

The quality of antimalarials

A study in selected African countries

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Acronyms

AFRO	Regional Office for Africa
BP	British Pharmacopoeia
CENQAM	Centre for Quality Assurance of Medicines
CMS	Central medical stores
CQS	Chloroquine syrup
CQT	Chloroquine tablet
DH	District hospital
DMS	District medical stores
EDM/WHO	Essential Drugs and Medicines Policy Department, World Health Organization
GMP	Good manufacturing practices
HC	Health centre
H	Household
HPLC	High pressure liquid chromatography
P	Pharmacy
RSD	Related standard deviation
SPT	Sulphadoxine/pyrimethamine tablet
TH	Teaching hospital
V/S	Vendor/shop
USP	United States Pharmacopeia

Contents

Authors.....	iii
Country Research Team Leaders.....	iii
Laboratory Support	iii
Acknowledgements	iii
Acronyms.....	iv
Contents	v
Executive summary.....	ix
1. Background	1
2. Methodology	3
2.1 Analytical methods.....	4
2.1.1 Method for the assay of chloroquine syrup	4
2.1.2 Method for the assay of chloroquine tablets	5
2.1.3 Method for the assay of sulphadoxine/pyrimethamine tablets.....	5
2.2 Dissolution testing	6
2.2.1 Dissolution method for chloroquine tablets.....	6
2.2.2 Dissolution method for sulphadoxine/pyrimethamine tablets	6
3. Results.....	7
4. Discussion	9
4.1 Is there a problem?.....	9
4.2 What is the magnitude of the problem?.....	9
4.3 Is the problem limited to a particular distribution level?.....	10
4.4 Is the problem limited to imported or domestic products?	10
4.5 Limitations of the methodology.....	10
5. Conclusions and recommendations	13
5.1 Conclusions.....	13
5.2 Need for further studies.....	13
5.3 Recommendations for further studies.....	13
5.4 Recommendations for quality and bio-equivalence surveillance	14
References.....	15
Tables	17
Table I: Combined country results: percentage failure of samples.....	17
Table II: Combined country results: percentage failure of samples at various collection points	21
Table III: Percentage failure of samples as per origin (manufacturer)	24
Table IV: Number of samples collected and analysed.....	25
Table IVa: Country results from various collection points	26
Participating country: Gabon	26

Table IVb: Country results from various collection points	26
Participating country: Ghana	26
Table IVc: Country results from various collection points	27
Participating country: Kenya.....	27
Table IVd: Country results from various collection points.....	27
Participating country: Mali.....	27
Table IVe: Country results from various collection points	28
Participating country: Mozambique.....	28
Table IVf: Country results from various collection points.....	28
Participating country: Zimbabwe	28
Table IVg: Country results from various collection points	29
Participating country: Sudan.....	29
Table Va: Country results according to origin of manufacturer	29
Participating country: Gabon	29
Table Vb: Country results according to origin of manufacturer	30
Participating country: Ghana	30
Table Vc: Country results according to origin of manufacturer	30
Participating country: Kenya.....	30
Table Vd: Country results according to origin of manufacturer	31
Participating country: Mali.....	31
Table Ve: Country results according to origin of manufacturer	31
Participating country: Mozambique.....	31
Table Vf: Country results according to origin of manufacturer	32
Participating country: Zimbabwe	32
Annexes.....	33
ANNEX: 1A.....	33
Country: Gabon Product: Chloroquine syrup	33
ANNEX: 1B	34
Country: Gabon Product: Chloroquine tablet.....	34
ANNEX: 1C.....	35
Country: Gabon Product: Sulphadoxine/ pyrimethamine tablets	35
ANNEX: 2A.....	36
Country: Ghana Product: Chloroquine syrup	36
ANNEX: 2B	37
Country: Ghana Product: Chloroquine tablets	37
ANNEX:2C.....	38
Country: Ghana Product: Sulphadoxine/ pyrimethamine tablets	38
ANNEX: 3A.....	39
Country: Kenya Product: Chloroquine syrup.....	39
ANNEX: 3B	40
Country: Kenya Product: Chloroquine tablets	40
ANNEX: 3C.....	41
Country: Kenya Product: Sulphadoxine/ pyrimethamine tablets.....	41
ANNEX: 4A.....	42
Country: Mali Product: Chloroquine syrup	42
ANNEX: 4B	43
Country: Mali Product: Chloroquine tablets.....	43
ANNEX: 4C.....	44
Country: Mali Product: Sulphadoxine/ pyrimethamine tablets.....	44
ANNEX: 5A.....	45

Country: Mozambique Product: Chloroquine syrup	45
ANNEX: 5B	46
Country: Mozambique Product: Chloroquine tablets	46
ANNEX: 5C	47
Country: Mozambique Product: Sulphadoxine/pyrimethamine tablets.....	47
ANNEX: 6A.....	49
Country: Sudan Product: Chloroquine syrup	49
ANNEX: 6B	50
Country: Sudan Product: Chloroquine tablets.....	50
ANNEX: 6C.....	51
Country: Sudan Product: Sulphadoxine/pyrimethamine tablets.....	51
ANNEX: 7A.....	52
Country: Zimbabwe Product: Chloroquine syrup	52
ANNEX: 7B	53
Country: Zimbabwe Product: Chloroquine tablets.....	53
ANNEX: 7C.....	54
Country: Zimbabwe Product: Sulphadoxine/pyrimethamine tablets.....	54

Executive summary

Aim: This was a pilot study to assess the quality of antimalarials (chloroquine and sulphadoxine/pyrimethamine) in selected African countries, and to determine whether the quality of these products was related to the level of the distribution chain at which the samples were collected.

Methods: Samples were collected systematically from seven participating countries that were coordinated by country team leaders. Each team leader was responsible for coordinating sample collection, coding and packaging for transportation to WHO/AFRO headquarters through the WHO country offices. The samples were then sent to a single contracted laboratory, the Centre for Quality Assessment of Medicines (CENQAM) in Potchefstroom, South Africa, for analysis.

Findings: The results identified several significant problems of substandard products within the drug distribution chains. They included percentage failures in ingredient content ranging from 20% to 67% for chloroquine tablet (CQT) and 5% to 38% for sulphadoxine/pyrimethamine tablet (SPT) and dissolution failures ranging from 5% to 29% for CQT and 75% to 100% for SPT. Such results cannot be ignored. In view of the potential danger that the substandard antimalarials could already be posing in the fight against malaria, an intervention plan should be developed immediately. For example, quality surveillance systems could be set up within drug regulatory authorities in the region and support given to manufacturers to improve compliance with good manufacturing practices (GMP).

The study faced a number of logistical difficulties. Of the eight participating countries, seven (Gabon, Ghana, Kenya, Mali, Mozambique, Sudan and Zimbabwe) submitted their samples in time for laboratory analysis. Some of the samples that were collected could not be analysed for various reasons, including spillage, crystallization of syrup samples, insufficient quantities and incorrect labelling.

No clear relationship between the quality of products and the level of the distribution chain was observed. Similarly, there was no difference between locally manufactured and imported products.

Conclusion and recommendations: The data from this pilot project indicate significant problems of substandard antimalarial products circulating within the drug distribution chains in the African region. This appears to be due to non-compliance with GMP guidelines by manufacturers in the production of the antimalarials. Additionally, the products evaluated in this study may also have been susceptible to handling problems, so rendering the observed patterns non conclusive. However, in view of the potential danger that the substandard antimalarials could already be posing in the region, there is justification for WHO's Roll Back Malaria programme and others to take the necessary remedial

measures to ensure access to good quality drug products. These measures should include support to national regulatory authorities in strengthening manufacturing and distribution channel inspections. Equally critical is the need for WHO to support regulatory authorities to work with the pharmaceutical manufacturers to improve compliance to GMP, and good procurement and distribution practices.

1. Background

Malaria accounts for a large part of the disease burden in poor countries, causing over a million deaths a year. With 90% of the deaths occurring in Africa, malaria presents a serious health and socio-economic challenge. Effective drug treatment continues to be a critical element of any strategy to control malaria. There have been widespread reports of antimalarial drug resistance in the African region at a time when globally the development of resistance is said to exceed the pace at which new antimalarial drugs are being developed.¹

In many settings, antimicrobial therapy is usually complicated not only because of microbial drug resistance but also patient-related factors, such as poor adherence to therapy, drug side-effects, such as vomiting, which lead to under-dosage, drug interactions and individual variations. Therapeutic failure also occurs due to pharmaceutical failure resulting from poor quality of products, instability of products, which leads to deterioration of their quality before they reach the patient, or the use of counterfeit products. Several WHO-sponsored studies have demonstrated significant instability of products such as ergometrine,^{2,3} and other essential medicines, during transport by sea, and also during road transport inland.^{4,5}

The problem of counterfeit drugs is well recognized within the African region as well as in other parts of the developing world.⁶ It prompted WHO/EDM to facilitate the Joint Project on Counterfeit Drugs which, among other activities, generated guidelines for developing measures to combat counterfeit drugs.⁷

It should also be noted that pharmaceutical products of poor quality might contribute to the emergence of resistance. This is because when patients are treated with poor-quality drugs, resulting in low bioavailability, it leads to drug under-dosage, which promotes the development of resistance. It is therefore important to consider product quality when dealing with the problem of antimalarial resistance.

Treatment failure, ascribed to resistance, may also be due to low quality, yet in most countries the quality of antimalarials is rarely independently verified, and the local capacity for independent drug quality assurance is worst where the disease burden is the highest. Although malaria-endemic countries carry out drug resistance monitoring in accordance with the WHO protocol,⁸ there are no data linking these treatment failures, i.e. drug resistance level with product quality.

As part of the WHO Roll Back Malaria effort, and the on-going activities of the Essential Drugs and Medicines Policy Department to improve access and promote rational use of good quality essential medicines, a preliminary, exploratory meeting of experts and others concerned, was held in Geneva in October 1998. The meeting concluded that poor quality of antimalarials posed a problem to malaria control, and therefore to public health, especially in countries

where there is little or no drug regulatory infrastructure. It was also proposed to set up a technical network of regional experts, with a primary focus on access to quality antimalarials.

