expiry date	Country	Label	Appearance	Identity	Content (% of stated amount)	Related substances	pH
5.06*	Retrovir 10mg, oral solution	4E005	Glass bottle	2 × 200	05/06	Nigeria	✓	✓	✓	99.6	✓	3.5
5.34*	Retrovir 10mg/ml, oral solution	4N014	Glass bottle	2 × 200	12/06	Kenya	✓	✓	✓	99.6	✓	3.5
5.35*	Retrovir 10mg/ml, oral solution	4M034	Glass bottle	2 × 200	11/06	Kenya	✓	✓	✓	98.7	✓	3.5

✓ = Complies; *=WHO-prequalified

6. Zidovudine

Test Plan B: Oral solutions (19 samples) – USP methods

SPECIFICATIONS:
Content of zidovudine: 90.0-110.0% of stated amount
Related substances: Thymine ≤ 3.0% (w/w) (USP)
pH : 3.0 to 4.0 (USP)

OMCL No.	Trade name, strength and dosage form	Batch	Primary pack	Sample and pack size	Expiry date	Country	Label	Appearance	Identity	Content (% of stated amount)	Related substances	pH
5.01	Azido 50mg/5ml oral sol.	00105	Glass bottle	2 × 200	02/07	Nigeria	✓	✓	✓	98.8	✓	3.5
5.02	Azido 50mg/5ml oral sol.	00104	Glass bottle	2 × 100	01/06	Nigeria	✓	✓	✓	94.6	✓	3.5
5.03*	Xilec 50mg/5ml oral sol.	G30476	Plastic bottle	2 × 100	07/05	Nigeria	✓	✓	✓	101.3	✓	3.5
5.07	Virex-Z 50mg/5ml oral sol.	LA8400N	Glass bottle	2 × 100	02/07	Nigeria	✓	✓	✓	**90.7**	✓	3.4
5.08*	Zidovir 50mg/5ml oral sol.	G50487 **As 5.43**	Plastic bottle	2 × 100	05/07	Cameroon	✓	✓	✓	99.7	✓	3.7
5.09*	Zidovir 50mg/5ml oral sol.	G50249	Plastic bottle	2 × 100	02/07	Cameroon	✓	✓	✓	100.1	✓	3.8
5.12*	Zidovir 50mg/5ml oral sol.	G50198	Plastic bottle	2 × 200	02/07	Uganda	✓	✓	✓	99.3	✓	3.8
5.15*	Zivir 50mg/5ml oral sol.	CA0506	Plastic bottle	2 × 100	07/06	Uganda	✓	✓	✓	99.5	✓	3.7
5.16*	Zidovir 50mg/5ml oral sol.	C40599	Plastic bottle	2 × 200	09/06	Tanzania	✓	✓	✓	99.5	✓	3.8
5.20*	Zidovir 50mg/5ml oral sol.	C40489	Plastic bottle	2 × 100	07/06	Tanzania	✓	✓	✓	100.3	✓	3.7
5.21*	Zidovir 50mg/5ml oral sol.	G50245	Plastic bottle	2 × 100	02/07	Tanzania	✓	✓	✓	100.7	✓	3.9
5.22*	Zidovir 50mg/5ml oral sol.	C40496	Plastic bottle	2 × 100	07/06	Tanzania	✓	✓	✓	98.2	✓	3.5
5.23*	Zidovir 50mg/5ml oral sol.	C40502	Plastic bottle	2 × 100	07/06	Tanzania	✓	✓	✓	100.1	✓	3.7
5.24*	Zidovir 50mg/5ml oral sol.	G50238	Plastic bottle	2 × 100	02/07	Tanzania	✓	✓	✓	100.5	✓	3.9
5.25*	Zidovir 50mg/5ml oral sol.	G41066	Plastic bottle	2 × 100	11/06	DRC	✓	✓	✓	101.0	✓	3.8
5.40	Zidine 50mg/5ml oral sol.	02A05005	Glass bottle	2 × 100	12/06	Zambia	✓	✓	✓	97.7	✓	3.5
5.42*	Zidovir 50mg/5ml oral sol.	G40839	Plastic bottle	2 × 100	09/06	Zambia	✓	✓	✓	100.3	✓	4.0
5.43*	Zidovir 50mg/5ml oral sol.	G50487 **As 5.08**	Plastic bottle	2 × 100	05/07	Zambia	✓	✓	✓	97.7	✓	3.7
5.44*	Zidovir 50mg/5ml oral sol.	G40838	Plastic bottle	2 × 100	09/06	Zambia	✓	✓	✓	99.8	✓	3.9

✓ = Complies; *=WHO-prequalified

6. Zidovudine

Test Plan C: Tablets (5 samples) – USP methods

SPECIFICATIONS:
Content of zidovudine: 90.0-110.0% of stated amount
Related substances: Thymine: ≤ 1.5%
Any individual impurity: ≤ 0.2%
Total impurities: ≤ 2.0%

OMCL No.	Trade name, strength and dosage form	Batch	Primary pack	Sample and pack size	Expiry date	Country	Label	Appearance	Identity	Disintegration	Content (% of stated amount)	Related substances	Uniformity of mass
5.05	Retrovir 300mg, tab	V14 **As 5.36**	Blister strips	2 × 60	11/07	Nigeria	✓	✓	✓	✓	100.8	**(a)**	mean: 374.3mg -2.1% to +1.5%
5.29	Zido-H 300mg, tab	ZH40502	Plastic bottle	2 × 60	04/06	DRC	✓	✓	✓	✓	99.8	✓	mean: 370.9mg -1.8% to +2.5%
5.36	Retrovir 300mg, tab	V14 **As 5.05**	Blister strips	2 × 60	11/07	Kenya	✓	✓	✓	✓	101.1	**(b)**	mean: 374.7mg -0.7% to +1.0%
5.37*	Zidovudine 300mg, tab	ZV 3003005	Plastic bottle	3 × 10	11/06	Zambia	✓	✓	✓	✓	98.8	✓	mean: 346.0mg -1.5% to +0.8%
5.39	Zidine 300mg, tab	LZI0401	Plastic bottle	2 × 60	06/06	Zambia	✓	✓	✓	✓	99.3	✓	mean: 424.9mg -1.3% to +0.9%