There was a need to clarify the nature and magnitude of the problem of quality and consequently how it could be specifically addressed. As a prelude to a comprehensive study on the quality of antimalarials in African countries and the complex issues that might be involved, it was decided to carry out a pilot study in selected countries. It was hoped that this would provide an indication of the nature and gravity of the problem. The study results would then guide the design of intervention strategies.

2. Methodology

The study addressed the following research questions:

- Is there a problem of poor quality of chloroquine tablets and syrup formulations and of sulphadoxine/pyrimethamine tablets in countries where they are used?
- If so, what is the magnitude of this problem?
- Is the problem limited to a particular level of the distribution chain?

Study design and sampling

The most widely used antimalarials, chloroquine and sulphadoxine/pyrimethamine were evaluated. Two dosage forms, tablets and syrup, were sampled for chloroquine (CQT and CQS respectively) while only the tablet form of sulphadoxine/pyrimethamine were sampled (SPT). The study was designed to collect samples at various levels of the drug distribution chain, such as medical stores, teaching hospitals, district hospitals, health centres, private sector pharmacies, shops, street vendors and households. Quality indicators measured were the content of the active ingredient and dissolution rate (for tablets only) in comparison to standard specifications for these products in the relevant pharmacopoeia.

Eight African countries, Gabon, Ghana, Kenya, Mali, Mozambique, Sudan, the United Republic of Tanzania and Zimbabwe were chosen to participate in the study. A team leader was chosen from each country to coordinate sample collection following the standard sampling protocol, coding and packaging for transportation to the WHO/AFRO Regional Adviser through the WHO country office.

The sample identification system was based upon an agreed coding method for all the countries involved in the study. Samples were collected at the various levels of the distribution chain (see list above). Each participating country collected a minimum of 20 samples of each of the three drug products. The sample collectors adopted the actual quantities from each level to their local situation using the following suggested steps:

- Identify the level and institution from which samples will be collected.
- Visit the authorities at the institution and household and acquaint them with the purpose and importance of the study, as well as the information that will be collected.
- Agree on the basis for replacement of drugs to be obtained as samples, if necessary.
- Define sample identification and coding.
- Obtain standardized packaging for samples.
- Collect and carefully label samples at the point of collection.
- Collate all the samples, prepare them for dispatch and deposit them with the WHO country office for onward freighting to WHO/AFRO.

- Send a summary of the sample dispatch report, including coding, to the team leader.

Information obtained for each sample included the name of the drug (brand or generic), strength, dosage form, date of manufacture, date of expiry, description of packaging material, any remarks on storage, location of sample collection point, and date of sample collection. Information on expiry dates was not consistently available and therefore it was not recorded as part of the study.

The samples were sent to the WHO/AFRO Regional Office, and then channelled to the Centre for Quality Assurance of Medicines (CENQAM) in Potchefstroom, South Africa, for analysis.

Analysis of samples

Samples were analysed according to pharmacopoeial specifications to assess the quality of the products. Tests were on the content of active pharmaceutical ingredient for tablets and syrup, and dissolution and content for tablets.

2.1 Analytical methods

2.1.1 Method for the assay of chloroquine syrup

There is no analytical monograph in the United States Pharmacopeia (USP) or British Pharmacopoeia (BP) for the assay of chloroquine syrup. A high pressure liquid chromatography (HPLC) method was developed and validated in-house for the determination of chloroquine in chloroquine syrup. Validation of the method was carried out according to the validation criteria of the USP and the guidelines of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use. Validation parameters, such as specificity, linearity, accuracy and precision, as well as chromatographic parameters, such as peak symmetry and resolution, were assessed and optimized.

As the laboratory did not know the type of excipients used in the various formulations, the method was only validated for interference from the most generally used preservatives such as the parabens (hydroxy benzoates) and benzoic acid. Evidence of interference from any other preservative not validated for could not be detected during the analysis, and therefore the HPLC method was assumed to be specific for the determination of chloroquine in chloroquine syrup.

The method parameters were as follows:

HPLC column:	C ₁₈ , 150 x 4.6 mm
Mobile phase:	75% 0.1M KH ₂ PO ₄ : 25% acetonitrile, 200mg heptane sulfonic acid (pH 3.5)
Detection:	UV at 330 nm
Flow rate:	2ml/min
Injection volume:	20 µl

Performance criteria of the method:

Specificity:	Specific for chloroquine in the presence of hydroxy benzoates and benzoic acid
Precision:	%RSD < 2.0
Linearity:	> 0.98.
Symmetry:	<1.5

Although the method was not specifically validated to indicate all five possible decomposition products due to photo degradation, no peaks suggesting the decomposition of the analyte before or during the analyses were observed.

2.1.2 Method for the assay of chloroquine tablets

The content of chloroquine was determined by UV-spectrophotometry in accordance with an adapted method for chloroquine phosphate tablets of the USP 24. The method consists of recording the UV absorbance of the sample at a wavelength of 343 nm and comparing it to the absorbance of a reference standard in a concentration range representing a 100% label claim at the same wavelength.

The method was adapted in such a way that it was possible to determine the quantity of the different salt forms of chloroquine in the tablets, where applicable. As all USP methods are specific for the analyte, the method was only validated in terms of precision. Interference from excipients was validated by superimposing the UV spectra of the sample and standard.

No interference from excipients was noted, and the precision of the method was %RSD < 2.

2.1.3 Method for the assay of sulphadoxine/pyrimethamine tablets

The content of sulphadoxine and pyrimethamine was determined by means of the HPLC method for the assay of sulphadoxine/pyrimethamine tablets described in the USP 24. The chromatographic parameters were as follows:

HPLC column:	C ₁₈ , 25cm x 4.6mm
Mobile phase:	80% glacial acetic acid (1:100), 20% acetonitrile, 500µl triethylamine
Detection:	UV at 254 nm
Flow rate:	2ml/min
Injection volume:	10µl
The performance parameters were as follows:	

Specificity:	Specific for sulphadoxine and pyrimethamine as per USP
Precision:	%RSD<2
Linearity:	>0.98
Peak symmetry:	<1.9
Resolution:	>1

No interfering peaks were observed during the analysis. The method was able to have indicated a counterfeit substance in some of the samples.

2.2 Dissolution testing

The general method and apparatus of the USP 24 were used for testing the dissolution characteristics of both chloroquine and sulphadoxine/pyrimethamine tablets according to their respective dissolution monographs.

2.2.1 Dissolution method for chloroquine tablets

The dissolution parameters for chloroquine tablets (USP 24) were as follows:

Apparatus:	Apparatus 2 of the USP
Stir rate:	100 rpm
Dissolution medium:	900 ml water
Q-value:	75%
Time:	45 minutes
Sample volume:	5 ml

Six tablets^a were introduced into the dissolution vessels. Samples (5ml) of the dissolution media in the different vessels were withdrawn after 45 minutes and after further dilution, analysed for chloroquine content according to the prescribed UV spectrophotometric method in the USP for the dissolution testing of chloroquine phosphate tablets. The amount of chloroquine dissolved after 45 minutes is expressed as a percentage of the label claim.

2.2.2 Dissolution method for sulphadoxine/pyrimethamine tablets

The dissolution parameters for sulphadoxine/pyrimethamine tablets (USP 24) were as follows:

Apparatus:	Apparatus 2 of the USP
Stir rate:	75 rpm
Dissolution medium:	1000 ml phosphate buffer (pH 6.8)
Q-value:	60%
Time:	30 minutes
Sample volume:	2 ml

Six tablets were introduced into the dissolution vessels. Samples (2ml) of the dissolution media in the different vessels were withdrawn after 30 minutes and without any further dilution, analysed for sulphadoxine and pyrimethamine content according to the HPLC method described in the USP for dissolution testing of these tablets. The amount of sulphadoxine and pyrimethamine dissolved after 30 minutes is expressed as a percentage of the label claim.

^a Where fewer than six tablets were available, at least three were analysed for dissolution in order to indicate trends

3. Results

Full data and detailed results

Seven of the eight participant countries (Gabon, Ghana, Kenya, Mali, Mozambique, Sudan and Zimbabwe) submitted samples to CENQAM for sample analysis (Table I). Samples from Tanzania were not collected in time for the initial analysis due to logistical problems. The full data and detailed results are annexed at the end of this report.

Summary of results

Table I and Figures 1-5 show the combined results from all countries with the results expressed as a percentage of the samples failing pharmacopoeial standards out of the total number of samples analysed. Failed samples were found in all countries for at least one of the three formulations (CQT, CQS, SPT). Most failures were "low" failures, i.e. sample content found to be below the minimum levels recommended for the products. The average percentage failures for the active ingredients were 38.3% for CQT, 23.0% for CQS and 7.6% for SPT. The average percentage failures for dissolution tests were 12.2% for CQT and 91.1%^b for SPT. Every country had low failures for ingredient content for CQT and for SPT dissolution indicating these as the most serious problems (**Figures 2a and 5a**). Ghana, Zimbabwe and Mali had the highest CQT ingredient content failures with 67%, 57% and 47.3% respectively. All participating countries had high failure levels of SPT dissolution (greater than 75%), except for Gabon where there were insufficient samples for this analysis. Only Mozambique had some "high" content failures, i.e. samples above the upper limit of specification. These failures were in the ingredient content for CQS (25%) and SPT (3%).

Table II and Figures 6-10 show the combined results from samples collected at each distribution channel and expressed as a percentage of the samples failing to meet the respective pharmacopoeial specifications. The highest percentage failures in ingredient content for CQT were found at the district hospital (70.0%), followed by district medical stores (58.3%), vendors/shops (50.0%), health centres (46.1%), teaching hospitals (44.4%), pharmacies (43.3%), and households (35.0%). For CQS, the highest percentage ingredient content failures were recorded at the district medical stores (27.2%), household (26.7%), and vendors/shops (21.0%). SPT had the highest percentage ingredient failures at household level (30.7%) followed by district hospitals at 18.2%. High SPT dissolution failures were found at all collection points (ranging from 58.8-100%) topped by households (100%), health centres (85.8%), vendors/shops at 73.0%, district hospitals 72.2%, district medical stores 72.2%, pharmacies 69.8%, and the lowest failures in teaching hospitals, at 58.8%. The high failures in ingredient content found on CQS and SPT in Mozambique were collected at district hospitals and pharmacies.

^b As percentage failure due to the dissolution of the pyrimethamine component

Table III and Figure 11 show the combined country results (excluding the samples collected in Sudan), according to the origin of the manufacturer, expressed as percentages. For active ingredient content the local versus foreign manufactured products results were: CQT 56.2% (27/48) versus 47.2% (17/36), CQS 28% (7/25) versus 13.0% (3/23). For the dissolution test the local versus foreign manufactured products results were: CQT 20.8% (10/48) versus 13.0% (5/36). The high failures in ingredient content found in CQS and SPT in Mozambique were from foreign manufacturers.

4. Discussion

4.1 Is there a problem?

Significant quality problems were detected in this study. **Table I** shows that CQS had content failure rates averaging 23.0% and headed by Mali with 66.7% failures, Sudan 26.6%, and Kenya and Mozambique with 25% each. Content failure for CQT was very significant, with the highest levels being in the samples from Ghana (66.7%), followed by Zimbabwe (57.1%), Mali (47.3%), Kenya (42.8%), Gabon (29.0%), Mozambique (20.0%) and Sudan (5.2%). This indicates a very serious problem which warrants further investigation and intervention. Dissolution failure rates for CQT were generally below 10%, except for Kenya and Ghana with 28.6% and 20% respectively.

SPT had problems mostly with the dissolution of the pyrimethamine component of the formulation, and averaged at 91.1%. Mali, Mozambique and Zimbabwe all had a failure level of 100% for the SPT samples analysed. Kenya had a failure level of 91.7%, Sudan 80.0% and Ghana 75.0%. Samples from Gabon were not sufficient to carry out this test. These findings indicate another very serious problem that warrants further investigation and intervention.

SPT content (pyrimethamine) failures were generally low (10% or lower) except for samples from Ghana, which showed a significant level at 37.5%.

These figures suggest a significant problem of substandard products being found in most countries and at all levels of the distribution chain. The main problem seemed to be samples below the lower limit of specification. Generally there were no "high" failures except in Mozambique where there was 25% failure in CQS ingredient content and 2.8% high failure of active ingredient content of SPT.

4.2 What is the magnitude of the problem?

The data presented in this report indicate that there is a significant problem of substandard antimalarial drug products circulating in the markets of the participating countries. The most significant results were the low content failures for CQT (ranging from a low of 5.2% in Sudan to a high of 66.7% in Ghana) and SPT dissolution (ranging from a low of 75% in Ghana to 100% for Mali, Mozambique and Zimbabwe). However, as this study faced a number of logistical problems, i.e. sample containers, sample quantities, labelling and coding, these results can only be taken as indicative, but not conclusive.

4.3 Is the problem limited to a particular distribution level?

Analysis of the product failure rates by the level of the distribution chain (**Table II**) showed the highest failures for ingredient content of CQS at district medical stores (27.2%), followed by households (26.7%), vendor/shops (21%), pharmacies (14.2%), and health centres (11.1%). For CQT, the highest percentage ingredient content failures were recorded at the district hospital level (70.0%), followed by district medical stores (58.3%) and shops/vendors (50.0%). SPT had the highest percentage ingredient content failures at household level (30.7%). This may be linked to inadequate storage conditions in the homes. High SPT dissolution failures were found at all collection points, led by households (100%), health centres (85.7%), vendor/shops (73%), district hospitals (72.8%), district medical stores (72.2%) and pharmacies (69.8%), with teaching hospitals lowest (58.8%). The high failures in ingredient content found in CQS and SPT in Mozambique were collected at district hospitals and pharmacies. These products were imported into the country.

4.4 Is the problem limited to imported or domestic products?

No significant trend was noted in comparing local versus foreign manufacturers, as shown in **Table III**. There were failures of 56% (27/48) amongst locally made products, compared to 47.2% (17/36) for foreign products for CQT active ingredient content, and 28% (7/25) versus 13% (3/23) CQS active ingredient content. Further investigation of this phenomenon will be important since it is easier for national drug regulatory authorities to act and correct problems that involve domestic manufacturers.

4.5 Limitations of the methodology

Sample containers: Most of the samples were repacked in containers different from the packaging in which the product was marketed, although care was taken to use adequate materials. The closures of the packaging material were however inadequate in the case of liquid preparations and leakage occurred which may have compromised the integrity of the products.

Sample content: The physical and organoleptic properties of some of the CQS were unacceptable, due to crystallization of the content of the container. The crystallization could not be reversed by agitation, and so the samples were rendered unsuitable for analysis. The tendency towards crystallization might have been due to exposure to extremes of temperatures or to loss of content due to the evaporation of liquid vehicle as a result of insufficient sealing of the closures.

The content of some of the samples produced a foul smell, probably due to insufficient preservation. This phenomenon may be related to an unacceptable formulation but it may also be related to insufficient sealing of the closures, or contamination during manufacturing.

In the case of solid dosage forms, broken tablets were noted in some samples. This could be due to a formulation variable that did not support severe handling of the tablets. On the other hand, it may also be that, when removed from the original packaging, the tablets were not adequately repackaged to withstand the stress conditions of transportation.

Sample quantities: Many samples did not have the required number of units for performing all the required tests. In such cases the tests were performed on fewer than the required number of units. Although the results might give an indication of the property evaluated, statistical variance would be high, due to the limited number of units tested. In such cases the results had to be interpreted with caution when trying to arrive at an absolute value for the particular property tested.

5. Conclusions and recommendations

Some general conclusions can be drawn from this quality screening study for antimalarials sampled in various African countries:

5.1 Conclusions

Significant problems of substandard products exist within the drug distribution chains. Percentage failure of samples based on ingredient content ranging from 20% to 67% for CQT and 5% to 28% for SPT, and in dissolution failures ranging from 5% to 33% for CQT and 75% to 100% for SPT, cannot be ignored. In view of the potential danger that substandard antimalarials could already be posing in the fight against malaria, an intervention plan should be developed immediately. This could involve setting up quality surveillance systems within drug regulatory authorities in the region and supporting manufacturers to improve GMP compliance.

5.2 Need for further studies

There is a need for more carefully planned and executed studies in order to define quality problems further. The lessons learnt from this pilot study could be valuable in that next phase of investigations, as well as when carrying out interventions to improve the quality of antimalarials and other medicines moving in domestic and international markets.

5.3 Recommendations for further studies

This pilot study was conducted as a prelude to a comprehensive study on the quality of antimalarials and the complex issues involved. The critical methodological and analytical considerations highlighted in this report should be taken into account when planning further studies. This means:

- Working closely with the analytical laboratory during the planning phase of such a study in order to accommodate the analytical laboratory's needs regarding sample and analytical information, sample containers, and the quantities of sample needed.
- Products should not be taken from the original packaging material in which they are marketed. The use of other packaging material than that used by the manufacturer for sampling may compromise the integrity of the product.
- The storage and transport of samples after sampling should be validated to assure the stability of the samples.
- A standard operational procedure should be used to guide sampling and handling of sampled products in order to standardize procedures in all

countries. Where possible, the formulation of the product and/or the analytical method that the manufacturer uses for batch release should be made available to the analytical laboratory. This is in order to assure the specificity of the analytical method to be employed by the testing laboratory.

- More emphasis should be given to dissolution of solid dosage forms, as this gives an indication of the pharmaceutical availability and interchangeability of products.
- Tests for preservative efficacy should be considered for liquid dosage forms.

5.4 Recommendations for quality and bio-equivalence surveillance

Despite the logistical problems, this study demonstrated that there is a significant problem of low quality. In view of the potential danger that substandard antimalarials could already be posing in the fight against malaria in the region, there was enough justification to recommend definitive action to be taken at country level to address this problem. The WHO Roll Back Malaria Programme should assist countries to take measures to minimize poor quality antimalarial products reaching patients. Such measures should include: promoting good procurement practices in the public sector; monitoring and supporting manufacturers' and suppliers' GMP compliance; and supporting the implementation of sound and effective post-marketing surveillance programmes within drug regulatory authorities, to ensure safe use of good quality antimalarial products.

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Tables

Table I: Combined country results: percentage failure of samples

Country	Chloroquine syrup	Chloroquine tablets		Sulphadoxine/ pyrimethamine tablets*	
	Content	Content	Dissolution	Content	Dissolution
Gabon	0 (0/8)	29.0 (5/17)	5.8 (1/7)	0 (0/10)	-
Ghana	5.0 (1/20)	66.7 (12/18)	20.0 (3/15)	37.5 (3/8)	75.0 (3/4)
Mali	66.7 (4/6)	47.3 (9/19)	5.2 (1/19)	0 (0/7)	100 (7/7)
Kenya	25.0 (2/8)	42.8 (3/7)	28.6 (2/7)	0 (0/12)	91.7 (11/12)
Mozambique	25.0 (3/12)	20.0 (3/15)	6.7 (1/15)	5.5 (1/18)	100 (18/18)
Sudan	26.6 (4/15)	5.2 (1/19)	12.5 (2/16)	0 (0/20)	80.0 (12/15)
Zimbabwe	13.3 (2/15)	57.1 (8/14)	7.1 (1/14)	10.0 (1/10)	100 (10/10)
Average failure (%)	23.0	38.3	12.2	7.6	91.1 (n=6)
Range (%)	0 - 66.7	20 - 66.7	5.2 - 28.6	0 - 37.5	75 - 100 (n=6)

*Indicated as % failure due to the content and dissolution rate of the pyrimethamine component