✓ = Complies; *=WHO-prequalified

7. Lamivudine/zidovudine

Test Plan A: Tablets, not prequalified (8 samples) – methods of the Indian Pharmacopoeia

SPECIFICATIONS:

Content:	90.0-110.0% of stated amount for both active ingredients	
Related substances:	Thymine:	≤ 2.0%
	β-thymidine:	≤ 1.0%
	Salicylic acid:	≤ 0.2%
	Any individual impurity:	≤ 0.5%
	Total impurities:	≤ 3.0%

OMCL No.	Trade name, strength and dosage form	Batch	Primary pack	Sample and pack size	Expiry date	Country	Label	Ap-pear-ance	Identity of each active ingre-dient	Dis-integra-tion	Content (% of stated amount)		Related sub-stances	Uniformity of mass
											lami-vudine	zido-vudine		
7.04	Virex-LZ 150/300mg, tab	TA4100N	Plastic bottle	2 × 60	02/07	Nigeria	✓	✓	✓	**(4)**	94.7	95.4	✓	mean: 615.3mg -1.4% to +1.9%
7.20	Lazid 150/300mg, tab	01A05005	Plastic bottle	2 × 60	02/07	Tanzania	✓	✓	✓	✓	97.6	96.4	✓	mean: 622.7mg -1.2% to +1.4%
7.26	Zidolam 150/300mg, tab	ZL40817	Plastic bottle	2 × 60	07/06	DRC	✓	✓	✓	✓	98.3	98.9	✓	mean: 715.2mg -3.3% to +3.4%
7.27	Zidolam 150/300mg, tab	Zl40938	Plastic bottle	2 × 60	08/06	DRC	✓	✓	✓	✓	97.1	98.7	✓	mean: 714.6mg -2.8% to +2.0%
7.28	Zidolam 150/300mg, tab	ZL41043	Plastic bottle	2 × 60	09/06	Kenya	✓	✓	✓	✓	98.3	101.3	✓	mean: 710.5mg -3.5% to +2.4%
7.34	Lazid 150/300mg, tab	01A05002	Plastic bottle	2 × 60	02/07	Zambia	✓	✓	✓	✓	98.5	97.1	✓	mean: 626.7mg -1.5% to +1.9%
7.35	Avocomb 150/300mg, tab	1419577	Plastic bottle	2 × 60	06/06	Zambia	✓	✓	✓	✓	98.1	96.5	✓	mean: 763.4mg -1.1% to +0.9%
7.37	Bivir 150/300mg, tab	S50060	Plastic bottle	2 × 60	03/06	Zambia	✓	✓	✓	✓	96.6	99.0	✓	mean: 760.7mg -1.1% to +: 0.9%

(4) Does not comply (WHO sampling number NG41LZT)

✓ = Complies

7. Lamivudine/zidovudine

Test Plan B: Tablets, prequalified (29 samples) – Swissmedic methods

SPECIFICATIONS:

Content:	95.0-105% of the stated amount for both active ingredients	
Related substances :	Impurity A - Ph.Eur. 5.3, 01/2006:2217:	≤ 0.3%
	Impurity B - Ph.Eur. 5.3, 01/2006:2217:	≤ 0.2%
	Thymine:	≤ 3.0%
	Impurity B - Ph.Eur. 5.1, 04/2005:1059:	≤ 1.0%
	Any unspecified impurity:	≤ 0.5%
	Total lamivudine-related impurities	≤ 0.6%
	Total zidovudine-related impurities	≤ 4.0%
Dissolution:	Not less than 80% (Q) of the stated amount of both active ingredients dissolved in 30 minutes	