Fig. 1. Percentage failure - chloroquine syrup

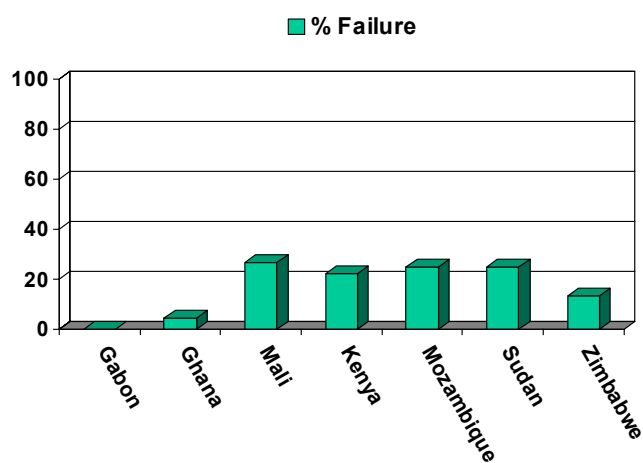


Fig. 2. Percentage failure - chloroquine tablets (content)

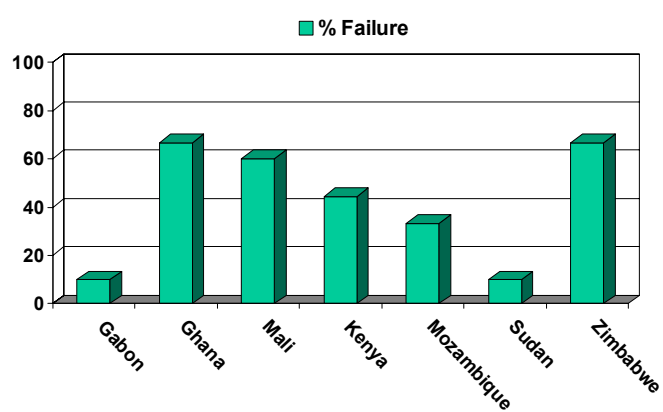


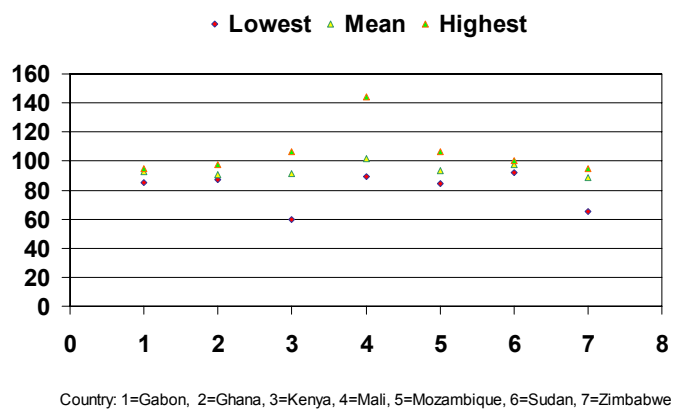
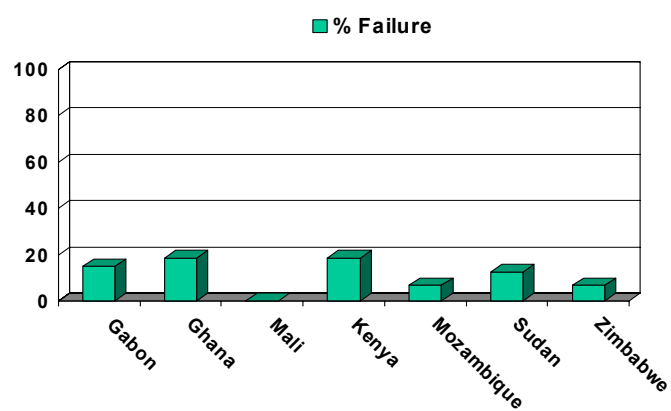
Fig. 2a. Content (%) - chloroquine tablets**Fig. 3. Percentage failure - chloroquine tablets (dissolution)**

Fig. 4. Percentage failure - sulphadoxine/pyrimethamine tablets (pyrimethamine content)

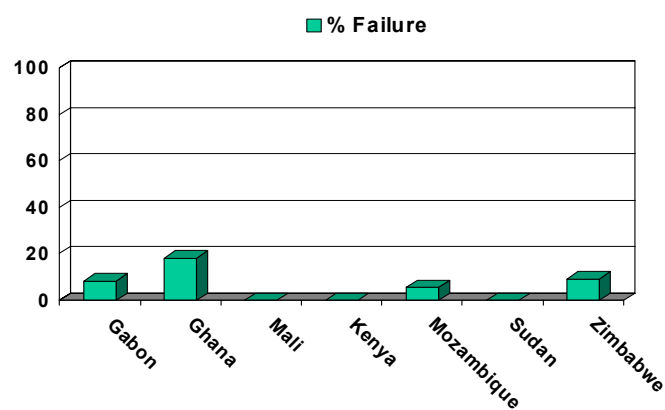
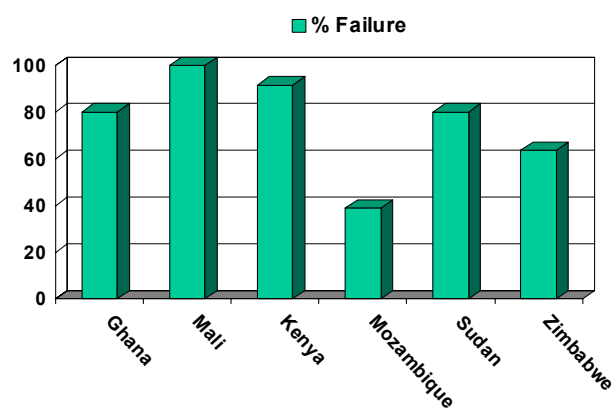


Fig. 5. Percentage failure - sulphadoxine/pyrimethamine tablets (pyrimethamine dissolution)



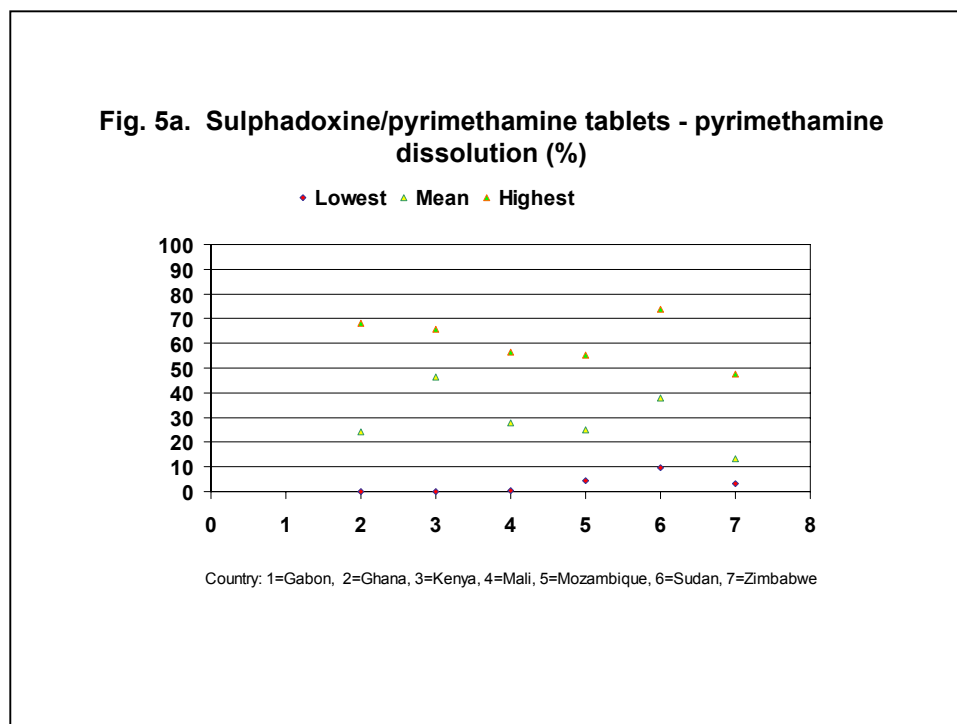


Table II: Combined country results: percentage failure of samples at various collection points

Level of collection	Chloroquine syrup	Chloroquine tablets		Sulphadoxine/pyrimethamine tablets	
	Content	Content	Dissolution	Content	Dissolution
Teaching hospital (TH)	0 (0/5)	44.4 (4/9)	22.2 (2/9)	5.8 (1/17)	58.8 (10/17)
District hospital (DH)	16.7 (1/6)	70.0 (7/10)	10.0 (1/10)	18.1 (2/11)	72.2 (8/11)
District medical stores (DMS)	27.2 (3/11)	58.3 (7/12)	33.3 (4/12)	11.1 (2/18)	72.2 (13/18)
Health centre (HC)	11.1 (1/9)	46.1 (6/13)	0 (0/13)	0 (0/21)	85.7 (18/21)
Pharmacy (P)	14.2 (3/21)	43.4 (10/23)	4.3 (1/23)	11.6 (5/43)	69.8 (30/43)
Vendor/shop (V/S)	21.0 (4/19)	50.0 (16/32)	12.5 (4/32)	5.4 (2/37)	73.0 (27/37)
Household (H)	26.7 (4/15)	35.0 (7/20)	25.0 (4/16)	30.7 (4/13)	100 (8/8)

Fig. 6. Percentage failure - chloroquine syrup

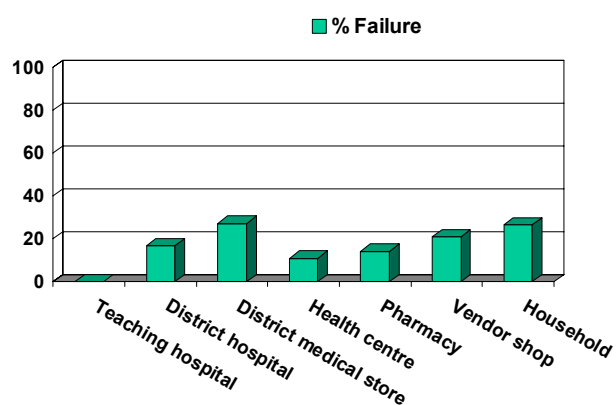


Fig. 7. Percentage failure - chloroquine tablets (content)

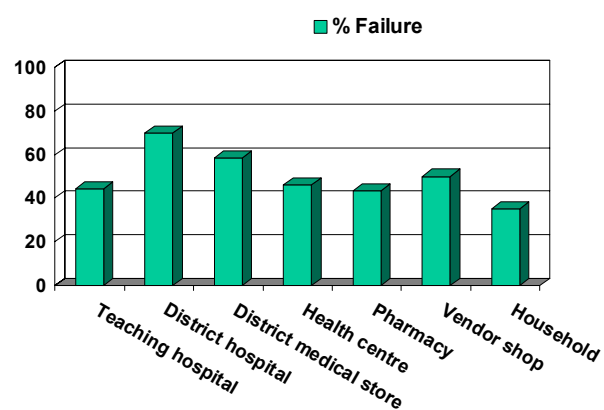


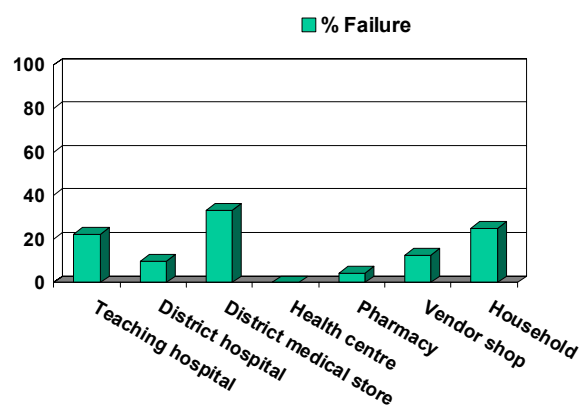
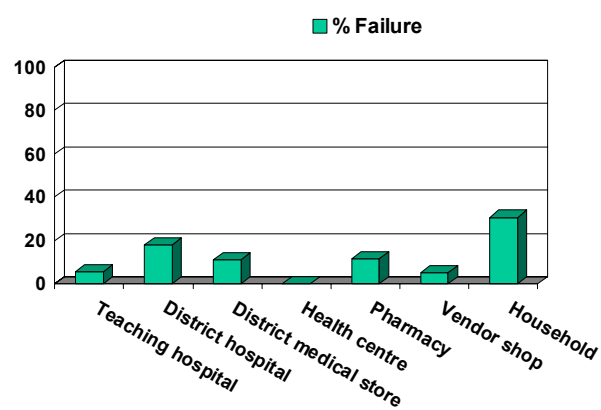
Fig. 8. Percentage failure - chloroquine tablets (dissolution)**Fig. 9. Percentage failure - sulphadoxine/pyrimethamine (pyrimethamine content)**

Fig. 10. Percentage failure - sulphadoxine/pyrimethamine (pyrimethamine dissolution)

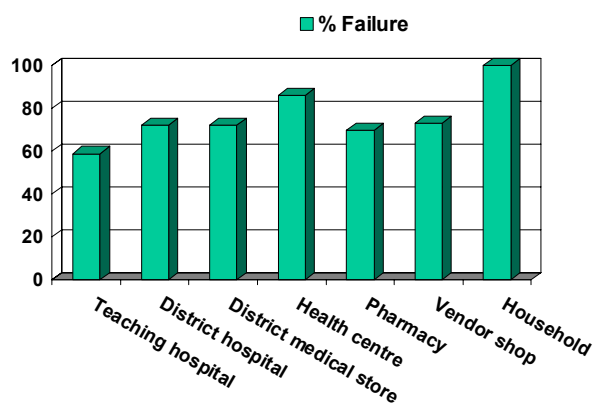


Table III: Percentage failure of samples as per origin (manufacturer)

Product source	Chloroquine syrup	Chloroquine tablets		Sulphadoxine/pyrimethamine tablets	
	Content	Content	Dissolution	Content	Dissolution
Domestic manufacturer	28.0 (7/25)	56.2 (27/48)	20.8 (10/48)	8.3 (4/48)	71.7 (33/46)
Foreign manufacturer	13.0 (3/23)	47.2 (17/36)	13.8 (5/36)	8.7 (7/80)	76.2 (61/80)
Not identified	8.3 (2/24)	56.2 (9/16)	6.2 (1/16)	18.7 (3/16)	75.0 (12/16)
Mean failure rate*	16.4	53.2	13.6	11.9	74.3

* Does not include samples collected in Sudan

Fig.11. Percentage failure - sulphadoxine/pyrimethamine (source)

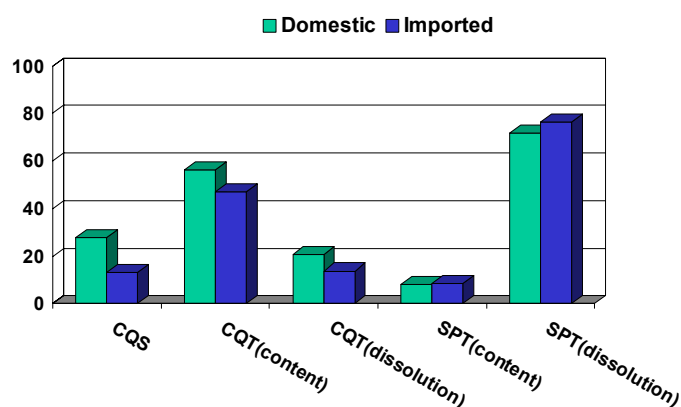


Table IV: Number of samples collected and analysed

Country	No. of samples collected			No. of samples analysed		
	CQT*	CQS**	SPT***	CQT	CQS	SPT
Gabon	20	11	24	19	9	24
Ghana	22	22	22	20	21	22
Kenya	13	11	25	11	9	24
Mali	23	16	14	20	6	14
Mozambique	18	12	40	15	12	36
Sudan	20	20	20	20	16	15
Zimbabwe	15	15	26	15	15	22
Totals	131	107	171	120	88	157

*CQT: Chloroquine tablets

**CQS: Chloroquine syrup

***SPT: Sulphadoxine/pyrimethamine tablets

Table IVa: Country results from various collection points**Participating country: Gabon**

CP	No. of samples analysed			No. of samples below lower limit of specification (low failures)					No. of samples above upper limit of specification (high failures)					No. of samples within limit of specification (passes)						
	CQT	CQS	SPT	CQT		CQS		SPT		CQT		CQS		SPT		CQT		CQS		SPT
				A	D	A	A	D	A	D	A	A	D	A	D	A	A	A	D	
TH	1	-	2	0	0	0	0	1	0	0	0	0	-	1	1	0	2	1		
DH	1	-	2	1	0	0	0	-	0	0	0	0	-	0	1	0	2	-		
MS	-	-	-	-	-	0	0	-	-	0	0	0	-	-	-	0	-	-		
HC	1	0	2	1	0	0	0	-	0	0	0	0	-	1	1	0	2	-		
P	3	3	4	1	0	0	0	-	0	0	0	0	-	2	3	3	4	-		
VS	8	4	12	5	1	0	1	-	0	0	0	0	-	3	7	4	11	-		
H	4	2	0	0	1	0	0	-	0	0	0	0	-	4	3	2	-	-		
NK	1	0	2	2	0	0	0	-	0	0	0	0	-	0	1	0	2	-		
Total	19	9	24	10	2	0	1	1	0	0	0	0	-	11	17	9	23	1		

CP: Collection point

CQS: Chloroquine syrup

A: Content of active ingredient

DH: District hospital

P: Pharmacy

NK: Not known

CQT: Chloroquine tablets

SPT: Sulphadoxine/pyrimethamine tablets

D: Dissolution rate

MS: Medical stores

VS: Vendor/shop

TH: Teaching hospital

HC: Health centre

H: Household

Table IVb: Country results from various collection points**Participating country: Ghana**

CP	No. of samples analysed			No. of samples below lower limit of specification (low failures)					No. of samples above upper limit of specification (high failures)					No. of samples within limit of specification (passes)						
	CQT	CQS	SPT	CQT		CQS		SPT		CQT		CQS		SPT		CQT		CQS		SPT
				A	D	A	A	D	A	D	A	A	D	A	D	A	A	A	D	
TH	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
DH	3	1	2	2	0	0	2	-	0	-	0	0	-	0	2	1	0	-	-	
MS	2	4	2	1	0	0	2	-	0	-	0	0	-	0	1	4	0	-	-	
HC	2	3	0	1	0	0	-	-	0	-	0	0	-	1	2	3	-	-	-	
P	7	5	10	4	1	1	2	3	0	-	0	0	-	3	5	4	8	5	5	
VS	4	3	2	3	2	0	0	2	0	-	0	0	-	1	2	3	2	0	0	
H	2	4	6	1	0	0	4	0	0	-	0	0	-	1	1	4	2	-	-	
NK	0	1	0	0	0	0	0	0	0	-	0	0	-	0	0	1	-	-	-	
Total	20	21	22	12	3	1	10	5	0	-	0	0	-	6	13	20	12	5	5	

CP: Collection point

CQS: Chloroquine syrup

A: Content of active ingredient

DH: District hospital

P: Pharmacy

NK: Not known

CQT: Chloroquine tablets

SPT: Sulphadoxine/pyrimethamine tablets

D: Dissolution rate

MS: Medical stores

VS: Vendor/shop

TH: Teaching hospital

HC: Health centre

H: Household

Table IVc: Country results from various collection points

Participating country: Kenya

CP	No. of samples analysed			No. of samples below lower limit of specification (low failures)					No. of samples above upper limit of specification (high failures)					No. of samples within limit of specification (passes)				
	CQT	CQS	SPT	CQT		CQS		SPT	CQT		CQS		SPT	CQT		CQS		SPT
				A	D	A	A	D	A	D	A	A	D	A	D	A	A	D
TH	1	1	2	1	0	0	0	1	0	0	0	0	0	0	1	1	2	1
DH	1	1	2	1	0	1	0	1	0	0	0	0	0	0	1	0	2	1
MS	2	2	4	1	1	0	0	4	0	0	0	0	0	1	1	2	4	0
HC	1	1	2	0	0	0	0	1	0	0	0	0	0	1	1	1	2	1
P	3	3	6	1	0	1	0	3	0	0	0	0	0	2	3	2	6	3
VS	3	1	8	0	1	0	0	3	0	0	0	0	0	2	2	1	8	5
H	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
NK	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	11	9	24	4	2	2	0	13	0	0	0	0	0	6	9	7	24	11