OMCL No.	Trade name, strength and dosage form	Batch number	Primary pack	Sample and pack size	Expiry date	Country	Label	Ap-pear-ance	Identity of each active ingre-dient	Content (% of stated amount)		Related sub-stances	Dissolution (% of stated amount)		Uniformity of mass
										lami-vudine	zido-vudine		lamivudine	zidovudine	
7.01*	Combivir 150/300mg, tab	B136096	Blister strips	2 × 6 × 10	06/06	Nigeria	✓	✓	✓	98.0	98.1	✓	101.3-104.8 ξ= 103.5	99.6-102.5 ξ= 101.1	mean: 771.2mg -1.8% to +2.3%
7.02*	Arved 150/300mg, tab	G32655	Plastic bottle	2 × 60	11/05	Nigeria	✓	✓	✓	99.1	96.5	✓	98.9-103.7 ξ= 101.9	99.3-105.7 ξ= 102.7	mean: 764.0mg -0.9% to +1.3%
7.03*	Combivir 150/300mg, tab	B136389	Blister strips	2 × 6 × 10	06/06	Nigeria	✓	✓	✓	96.9	97.8	✓	101.2-103.7 ξ= 102.4	100.4-102.4 ξ= 101.1	mean: 768.6mg -1.9% to +1.3%
7.05*	Duovir 150/300mg, tab	G44493	Plastic bottle	2 × 60	04/06	Cameroon	✓	✓	✓	95.6	97.1	✓	95.3-98.5 ξ= 97.1	101.6-105.3 ξ= 103.5	mean: 757.5mg -2.3% to +2.9%
7.06*	Duovir 150/300mg, tab	G54307	Plastic bottle	2 × 60	02/07	Cameroon	✓	✓	✓	96.6	101.8	✓	101.8-104.5 ξ= 102.9	100.1-103.9 ξ= 101.6	mean: 753.8mg -3.5% to +3.1%
7.07*	Duovir 150/300mg, tab	G54308	Plastic bottle	2 × 60	02/07	Cameroon	✓	✓	✓	97.3	98.3	✓	94.1-100.6 ξ= 98.0	100.5-101.0 ξ= 100.8	mean: 758.2mg 19 tablets : -4.0% to +3.2% **1 tablet : + 8.4%**
7.08*	Duovir 150/300mg, tab	G44538	Plastic bottle	2 × 60	05/06	Cameroon	✓	✓	✓	96.1	97.9	✓	95.9-99.9 ξ= 98.5	98.4-99.8 ξ= 99.4	mean: 756.9mg -3.2% to +2.8%
7.09*	Duovir 150/300mg, tab	C40301	Plastic bottle	2 × 60	04/06	Cameroun	✓	✓	✓	96.8	98.7	✓	98.7-101.5 ξ= 99.8	99.9-103.2 ξ= 101.1	mean: 757.6mg -1.4% to +3.1%
7.10*	Bivir 150/300mg, tab	G54200 **As 7.15**	Plastic bottle	1 × 60	01/07	Uganda	✓	✓	✓	96.1	99.2	✓	98.9-101.0 ξ= 99.9	98.5-104.4 ξ= 102.1	mean: 754.0mg -3.2% to +2.9%
7.11*	Bivir 150/300mg, tab	C30521	Plastic bottle	1 × 60	11/05	Uganda	✓	✓	✓	98.8	100.2	✓	97.0-100.6 ξ= 98.6	88.6-100.4 ξ= 96.6	mean: 756.1mg -1.5% to +2.0%
7.12*	Combivir 150/300mg, tab	R170752 **As 7.14**	Plastic bottle	2 × 60	04/07	Uganda	✓	✓	✓	95.2	97.3	✓	97.6-98.5 ξ= 98.2	98.6-100.9 ξ= 100.0	mean: 763.2mg -1.2% to +2.2%
7.13*	Duovir 150/300mg, tab	G54306	Plastic bottle	2 × 60	02/07	Uganda	✓	✓	✓	96.3	100.0	✓	96.4-99.6 ξ= 98.2	100.3-104.6 ξ= 102.1	mean: 761.0mg -3.4% to +3.5%

✓ = Complies; *=WHO-prequalified

7. Lamivudine/zidovudine

Test Plan B: Tablets, prequalified (29 samples) – Swissmedic methods **(continued)**

SPECIFICATIONS:

Content:	95.0-105% of the stated amount for both active ingredients	
Related substances :	Impurity A - Ph.Eur. 5.3, 01/2006:2217:	≤ 0.3%
	Impurity B - Ph.Eur. 5.3, 01/2006:2217:	≤ 0.2%
	Thymine:	≤ 3.0%
	Impurity B - Ph.Eur. 5.1, 04/2005:1059:	≤ 1.0%
	Any unspecified impurity:	≤ 0.5%
	Total lamivudine-related impurities	≤ 0.6%
	Total zidovudine-related impurities	≤ 4.0%
Dissolution:	Not less than 80%(Q) of the stated amount of both active ingredients dissolved in 30 minutes	

OMCL No.	Trade name, strength and dosage form	Batch number	Primary pack	Sample and pack size	Expiry date	Country	Label	Ap-pear-ance	Identity of each active ingre-dient	Content (% of stated amount)		Related sub-stances	Dissolution (% of stated amount)		Uniformity of mass
										lami-vudine	zido-vudine		lamivudine	zidovudine	
7.14*	Combivir 150/300mg, tab	R170752 **As 7.12**	Plastic bottle	2 × 60	04/07	Uganda	✓	✓	✓	97.3	99.1	✓	98.9-103.4 ξ= 100.9	100.0-100.9 ξ= 100.5	mean: 765.4mg -1.9% to +2.5%
7.15*	Duovir 150/300mg, tab	G54200 **As 7.10**	Plastic bottle	2 × 60	01/07	Uganda	✓	✓	✓	96.0	99.5	✓	97.4-104.0 ξ= 101.0	102.1-104.5 ξ= 103.3	mean: 762.0mg -1.9% to +2.5%
7.16*	Duovir 150/300mg, tab	C40031	Plastic bottle	2 × 60	12/05	Tanzania	✓	✓	✓	96.5	98.6	✓	100.1-102.9 ξ= 101.6	102.7-104.1 ξ= 103.5	mean: 763.5mg -1.6% to +2.8%
7.17*	Duovir 150/300mg, tab	C50088	Plastic bottle	2 × 60	01/07	Tanzania	✓	✓	✓	100.2	96.1	✓	95.2-101.3 ξ= 98.6	99.8-101.3 ξ= 100.7	mean: 762.8mg -1.7% to +1.5%
7.18*	Combivir 150/300mg, tab	B142682 **As 7.23**	Plastic bottle	2 × 60	09/06	Tanzania	✓	✓	✓	96.8	97.4	✓	94.9-102.4 ξ= 98.1	100.7-102.0 ξ= 101.3	mean: 761.3mg -1.9% to +0.9%
7.19*	Duovir 150/300mg, tab	050194	Plastic bottle	2 × 60	02/07	Tanzania	✓	✓	✓	98.1	98.9	✓	97.9-101.5 ξ= 99.4	98.5-101.8 ξ= 100.4	mean: 764.1mg -2.5% to +1.9%
7.21*	Duovir 150/300mg, tab	C50145	Plastic bottle	2 × 60	02/07	Tanzania	✓	✓	✓	96.8	99.5	✓	95.6-100.9 ξ= 98.7	100.7-103.5 ξ= 101.7	mean: 762.2mg -2.8% to +2.9%
7.22*	Combivir 150/300mg, tab	B140423	Plastic bottle	2 × 60	08/06	Tanzania	✓	✓	✓	98.9	98.7	✓	99.1-101.2 ξ= 100.0	99.7-101.8 ξ= 100.5	mean: 766.6mg -2.1% to +2.2%
7.23*	Combivir 150/300mg, tab	B142682 **As 7.18**	Plastic bottle	2 × 60	09/06	Tanzania	✓	✓	✓	96.5	98.7	✓	99.1-100.7 ξ= 99.8	100.6-102.1 ξ= 101.1	mean: 763.1mg -2.3% to +1.4%
7.24*	Duovir 150/300mg, tab	G32493	Plastic bottle	1 × 60	09/05	DRC	✓	✓	✓	99.0	95.8	✓	51.6-93.8 ξ= 77.5 **(6)**	50.6-93.2 ξ= 75.0 **(6)**	mean: 762.3mg -3.0% to +1.8%
7.25*	Duovir 150/300mg, tab	G44055	Plastic bottle	2 × 60	12/05	DRC	✓	✓	✓	98.5	96.8	✓	92.5-99.2 ξ= 96.9	100.6-102.8 ξ= 102.0	mean: 752.6mg -1.4% to +1.5%