CP: Collection point

CQS: Chloroquine syrup

A: Content of active ingredient

DH: District hospital

P: Pharmacy

NK: Not known

CQT: Chloroquine tablets

SPT: Sulphadoxine/pyrimethamine tablets

D: Dissolution rate

MS: Medical stores

VS: Vendor/shop

TH: Teaching hospital

HC: Health centre

H: Household

Table IVd: Country results from various collection points

Participating country: Mali

CP	No. of samples analysed			No. of samples below lower limit of specification (low failures)					No. of samples above upper limit of specification (high failures)					No. of samples within limit of specification (passes)				
	CQT	CQS	SPT	CQT		CQS		SPT	CQT		CQS		SPT	CQT		CQS		SPT
				A	D	A	A	D	A	D	A	A	D	A	D	A	A	D
TH	1	0	2	1	0	0	0	1	0	0	0	0	0	0	1	-	2	1
DH	1	0	0	0	0	0	0	0	0	0	0	0	0	1	1	-	-	1
MS	2	1	2	1	0	0	0	1	0	0	0	0	0	1	2	1	2	1
HC	1	0	0	1	0	0	0	0	0	0	0	0	0	0	1	-	-	-
P	3	1	6	2	0	0	0	5	0	0	0	0	0	1	3	1	6	1
VS	7	2	4	6	0	2	0	2	0	0	0	0	0	1	7	-	4	2
H	5	2	0	1	0	2	0	0	0	0	0	0	0	4	5	-	-	-
NK	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	20	6	14	12	0	4	0	9	0	0	0	0	0	8	20	2	14	6

CP: Collection point

CQS: Chloroquine syrup

A: Content of active ingredient

DH: District hospital

P: Pharmacy

NK: Not known

CQT: Chloroquine tablets

SPT: Sulphadoxine/pyrimethamine tablets

D: Dissolution rate

MS: Medical stores

VS: Vendor/shop

TH: Teaching hospital

HC: Health centre

H: Household

Table IVe: Country results from various collection points**Participating country: Mozambique**

CP	No. of samples analysed			No. of samples below lower limit of specification (low failures)						No. of samples above upper limit of specification (high failures)						No. of samples within limit of specification (passes)					
	CQT	CQS	SPT	CQT		CQS		SPT		CQT		CQS		SPT		CQT		CQS		SPT	
				A	D	A	A	D		A	D	A	A	D		A	D	A	A	D	
TH	3	2	6	1	0	0	0	0	0	0	0	0	0	0	0	2	3	2	6	3	
DH	-	-	-	-	-	-	-	-	-	-	-	0	-	-	1	-	-	-	-	-	
MS	4	3	8	3	1	0	0	0	2	0	-	0	0	0	1	3	1	8	3		
HC	3	0	6	0	0	0	0	0	-	0	0	0	0	0	3	3	0	6	1		
P	3	7	10	1	0	0	1	0	1	0	0	0	0	0	2	3	6	9	3		
VS	1	0	4	0	0	0	0	0	0	0	0	0	0	0	1	1	0	3	1		
H	1	0	2	0	0	0	0	0	0	0	0	0	0	0	1	1	0	2	0		
NK	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
Total	15	12	36	5	1	0	1	0	3	0	0	0	0	0	11	14	9	34	11		

CP: Collection point

CQS: Chloroquine syrup

A: Content of active ingredient

DH: District hospital

P: Pharmacy

NK: Not known

CQT: Chloroquine tablets

SPT: Sulphadoxine/pyrimethamine tablets

D: Dissolution rate

MS: Medical stores

VS: Vendor/shop

TH: Teaching hospital

HC: Health centre

H: Household

Table IVf: Country results from various collection points**Participating country: Zimbabwe**

CP	No. of samples analysed			No. of samples below lower limit of specification (low failures)						No. of samples above upper limit of specification (high failures)						No. of samples within limit of specification (passes)					
	CQT	CQS	SPT	CQT		CQS		SPT		CQT		CQS		SPT		CQT		CQS		SPT	
				A	D	A	A	D		A	D	A	A	D		A	D	A	A	D	
TH	2	1	4	1	0	0	1	3	0	0	0	0	0	0	1	2	1	3	1		
DH	3	4	4	2	0	0	0	3	0	0	0	0	0	0	1	3	4	4	1		
MS	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
HC	4	4	10	2	0	1	0	9	0	0	0	0	0	0	2	4	3	10	1		
P	1	1	4	1	0	0	0	3	0	0	0	0	0	0	0	1	1	4	1		
VS	2	2	0	1	0	0	0	0	0	0	0	0	0	0	1	2	2	0	0		
H	3	3	0	3	1	1	0	0	0	0	0	0	0	0	0	2	2	0	0		
NK	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
Total	15	15	22	10	1	2	1	18	0	0	0	0	0	0	5	14	13	21	4		

CP: Collection point

CQS: Chloroquine syrup

A: Content of active ingredient

DH: District hospital

P: Pharmacy

NK: Not known

CQT: Chloroquine tablets

SPT: Sulphadoxine/pyrimethamine tablets

D: Dissolution rate

MS: Medical stores

VS: Vendor/shop

TH: Teaching hospital

HC: Health centre

H: Household

Table IVg: Country results from various collection points

Participating country: Sudan

CP	No. of samples analysed			No. of samples below lower limit of specification (low failures)						No. of samples above upper limit of specification (high failures)						No. of samples within limit of specification (passes)					
	CQT	CQS	SPT	CQT		CQS		SPT		CQT		CQS		SPT		CQT		CQS		SPT	
				A	D	A	A	D		A	D	A	A	D		A	D	A	A	D	
TH	1	1	1	0	0	0	0	1	0	0	0	0	0	0	1	1	1	1	1	0	
DH	1	-	1	0	0	-	0	1	0	0	-	0	0	1	1	-	1	0	1	0	
MS	2	1	2	0	1	1	0	1	0	0	0	0	0	0	2	1	0	2	1		
HC	1	1	1	0	0	0	0	1	0	0	0	0	0	0	1	1	1	1	0		
P	3	2	3	0	0	0	0	3	0	0	1	0	0	3	3	1	3	0			
VS	7	7	7	0	0	0	0	5	0	0	1	0	0	7	7	6	7	2			
H	5	4	5	1	ns	0	0	ns	1	ns	1	0	ns	3	ns	3	5	ns			
NK	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
Total	20	16	20	1	1	1	0	12	1	0	3	0	0	18	14	12	20	3			

CP: Collection point

CQS: Chloroquine syrup

A: Content of active ingredient

DH: District hospital

P: Pharmacy

NK: Not known

CQT: Chloroquine tablets

SPT: Sulphadoxine/pyrimethamine tablets

D: Dissolution rate

MS: Medical stores

VS: Vendor/shop

ns: Sample not sufficient

TH: Teaching hospital

HC: Health centre

H: Household

Table Va: Country results according to origin of manufacturer

Participating country: Gabon

Origin of manufacturer	No. of samples analysed			No. of samples below lower limit of specification (low failures)						No. of samples above upper limit of specification (high failures)						No. of samples within limit of specification (passes)					
	CQT	CQS	SPT	CQT		CQS		SPT		CQT		CQS		SPT		CQT		CQS		SPT	
				A	D	A	A	D		A	D	A	A	D		A	D	A	A	D	
Foreign manufacturer	14	9	22	8	2	0	0	-	0	0	0	1	-	6	12	9	21	-			
Not known	2	0	2	1	0	-	0	1	0	0	0	0	-	1	2	-	2	1			
Local manufacturer	3	0	0	0	0	-	-	-	0	0	0	-	-	3	3	-	-	-			
Totals	19	9	24	9	2	0	0	1	0	0	0	1	-	10	17	9	23	1			

CQT: Chloroquine tablets

SPT: Sulphadoxine/pyrimethamine tablets

D: Dissolution rate

CQS: Chloroquine syrup

A: Content of active ingredient

Table Vb: Country results according to origin of manufacturer**Participating country: Ghana**

Origin of manu- facturer	No. of samples analysed			No. of samples below lower limit of specification (low failures)					No. of samples above upper limit of specification (high failures)					No. of samples within limit of specification (passes)						
	CQT	CQS	SPT	CQT		CQS		SPT		CQT		CQS		SPT		CQT		CQS		SPT
				A	D	A	A	D	A	D	A	A	D	A	D	A	A	D		
Foreign manu- facturer	2	2	14	2	-	0	5	4	0	0	0	0	0	0	-	2	9	4		
Not known	7	19	4	6	1	1	2	-	0	0	0	0	0	1	6	18	2	-		
Local manu- facturer	11	0	4	6	2	-	3	1	0	0	-	0	0	5	7	-	1	1		
Totals	20	21	22	14	3	1	10	5	0	0	0	0	0	6	13	20	12	5		

CQT: Chloroquine tablets

SPT: Sulphadoxine/pyrimethamine tablets

D: Dissolution rate

CQS: Chloroquine syrup

A: Content of active ingredient

Table Vc: Country results according to origin of manufacturer**Participating country: Kenya**

Origin of manu- facturer	No. of samples analysed			No. of samples below lower limit of specification (low failures)					No. of samples above upper limit of specification (high failures)					No. of samples within limit of specification (passes)						
	CQT	CQS	SPT	CQT		CQS		SPT		CQT		CQS		SPT		CQT		CQS		SPT
				A	D	A	A	D	A	D	A	A	D	A	D	A	A	D		
Foreign manu- facturer	4	0	6	1	0	0	0	3	1	0	-	0	0	2	4	-	6	3		
Not known	0	2	2	-	-	0	0	1	-	0	0	0	0	-	-	2	2	1		
Local manu- facturer	7	7	16	3	2	2	0	9	0	0	0	0	0	4	2	5	16	7		
Totals	11	9	24	4	2	2	0	13	1	0	0	0	0	6	6	7	24	11		