(6) Dissolution of lamivudine and zidovudine were below specifications (WHO sampling number BR 004/RDC)

✓ = Complies; *=WHO-prequalified

7. Lamivudine/zidovudine

Test Plan B: Tablets, prequalified (29 samples) – Swissmedic methods **(continued)**

SPECIFICATIONS:

Content:	95.0-105% of the stated amount for both active ingredients	
Related substances :	Impurity A - Ph.Eur. 5.3, 01/2006:2217:	≤ 0.3%
	Impurity B - Ph.Eur. 5.3, 01/2006:2217:	≤ 0.2%
	Thymine:	≤ 3.0%
	Impurity B - Ph.Eur. 5.1, 04/2005:1059:	≤ 1.0%
	Any unspecified impurity:	≤ 0.5%
	Total lamivudine-related impurities	≤ 0.6%
	Total zidovudine-related impurities	≤ 4.0%
Dissolution:	Not less than 80%(Q) of the stated amount of both active ingredients dissolved in 30 minutes	

OMCL No.	Trade name, strength and dosage form	Batch number	Primary pack	Sample and pack size	Expiry date	Country	Label	Ap-pear-ance	Identity of each active ingre-dient	Content (% of stated amount)		Related sub-stances	Dissolution (% of stated amount)		Uniformity of mass
										lami-vudine	zido-vudine		lamivudine	zidovudine	
7.29*	Duovir 150/300mg, tab	C50286	Plastic bottle	2 × 60	04/07	Kenya	✓	✓	✓	100.2	97.8	✓	99.1-101.7 ξ= 100.4	101.0-103.1 ξ= 101.9	mean: 762.3mg -1.0% to +1.1%
7.30*	Duovir 150/300mg, tab	C50239	Plastic bottle	2 × 60	03/07	Kenya	✓	✓	✓	99.3	96.2	✓	98.9-102.4 ξ= 100.7	99.8-102.2 ξ= 100.8	mean: 760.0mg -1.9% to +2.0%
7.31*	Combivir 150/300mg, tab	R156514	Plastic bottle	2 × 60	02/07	Kenya	✓	✓	✓	95.5	97.6	✓	94.4-102.4 ξ= 99.5	100.0-100.3 ξ= 100.2	mean: 761.1mg -2.9% to +1.4%
7.32*	Combivir 150/300mg, tab	R154801	Plastic bottle	2 × 60	11/06	Kenya	✓	✓	✓	97.7	98.1	✓	101.4-103.1 ξ= 102.2	100.4-101.8 ξ= 101.0	mean: 768.0mg -1.3% to +1.0%
7.33*	Combivir 150/300mg, tab	R172060	Blister strips	2 × 60	04/07	Kenya	✓	✓	✓	98.1	97.3	✓	101.0-102.7 ξ= 102.0	100.1-101.5 ξ= 101.1	mean: 770.9mg -1.5% to +1.9%
7.36*	Duovir 150/300mg, tab	C50268	Plastic bottle	2 × 60	04/07	Zambia	✓	✓	✓	101.7	95.3	✓	91.6-101.5 ξ= 98.6	99.5-101.0 ξ= 100.1	mean: 759.2mg -1.1% to +1.2%

✓ = Complies; *=WHO-prequalified

8. Stavudine/lamivudine

Tablets, not prequalified (16 samples) – methods of the Indian Pharmacopoeia

SPECIFICATIONS:

Content: 90.0-110.0% of stated amount for both active ingredients

Related substances: Thymine: ≤ 3.0%
Any other impurity: ≤ 1.0%
Total impurities: ≤ 3.5%