CQT: Chloroquine tablets

SPT: Sulphadoxine/pyrimethamine tablets

D: Dissolution rate

CQS: Chloroquine syrup

A: Content of active ingredient

Table Vd: Country results according to origin of manufacturer**Participating country: Mali**

Origin of manufacturer	No. of samples analysed			No. of samples below lower limit of specification (low failures)					No. of samples above upper limit of specification (high failures)					No. of samples within limit of specification (passes)				
	CQT	CQS	SPT	CQT		CQS		SPT	CQT		CQS		SPT	CQT		CQS		SPT
				A	D	A	A	D	A	D	A	A	D	A	D	A	A	D
Foreign manufacturer	3	1	10	2	0	0	0	7	0	0	0	0	-	1	3	1	10	3
Not known	5	1	2	2	0	1	0	1	0	0	0	0	-	3	5	0	2	1
Local manufacturer	12	4	2	8	0	3	0	1	0	0	0	0	-	4	12	1	2	1
Totals	20	6	14	12	0	4	0	9	0	0	0	0	-	8	20	2	14	5

CQT: Chloroquine tablets

SPT: Sulphadoxine/pyrimethamine tablets

D: Dissolution rate

CQS: Chloroquine syrup

A: Content of active ingredient

Table Ve: Country results according to origin of manufacturer**Participating country: Mozambique**

Origin of manufacturer	No. of samples analysed			No. of samples below lower limit of specification (low failures)					No. of samples above upper limit of specification (high failures)					No. of samples within limit of specification (passes)				
	CQT	CQS	SPT	CQT		CQS		SPT	CQT		CQS		SPT	CQT		CQS		SPT
				A	D	A	A	D	A	D	A	A	D	A	D	A	A	D
Foreign manufacturer	13	11	26	5	1	0	0	18	0	0	3	1	-	8	12	8	25	8
Not known	2	0	6	0	0	-	1	5	0	0	-	0	-	2	2	1	5	1
Local manufacturer	0	1	4	-	-	0	0	3	0	0	0	0	-	-	0	-	4	1
Totals	15	12	36	5	1	0	1	26	0	0	3	1	-	10	14	9	34	10

CQT: Chloroquine tablets

SPT: Sulphadoxine/pyrimethamine tablets

D: Dissolution rate

CQS: Chloroquine syrup

A: Content of active ingredient

Table Vf: Country results according to origin of manufacturer**Participating country: Zimbabwe**

Origin of manufacturer	No. of samples analysed			No. of samples below lower limit of specification (low failures)						No. of samples above upper limit of specification (high failures)						No. of samples within limit of specification (passes)					
	CQT	CQS	SPT	CQT		CQS		SPT		CQT		CQS		SPT		CQT		CQS		SPT	
				A	D	A	A	D		A	D	A	A	D		A	D	A	A	D	
Foreign manufacturer	0	0	2	-	-	-	0	1		0	0	-	0	-		-	-	0	2	1	
Not known	0	2	0	-	-	1	-	-		0	0	0	0	-		-	-	1	-	-	
Local manufacturer	15	13	20	10	1	1	1	17		0	0	0	0	-		5	14	12	19	3	
Totals	15	15	22	10	1	2	1	18		0	0	0	0	-		5	14	13	21	4	

CQT: Chloroquine tablets

SPT: Sulphadoxine/pyrimethamine tablets

D: Dissolution rate

CQS: Chloroquine syrup

A: Content of active ingredient

Annexes

ANNEX: 1A

Country: Gabon

Product: Chloroquine syrup

CENQAM LAB RESULTS

CENQAM REF NO	Sample number	CP	Manufacturer	Active ingredient content						
				1st	2nd	3rd	Mean	Low	High	Pass
				value	value	value	value	fail <90%	fail >110%	90 - 110%
20010563	GA/CQS/SH02	S	RPR, France	100.68	99.69	98.97	99.78	-	-	99.78
20010564	GA/CQS/HH07	H	RPR, France	102.27	100.56	100.53	101.12	-	-	101.12
20010565	GA/CQS/PH09	P	RPR, France	101.48	104.70	102.49	102.89	-	-	102.89
20010566	GA/CQS/PH10	P	RPR, France	100.84	98.48	99.13	99.48	-	-	99.48
20010567	GA/CQS/HH08	H	RPR, France	103.15	102.79	104.36	103.43	-	-	103.43
20010568	GA/CQS/PV12	-	RPR, France	100.54	100.18	101.16	100.63	-	-	100.63
20010569	GA/CQS/SH04	S	RPR, France	103.14	102.25	102.22	102.54	-	-	102.54
20010570	GA/CQS/SH05	S	RPR, France	101.63	100.09	100.82	100.85	-	-	100.85
20010571	GA/CQS/PH11	P	RPR, France	104.84	104.96	104.66	104.82	-	-	104.82

REF NO: Reference number

H: Household

TH: Teaching hospital

CP: Collection point

P: Pharmacy

DH: District hospital

S: Shop

ANNEX: 1B

Country: Gabon
Product: Chloroquine tablet

CENQAM LAB RESULTS

CENQAM REF NO	Sample number	CP	Manu- facturer	Dissolution test				Active ingredient content						
				Mean dissol- ution	% RSD (n=6)	Low Fail <80%	Pass >80%	1st value	2nd value	3rd value	Mean value	Low fail <93%	High fail >107%	Pass 93- 107%
20010538	GA/CQT/VE09	SV	RPR, France	88.12	4.07	-	88.12	93.02	92.45	93.37	92.95	92.95	-	-
20010539	GA/CQT/VE05	SV	Robert's Pharm, Lagos	91.30	3.54	-	91.30	89.60	95.50	88.30	91.18	91.18	-	-
20010540	GA/CQT/SH06	S	RPR, France	93.61	4.33	-	93.61	91.97	93.23	95.48	93.56	-	-	93.56
20010541	GA/CQT/PH20	P	SmithKline Beecham, UK	91.47	1.70	-	91.47	92.11	89.95	-	91.03	91.03	-	-
20010542	GA/CQT/SH02	S	RPR, France	94.94	2.36	-	94.94	93.19	92.69	95.31	93.73	-	-	93.73
20010543	GA/CQT/SH03	S	RPR, France	93.37	1.69	-	93.37	83.60	85.78	85.19	84.86	84.86	-	-
20010544	GA/CQT/DH07	DH	SmithKline Beecham, UK	92.94	0.49	-	92.94	91.88	91.01	-	91.45	91.45	-	-
20010545	GA/CQT/VE08	SV	Shalina lab, India	79.47	11.79	79.48	-	90.68	91.29	90.57	90.85	90.85	-	-
20010546	GA/CQT/HH12	H	RPR, France	50.84	25.86	50.84	-	94.31	94.36	95.54	94.37	-	-	94.37
20010547	GA/CQT/HH14	H	Unknown	87.97	3.64	-	87.97	94.58	93.55	94.82	94.32	-	-	94.32
20010548	GA/CQT/HH15	H	Unknown	BLOQ	-	-	-	BLOQ	BLOQ	BLOQ	BLOQ	-	-	-
20010549	GA/CQT/PV17	-	Creat lab, France	94.64	2.39	-	94.64	92.61	91.79	91.82	92.07	92.07	-	-
20010550	GA/CQT/HC01	HC	Pharmamed Ltd, Malta	89.58	1.67	-	89.58	93.07	92.75	92.98	92.93	92.93	-	-
20010551	GA/CQT/TB16	-	Unknown	92.86	1.16	-	92.86	92.02	91.05	91.36	91.48	91.48	-	-
20010552	GA/CQT/PH19	P	RPR, France	92.97	1.74	-	92.97	93.06	94.11	95.08	94.08	-	-	94.08
20010553	GA/CQT/HH13	H	RPR, France	90.71	0.54	-	90.71	94.34	96.05	92.58	94.06	-	-	94.06
20010554	GA/CQT/VE04	SV	SSG Pharm, Gabon	92.44	3.23	-	92.44	93.38	92.61	93.01	93.00	-	-	93.00
20010555	GA/CQT/PH18	P	SSG Pharm, Gabon	98.02	11.49	-	98.02	95.56	94.45	95.48	95.17	-	-	95.17
20010556	GA/CQT/HH11	H	SSG Pharm, Gabon	94.60	2.41	-	94.60	95.34	95.82	93.66	94.94	-	-	94.94
20010557	GA/CQT/TH10	TH	Sedapharm lab, France	90.51	1.33	-	90.51	93.75	93.88	94.32	93.98	-	-	93.98

REF NO: Reference number RSD: Related standard deviation CP: Collection point
 DH: District hospital H: Household HC: Health centre
 P: Pharmacy S: Shop SV: Street vendor TH: Teaching hospital
 BLOQ: Below limit of quantification