OMCL No.	Trade name, strength and dosage form	Batch	Primary pack	Sample and pack size	Expiry date	Country	Label	Appearance	Identity of each active ingredient	Disintegration	Content (% of stated amount)		Related substances	Uniformity of mass
											stavudine	lamivudine		
8.01	Stavudine 40/150mg, tab	050705	Blister strips	2 × 60	04/07	Kenya	✓	✓	✓	✓	100.8	98.3	✓	mean: 455.8mg -1.6% to +1.9%
8.02	Stavudine 40/150mg, tab	SA0403003	Plastic bottle	2 × 60	11/05	Kenya	✓	✓	✓	✓	103.2	99.4	✓	mean: 458.7mg -2.5% to +3.3%
8.03	Coviro-LS 30/150mg, tab	1386490	Blister strips	2 × 60	02/06	Kenya	✓	✓	✓	✓	99.9	99.0	✓	mean: 497.2mg -1.7% to +1.4%
8.04	Coviro-LS 30/150mg, tab	1386499	Blister strips	2 × 60	02/06	Kenya	✓	✓	✓	✓	98.6	99.9	✓	mean: 498.1mg -1.7% to +1.4%
8.05	Coviro-LS 30/150mg, tab	1386486	Blister strips	2 × 60	02/06	Kenya	✓	✓	✓	✓	98.4	100.9	✓	mean: 498.4mg -1.5% to +1.8%
8.06	Lamivir-S 30/150mg, tab	K41005	Plastic bottle	2 × 60	10/06	Kenya	✓	✓	✓	✓	100.9	98.2	✓	mean: 445.6mg -1.8% to +1.2%
8.07	Lamivir-S 30/150mg, tab	K41090	Plastic bottle	2 × 60	11/07	Kenya	✓	✓	✓	✓	99.9	101.5	✓	mean: 448.7mg -1.6% to +2.1%
8.08	Lamivir-S 30/150mg, tab	K40631	Plastic bottle	4 × 30	06/06	Kenya	✓	✓	✓	✓	97.5	100.1	✓	mean: 450.2mg -1.9% to +1.7%
8.09	Lamivir-S 30/150mg, tab	K50287	Plastic bottle	4 × 30	03/07	Kenya	✓	✓	✓	✓	104.5	98.0	✓	mean: 455.2mg -1.7% to +2.0%
8.10	Lamivir-S 30/150mg, tab	K50374	Plastic bottle	4 × 30	04/07	Kenya	✓	✓	✓	✓	99.8	100.8	✓	mean: 450.4mg -2.5% to +3.9%
8.11	Lamivir-S 40/150mg, tab	K50138	Plastic bottle	2 × 60	02/07	Kenya	✓	✓	✓	✓	97.6	99.6	✓	mean: 451.4mg -2.5% to +2.2%
8.12	Lamivir-S 40/150mg, tab	K50425	Plastic bottle	4 × 30	05/07	Kenya	✓	✓	✓	✓	99.0	98.9	✓	mean: 452.2mg -2.3% to +4.6%
8.13	Lamivir-S 40/150mg, tab	K40632	Plastic bottle	4 × 30	06/06	Kenya	✓	✓	✓	✓	97.5	100.6	✓	mean: 452.4mg -2.1% to +1.9%
8.14	Lamivir-S 40/150mg, tab	K50288	Plastic bottle	4 × 30	03/07	Kenya	✓	✓	✓	✓	102.3	98.5	✓	mean: 454.9mg -2.2% to +3.7%
8.15	Stavudine + Lamivudine 40/150mg, tab	7200585	Plastic bottle	2 × 60	05/07	Zambia	✓	✓	✓	✓	101.1	101.8	✓	mean: 351.0mg -1.8% to +4.1%
8.16	Emduo 40/150mg, tab	LEMH0401	Plastic bottle	2 × 60	06/06	Zambia	✓	✓	✓	✓	**90.5**	**92.1**	✓	mean: 420.0mg -1.6% to +2.7%

✓ = Complies

9. Stavudine/lamivudine/nevirapine

Test Plan A: Tablets, not prequalified (21 samples) – methods of the Indian Pharmacopoeia

SPECIFICATIONS:

Content: 90.0 to 110.0% of stated amount for each active ingredient

Related substances: Thymine: ≤ 3.0%
Any individual impurity: ≤ 1.0%
Total impurities: ≤ 3.5%

OMCL No.	Trade name, strength and dosage form	Batch	Primary pack	Sample and pack size	Expiry date	Country	Label	Appearance	Identity of each active ingredient	Disintegration	Content (% of stated amount)			Related substances	Uniformity of mass
											stavudine	lamivudine	nevirapine		
6.01	Stavex 30/150/200mg LN tab	SN0304002	Plastic bottle	2 × 60	12/05	Nigeria	✓	✓	✓	✓	102.0	103.5	102.7	✓	mean: 723.7mg -2.4% to +2.9%
6.09	Stavudine Lamivudine Nevirapine 40 / 150 / 200mg tab	ZEQ3009	Plastic bottle	2 × 60	08/05	Cameroon	✓	✓	✓	✓	98.1	99.5	98.9	✓	mean: 725.6mg -1.4% to +1.0%
6.22	Afri-Vir 30/150/200mg tab	AV05-L9001	Plastic bottle	2 × 60	04/07	DRC	✓	✓	✓	✓	103.7	99.1	97.1	✓	mean: 770.8mg -2.8% to +3.4%
6.27	Triviro- LNS 40/150/200mg tab	1395014	Blister strips	2 × 60	03/06	Kenya	✓	✓	✓	✓	100.4	100.2	99.3	✓	mean: 803.1mg -1.6% to +2.1%
6.28	Triviro- LNS 40/150/200mg tab	1386859	Blister strips	2 × 60	02/06	Kenya	✓	✓	✓	✓	99.9	101.0	100.0	✓	mean: 797.3mg -1.8% to +1.1%
6.29	Triviro- LNS 30/150/200mg tab	1410508	Blister strips	2 × 60	05/06	Kenya	✓	✓	✓	✓	100.3	103.8	102.4	✓	mean: 799.3mg -1.5% to +2.0%
6.30	Nevilast 30/150/200mg tab	NLT50403	Plastic bottle	2 × 60	03/07	Kenya	✓	✓	✓	✓	102.5	102.6	102.5	✓	mean: 702.5mg -1.8% to +1.7%
6.31	Nevilast 40/150/200mg tab	NST50303	Plastic bottle	2 × 60	02/07	Kenya	✓	✓	✓	✓	99.9	100.0	99.5	✓	mean: 699.5mg -1.8% to +2.8%
6.36	Emtri 30/150/200mg tab	HEMS502	Plastic bottle	2 × 60	12/06	Kenya	✓	✓	✓	✓	99.0	101.8	103.1	✓	mean: 576.8mg -1.2% to +1.2%
6.37	Emtri 30/150/200mg tab	HEMS404	Plastic bottle	2 × 60	06/06	Kenya	✓	✓	✓	✓	98.8	100.5	102.6	✓	mean: 575.7mg -0.8% to +1.3%
6.38	Emtri 30/150/200mg tab	HEMS506	Plastic bottle	2 × 60	01/07	Kenya	✓	✓	✓	✓	97.9	99.7	102.5	✓	mean: 577.0mg -1.1% to +1.1%
6.39	Emtri 30/150/200mg tab	HEMS 505	Plastic bottle	2 × 60	01/07	Kenya	✓	✓	✓	✓	98.1	99.7	102.0	✓	mean: 575.0mg -1.2% to +1.4%
6.40	Emtri 30/150/200mg tab	HEMS501	Plastic bottle	2 × 60	12/06	Kenya	✓	✓	✓	✓	99.3	101.7	103.3	✓	mean: 576.3mg -1.0% to +0.9%
6.41	Emtri 40/150/200mg tab	LTM0403	Plastic bottle	2 × 60	02/06	Kenya	✓	✓	✓	✓	94.7	97.1	100.5	✓	mean: 573.0mg -0.9% to +1.5%
6.42	Emtri 40/150/200mg tab	LTM0402	Plastic bottle	2 × 60	02/06	Kenya	✓	✓	✓	✓	94.5	97.4	100.5	✓	mean: 570.7mg -0.9% to +2.3%
6.43	Emtri 40/150/200mg tab	LTH0404	Plastic bottle	2 × 60	02/06	Kenya	✓	✓	✓	✓	94.8	97.1	100.2	✓	mean: 572.0mg -1.1% to +0.9%

✓ = Complies

9. Stavudine/lamivudine/nevirapine

Test Plan A: Tablets, not prequalified (21 samples) – methods of the Indian Pharmacopoeia **(continued)**

SPECIFICATIONS:

Content: 90.0 to 110.0% of stated amount for each active ingredient

Related substances: Thymine: ≤ 3.0%
Any individual impurity: ≤ 1.0%
Total impurities: ≤ 3.5%

OMCL No.	Trade name, strength and dosage form	Batch	Primary pack	Sample and pack size	Expiry date	Country	Label	Appearance	Identity of each active ingredient	Disintegration	Content (% of stated amount)			Related substances	Uniformity of mass
											stavudine	lamivudine	nevirapine		
6.44	Emtri 40/150/200mg tab	LTH0401	Plastic bottle	2 × 60	02/06	Kenya	✓	✓	✓	✓	95.6	97.5	100.6	✓	mean: 573.2mg -0.8% to +1.6%
6.45	Emtri 40/150/200mg tab	01A05003	Plastic bottle	2 × 60	02/07	Zambia	✓	✓	✓	✓	97.6	98.6	100.8	✓	mean: 573.8mg -1.4% to +1.0%
6.46	Triviro- LNS 30/150/200mg tab	1411652	Blister strips	2 × 60	05/06	Zambia	✓	✓	✓	✓	102.5	104.2	100.2	✓	mean: 806.0mg -1.1% to +1.6%
6.47	Maxivir 30/150/200mg tab	S50061	Plastic bottle	2 × 60	09/05	Zambia	✓	✓	✓	✓	96.4	99.6	100.5	✓	mean: 721.4mg -1.0% to +1.8%
6.48	Maxivir 40/150/200mg tab	S50062	Plastic bottle	2 × 60	09/05	Zambia	✓	✓	✓	✓	97.8	95.3	95.9	✓	mean: 720.9mg -2.2% to +2.3%

✓ = Complies

9. Stavudine / lamivudine / nevirapine

Test Plan B: Tablets, prequalified (31 samples)

SPECIFICATIONS:

Content: 90.0 to 110.0% of stated amount for each active ingredient

Related substances: *For stavudine and lamivudine*:
Thymine: ≤ 1.50%
Any other impurity (anhydrothymidine, β-thymidine, isomer of β-thymidine, carboxylic acid, salicylic acid, any individual unknown impurity): ≤ 0.50%
Sum of all impurities: ≤ 3.00%
For nevirapine:
Any individual impurity: ≤ 0.50%
Sum of all impurities: ≤ 1.00%

Dissolution: Not less than 80%(Q) of stated amount of each active ingredient dissolved in 45 minutes

OMCL No.	Trade name, strength and dosage form	Batch	Primary pack	Sample and pack size	Expiry date	Country	Label	Appearance	Identity of each active ingredient	Content (% of stated amount)			Related substances	Dissolution (% of stated amount)			Uniformity of mass
										stavudine	lamivudine	nevirapine		stavudine	lamivudine	nevirapine	
6.02*	Triomune 30/150/200mg, tab	G54286	Plastic bottle	2 × 60	08/07	Cameroon	✓	✓	✓	96.4	96.0	98.4	✓	93-103	96-101	94-104	mean: 715.1mg -2.8% to +2.9%
6.03*	Triomune 30/150/200mg, tab	G45275	Plastic bottle	2 × 60	04/07	Cameroon	✓	✓	✓	96.8	98.3	100.4	✓	94-99	97-99	96-99	mean: 723.9mg -1.2% to +1.4%
6.04*	Triomune 30/150/200mg, tab	G45274	Plastic bottle	2 × 60	05/07	Cameroon	✓	✓	✓	94.9	97.9	99.8	✓	93-100	99-103	98-102	mean: 723.2mg -1.9% to +1.9%
6.05*	Triomune 30/150/200mg, tab	G47409	Plastic bottle	2 × 60	04/07	Cameroon	✓	✓	✓	**90.2**	98.9	99.8	✓	85-96	101-106	99-103	mean: 713.0mg -2.8% to +3.0%
6.06*	Triomune 30/150/200mg, tab	G56978	Plastic bottle	2 × 60	11/07	Cameroon	✓	✓	✓	**91.3**	99.6	97.9	✓	87-95	99-103	97-103	mean: 724.3mg -4.8% to +2.1%
6.07*	Triomune 30/150/200mg, tab	G45203	Plastic bottle	2 × 60	05/07	Cameroon	✓	✓	✓	97.5	96.7	97.2	✓	90-100	94-99	93-97	mean: 722.9mg -3.6% to +2.2%
6.08*	Triomune 30/150/200mg, tab	G47132	Plastic bottle	2 × 60	02/07	Cameroon	✓	✓	✓	95.6	98.5	99.2	✓	91-99	99-102	96-99	mean: 720.8mg -2.9% to +2.5%
6.10*	Triomune 30/150/200mg, tab	G47133 **As 6.13**	Plastic bottle	2 × 60	02/06	Uganda	✓	✓	✓	100.0	97.1	99.7	✓	92-103	97-104	97-102	mean: 723.9mg -1.9% to +1.5%
6.11*	Triomune 30/150/200mg, tab	G46767	Plastic bottle	2 × 60	12/06	Uganda	✓	✓	✓	**90.3 (a)**	98.4	99.0	✓	90-96	99-105	98-104	mean: 719.3mg -4.1% to +3.2%
6.12*	Maxivir 30/150/200mg, tab	SK4008	Plastic bottle	2 × 60	08/05	Uganda	✓	✓	✓	93.4	101.1	102.1	✓	90-94	101-105	99-103	mean: 732.3mg -1.3% to +1.5%
6.13*	Triomune 30/150/200mg, tab	G47133 **As 6.10**	Plastic bottle	2 × 60	02/06	Uganda	✓	✓	✓	99.9	96.0	96.5	✓	96-104	95-98	94-98	mean: 721.2mg -2.1% to +2.1%

(a) 88.8% (n=2); check: 91.8% (n=2); ∅: 90.3%

✓ = Complies
*=WHO-prequalified

Results: Stavudine / lamivudine / nevirapine

Test Plan B: Tablets – prequalified (31 samples) **(continued)**

SPECIFICATIONS:

Content: 90.0 to 110.0% of stated amount for each active ingredient

Related substances: *For stavudine and lamivudine*:
Thymine: ≤ 1.50%
Any other impurity (anhydrothymidine, β-thymidine, isomer of β-thymidine, carboxylic acid, salicylic acid, any individual unknown impurity): ≤ 0.50%
Sum of all impurities: ≤ 3.00%
For nevirapine:
Any individual impurity: ≤ 0.50%
Sum of all impurities: ≤ 1.00%

Dissolution: Not less than 80%(Q) of stated amount of each active ingredient dissolved in 45 minutes

OMCL No.	Trade name, strength and dosage form	Batch	Primary pack	Sample and pack size	Expiry date	Country	Label	Appearance	Identity of each active ingredient	Content (% of stated amount)			Related substances	Dissolution (% of stated amount)			Uniformity of mass
										stavudine	lamivudine	nevirapine		stavudine	lamivudine	nevirapine	
6.14*	Triomune 30/150/200mg, tab	K50051	Plastic bottle	2 × 60	06/06	Tanzania	✓	✓	✓	105.8	97.5	98.5	✓	97-103	94-99	94-97	mean: 729.7mg -1.2% to +1.7%
6.15*	Triomune 30/150/200mg, tab	K50160	Plastic bottle	2 × 60	08/06	Tanzania	✓	✓	✓	98.0	100.1	99.6	✓	91-98	97-104	97-102	mean: 725.2mg -2.7% to +1.6%
6.16*	Triomune 30/150/200mg, tab	K41017	Plastic bottle	2 × 60	04/06	Tanzania	✓	✓	✓	117.0 **(7)**	95.3	99.4	✓	95-135 **(a)**	92-101	98-101	mean: 723.1mg -2.7% to +2.8%
6.17*	Triomune 30/150/200mg, tab	K50097	Plastic bottle	2 × 60	07/06	Tanzania	✓	✓	✓	98.2	96.5	101.6	✓	91-99	95-102	99-102	mean:731.4mg -1.4% to +1.6%
6.18*	Triomune 30/150/200mg, tab	K50123	Plastic bottle	2 × 60	07/06	Tanzania	✓	✓	✓	98.7	98.8	100.0	✓	94-100	99-102	98-101	mean: 724.5mg -1.0% to +1.2%
6.19*	Triomune 30/150/200mg, tab	K50101	Plastic bottle	2 × 60	07/06	Tanzania	✓	✓	✓	98.1	99.6	97.9	✓	93-99	98-102	96-100	mean: 724.7mg -2.0% to +1.1%
6.20*	Triomune 30/150/200mg, tab	K50050	Plastic bottle	4 × 60	06/06	DRC	✓	✓	✓	97.3	100.2	100.8	✓	90-95	97-100	96 -99	mean: 723.7mg -3.0% to +2.1%
6.21*	Triomune 40/150/200mg, tab	K41012	Plastic bottle	2 × 60	04/06	DRC	✓	✓	✓	100.8	102.5	102.2	✓	93-101	96-100	95-99	mean: 731.0mg -2.1% to +2.1%
6.23*	Triomune 40/150/200mg, tab	K41094	Plastic bottle	2 × 60	05/06	DRC	✓	✓	✓	104.2	101.1	99.2	✓	96-103	97-100	93.95	mean: 736.3mg -3.6% to +2.2%
6.24*	Triomune 30/150/200mg, tab	K50432	Plastic bottle	2 × 60	11/07	DRC	✓	✓	✓	97.7	101.5	101.5	✓	94-98	100-102	98-100	mean: 730.4mg -1.7% to +1.9%

(7) Confirmed by dissolution testing and test for uniformity of content (WHO sampling number: TAN PUT1 LSN 01/1)

(a) 95%-135%, checked: 93%-130%

✓ = Complies
*=WHO-prequalified

Results: Stavudine / lamivudine / nevirapine

Test Plan B: Tablets – prequalified (31 samples) **(continued)**

SPECIFICATIONS:

Content: 90.0 to 110.0% of stated amount for each active ingredient

Related substances: *For stavudine and lamivudine*:
Thymine: ≤ 1.50%
Any other impurity (anhydrothymidine, β-thymidine, isomer of β-thymidine, carboxylic acid, salicylic acid, any individual unknown impurity): ≤ 0.50%
Sum of all impurities: ≤ 3.00%
For nevirapine:
Any individual impurity: ≤ 0.50%
Sum of all impurities: ≤ 1.00%

Dissolution: Not less than 80%(Q) of stated amount of each active ingredient dissolved in 45 minutes

OMCL No.	Trade name, strength and dosage form	Batch	Primary pack	Sample and pack size	Expiry date	Country	Label	Appearance	Identity of each active ingredient	Content (% of stated amount)			Related substances	Dissolution (% of stated amount)			Uniformity of mass
										stavudine	lamivudine	nevirapine		stavudine	lamivudine	nevirapine	
6.25*	Triomune 40/150/200mg, tab	K50401	Plastic bottle	2 × 60	10/07	DRC	✓	✓	✓	99.3	98.5	99.8	✓	90-93	93-97	92-95	mean: 723.7mg -1.4% to +1.7%
6.26*	Triomune 40/150/200mg, tab	K50334	Plastic bottle	2 × 60	04/07	DRC	✓	✓	✓	100.8	102.3	102.1	✓	92-99	92-99	94-97	mean: 724.8mg -1.4% to +1.3%
6.32*	Triomune 30/150/200mg, tab	K40887	Plastic bottle	2 × 60	03/07	Kenya	✓	✓	✓	100.7	99.6	100.4	✓	94-102	97-102	96-100	mean: 724.8mg -2.3% to +2.0%
6.33*	Triomune 30/150/200mg, tab	G46590	Plastic bottle	2 × 60	10/05	Kenya	✓	✓	✓	102.5	100.1	99.2	✓	89-110	94-99	93-99	mean: 727.8mg -2.8% to +1.5%
6.34*	Triomune 30/150/200mg, tab	K40448	Plastic bottle	2 × 60	09/05	Kenya	✓	✓	✓	95.1	100.6	99.7	✓	87-92	97-99	93-95	mean: 723.5mg -1.3% to +1.2%
6.35*	Triomune 40/150/200mg, tab	K50006	Plastic bottle	2 × 60	06/07	Kenya	✓	✓	✓	100.3	99.4	101.5	✓	94-101	93-97	93-96	mean: 723.0mg -2.6% to +2.4%
6.49*	Triomune 40/150/200mg, tab	K50278	Plastic bottle	2 × 60	09/07	Zambia	✓	✓	✓	99.0	101.2	101.4	✓	89-99	94-99	93-97	mean: 722.8mg -2.6% to +1.5%
6.50*	Triomune 40/150/200mg, tab	AS5398	Plastic bottle	2 × 60	07/07	Zambia	✓	✓	✓	102.6	98.1	100.7	✓	98-104	94-99	93-98	mean: 721.9mg -2.0% to +2.2%
6.51*	Triomune 30/150/200mg, tab	K50280	Plastic bottle	2 × 60	09/07	Zambia	✓	✓	✓	99.2	101.1	100.8	✓	91-97	96-102	94-97	mean: 728.2mg -1.6% to +1.1%
6.52*	Triomune 40/150/200mg, tab	K50279	Plastic bottle	2 × 60	09/07	Zambia	✓	✓	✓	102.6	98.1	100.7	✓	95-102	94-97	93-98	mean: 728.0mg -2.5% to +2.5%

✓ = Complies
*=WHO-prequalified

Appendix 2: Batches with multiple samples tested

Active ingredient(s)	Test Plan	Batch number	OMCL numbers and countries of samples tested		
efavirenz	A	HV77220	4.21 Tanzania	4.24 Tanzania	
		NB35330	4.15 Uganda	4.17 Uganda	
	B	NB17260	4.07 Cameroon	4.32 Kenya	
lamivudine	A	1375882	2.05 Nigeria	2.06 Nigeria	
		01A05002	2.40 Tanzania	2.63 Zambia	
		031674	2.51 Kenya	2.62 Kenya	
	B	169400	2.22 Uganda	2.26 Uganda	2.57 Kenya
		B144178	2.07 Nigeria	2.13 Nigeria	
		G54329	2.37 Tanzania	2.39 Tanzania	
		Y41272	2.29 Tanzania	2.35 Tanzania	
nevirapine	B	407734	3.06 Nigeria	3.61 Kenya	
		C40467	3.29 Tanzania	3.36 Tanzania	
		NV40101	3.15 Uganda	3.19 Uganda	3.21 Uganda
	C	L457646A	3.33 Tanzania	3.35 Tanzania	
		L457647A	3.28 Tanzania	3.31 Tanzania	
		L457744A	3.13 Nigeria	3.64 Kenya	
stavudine	A	C40341	1.18 Uganda	1.32 DRC	
	C	0017	1.25 Tanzania	1.35 DRC	
		0023 (40mg cap)	1.26 Tanzania	1.28 Tanzania	
		0023 (30mg cap)	1.27 Tanzania	1.37 Kenya	
		0033	1.29 Tanzania	1.30 Tanzania	1.39 Kenya
		4K93177	1.23 Tanzania	1.46 Kenya	
zidovudine	A	G33616	5.04 Nigeria	5.26 DRC	
	B	G50487	5.08 Cameroon	5.43 Zambia	
	C	V14	5.05 Nigeria	5.36 Kenya	
lamivudine/ zidovudine	B	B142682	7.18 Tanzania	7.23 Tanzania	
		G54200	7.10 Uganda	7.15 Uganda	
		R170752	7.12 Uganda	7.14 Uganda	
stavudine/ lamivudine/ nevirapine	B	G47133	6.10 Uganda	6.13 Uganda	

The samples with the OMCL Numbers 1.43 (stavudine 40mg capsules) and 1.59 (stavudine 30mg capsules) shared batch number 0039. They were manufactured at different sites.