ANNEX: 1C

Country: Gabon

Product: Sulphadoxine/pyrimethamine tablets

CENQAM LAB RESULTS

CENQAM REF NO	Sample number	CP	Manu- facturer	Dissolution test				Active ingredient content						
				Mean dissol- ution	% RSD (n=6)	Low fail <65%	Pass >65%	1st value	2nd value	3rd value	Mean value	Low fail <90%	High fail >110%	Pass 90- 110%
20010526-P	GA/SPT/VE08	SV	Brintlodge Ltd, UK	-	-	-	-	101.76	99.92	102.48	101.39	-	-	101.39
20010526-S	GA/SPT/VE08	SV	Brintlodge Ltd, UK	-	-	-	-	95.75	95.47	94.64	95.28	-	-	95.28
20010527-P	GA/SPT/HC01	HC	Remedica, Cyprus	-	-	-	-	100.21	106.14	110.22	105.52	-	-	105.52
20010527-S	GA/SPT/HC01	HC	Remedica, Cyprus	-	-	-	-	97.97	99.29	101.23	99.49	-	-	99.49
20010528-P	GA/SPT/TB12	NK	Pharmamed Ltd, Malta	-	-	-	-	97.57	101.61	90.22	96.47	-	-	96.47
20010528-S	GA/SPT/TB12	NK	Pharmamed Ltd, Malta	-	-	-	-	106.36	102.59	99.21	102.72	-	-	102.72
20010529-P	GA/SPT/VE09	SV	Brintlodge Ltd, UK	-	-	-	-	90.20	93.91	91.43	91.85	-	-	91.85
20010529-S	GA/SPT/VE09	SV	Brintlodge Ltd, UK	-	-	-	-	97.17	97.61	96.09	96.96	-	-	96.96
20010530-P	GA/SPT/PH11	P	Roche lab, France	-	-	-	-	97.46	100.27	100.40	99.38	-	-	99.38
20010530-S	GA/SPT/PH11	P	Roche lab, France	-	-	-	-	96.08	99.94	102.47	99.50	-	-	99.50
20010531-P	GA/SPT/PH10	P	Gracure Pharm, India	-	-	-	-	103.09	96.40	99.21	99.57	-	-	99.57
20010531-S	GA/SPT/PH10	P	Gracure Pharm, India	-	-	-	-	98.99	95.19	98.20	97.46	-	-	97.46
20010532-P	GA/SPT/SH03	S	Roche lab, France	-	-	-	-	98.77	101.40	99.14	99.77	-	-	99.77
20010532-S	GA/SPT/SH03	S	Roche lab, France	-	-	-	-	78.52	80.24	101.37	86.71	86.71	-	-
20010533-P	GA/SPT/SH02	S	Gracure Pharm, India	-	-	-	-	98.18	96.47	100.35	98.34	-	-	98.34
20010533-S	GA/SPT/SH02	S	Gracure Pharm, India	-	-	-	-	97.16	93.54	99.27	96.66	-	-	96.66
20010534-P	GA/SPT/VE07	SV	Brintlodge Ltd, UK	-	-	-	-	92.47	88.04	91.83	90.78	-	-	90.78
20010534-S	GA/SPT/VE07	SV	Brintlodge Ltd, UK	-	-	-	-	90.07	94.68	95.29	93.35	-	-	93.35
20010535-P	GA/SPT/TH06	TH	Unknown	35.60	12.70	35.60	-	91.48	91.03	96.83	93.11	-	-	93.11
20010535-S	GA/SPT/TH06	TH	Unknown	72.40	7.07	-	72.40	82.42	101.53	97.38	93.78	-	-	93.78
20010536-P	GA/SPT/DH04	DH	Adjanta Pharma	-	-	-	-	100.87	95.66	93.94	96.82	-	-	96.82
20010536-S	GA/SPT/DH04	DH	Adjanta Pharma	-	-	-	-	100.34	101.68	101.34	101.12	-	-	101.12
20010537-P	GA/SPT/SH05	S	Roche lab, France	-	-	-	-	100.34	101.39	100.03	100.58	-	-	100.58
20010537-S	GA/SPT/SH05	S	Roche lab, France	-	-	-	-	101.38	99.61	100.74	100.58	-	-	100.58

REF NO: Reference number RSD: Related standard deviation CP: Collection point
 DH: District hospital HC: Health centre NK: Not known P: Pharmacy S: Shop
 SV: Street vendor TH: Teaching hospital P: Pyrimethamine S: Sulphadoxine

ANNEX: 2A

Country: Ghana
Product: Chloroquine syrup

CENQAM LAB RESULTS										
CENQAM REF NO	Sample number	CP	Manu- facturer	Active ingredient content						
				1st value	2nd value	3rd value	Mean value	Low fail <90%	High fail >110%	Pass 90- 110%
20010572	GH/CQS/SH45	S	Unknown	99.99	100.74	-	100.37	-	-	100.37
20010573	GH/CQS/HH82	H	Unknown	96.65	96.59	-	96.62	-	-	96.62
20010574	GH/CQS/DS87	DMS	Unknown	96.22	95.78	95.19	95.73	-	-	95.73
20010575	GH/CQS/HC24	HC	Unknown	101.80	100.07	-	100.94	-	-	100.94
20010576	GH/CQS/DS02	DMS	Unknown	103.44	99.53	-	101.48	-	-	101.48
20010577	GH/CQS/SH63	S	Unknown	98.67	98.15	97.63	98.15	-	-	98.15
20010578	GH/CQS/HH86	H	Unknown	91.13	90.53	-	90.83	-	-	90.83
20010579	GH/CQS/DH90	DH	Unknown	103.99	102.54	102.41	102.98	-	-	102.98
20010580	GH/CQS/PH47	P	Unknown	101.92	102.26	103.38	102.52	-	-	102.52
20010581	GH/CQS/SH43	S	Unknown	102.66	100.54	102.93	102.04	-	-	102.04
20010582	GH/CQS/DS03	DMS	Unknown	100.21	101.08	102.88	101.39	-	-	101.39
20010583	GH/CQS/PH57	P	Unknown	102.79	104.78	105.51	104.36	-	-	104.36
20010584	GH/CQS/HC32	HC	Unknown	93.44	92.91	92.33	92.89	-	-	92.89
20010585	GH/CQS/CS33	CMS	Unknown	101.84	99.43	-	100.63	-	-	100.63
20010586	GH/CQS/PH68	P	Unknown	106.40	107.02	103.33	105.58	-	-	105.58
20010587	GH/CQS/PH46	P	Unknown	78.43	86.87	84.42	83.24	83.24	-	-
20010588	GH/CQS/PH15	P	Unknown	90.60	96.78	-	93.69	-	-	93.69
20010589	GH/CQS/HH39	H	Unknown	101.41	102.47	-	101.94	-	-	101.94
20010590	GH/CQS/HH75	H	Unknown	98.22	97.35	-	97.79	-	-	97.79
20010591	GH/CQS/HC01	HC	Rivopharm Lab, Switzerland	102.19	102.32	99.44	101.31	-	-	101.31
20010592	GH/CQS/TB06	-	Gracure Pharm, India	102.16	102.26	102.66	102.36	-	-	102.36

REF NO: Reference number
 DH: District hospital
 H: Household

CP: Collection point
 DMS: District medical stores
 P: Pharmacy

CMS: Central medical stores
 HC: Health centre
 S: Shop

ANNEX: 2B

Country: Ghana
Product: Chloroquine tablets

CENQAM LAB RESULTS

CENQAM REF NO	Sample number	CP	Manu- facturer	Dissolution test				Active ingredient content						
				Mean dissol- ution	% RSD (n=6)	Low fail <80%	Pass >80%	1st value	2nd value	3rd value	Mean value	Low fail <93%	High fail >107%	Pass 93- 107%
20010513	GH/CQT/SH44	S	Dannex Ltd Accra	57.01	42.90	57.01	-	87.70	85.77	87.27	86.91	86.91	-	-
20010514- 1g	GH/CQT/PH55	P	Kinapharma Accra	90.05	1.92	-	90.05	93.16	93.43	93.13	93.24	-	-	93.24
20010514- 0.5g	GH/CQT/PH55	P	Kinapharma Accra	NS	-	-	-	89.96	89.23	90.61	89.93	89.93	-	-
20010515	GH/CQT/PH100	P	Letap Pharma- ceuticals	85.43	9.75	-	85.43	95.01	95.65	93.91	94.86	-	-	94.86
20010516	GH/CQT/PH67	P	Unknown	93.76	4.94	-	93.76	91.79	91.36	90.99	91.38	91.38	-	-
20010517	GH/CQT/DH91	DH	SKB, UK	N/A	-	-	-	-	-	-	N/A	-	-	-
20010518	GH/CQT/PH113	P	Unknown	71.76	7.98	71.76	-	78.40	76.63	77.05	77.36	77.36	-	-
20010519- 1g	GH/CQT/PH18	P	Kinapharma Accra	93.85	2.15	-	93.85	93.49	94.41	93.85	93.92	-	-	93.92
20010519- 0.5g	GH/CQT/PH18	P	Kinapharma Accra	83.43	2.12	-	83.43	91.89	91.36	91.48	91.58	91.58	-	-
20010520	GH/CQT/HH84	H	Healthcare (PZ), Ghana	90.71	8.33	-	90.71	97.95	97.59	97.00	97.51	-	-	97.51
20010521	GH/CQT/HH73	H	Dannex Ltd Accra	NS	-	-	-	84.18	82.36	-	83.27	83.27	-	-
20010522- 1g	GH/CQT/SH110	S	Kinapharma Accra	92.16	1.59	-	92.16	93.14	93.90	93.78	93.61	-	-	93.61
20010522- 0.5g	GH/CQT/SH110	S	Kinapharma Accra	81.34	2.46	-	81.34	90.62	90.41	91.09	90.70	90.70	-	-
20010523	GH/CQT/SH50	S	Dannex Ltd Accra	50.73	20.04	50.73	-	88.16	89.21	86.44	87.94	87.94	-	-
20010524	GH/CQT/DS88	DMS	SKB, UK	N/A	-	-	-	-	-	-	N/A	-	-	-
20010558	GH/CQT/HC77	HC	Unknown	92.08	3.59	-	92.08	90.67	90.77	91.67	91.04	91.04	-	-
20010559	GH/CQT/HC23	HC	Unknown	96.75	3.92	-	96.75	94.91	95.09	93.53	94.51	-	-	94.51
20010560	GH/CQT/DH04	DH	Unknown	88.28	3.32	-	88.28	90.94	91.03	90.47	90.81	90.81	-	-
20010561	GH/CQT/DH89	DH	Unknown	91.57	2.52	-	91.57	92.91	91.63	92.98	92.51	92.51	-	-
20010562	GH/CQT/CS25	CMS	Unknown	88.15	2.60	-	88.15	92.25	92.66	92.18	92.36	92.36	-	-

REF NO: Reference number RSD: Related standard deviation CP: Collection point
 CMS: Central medical stores DH: District hospital DMS: District medical stores
 HC: Health centre H: Household P: Pharmacy S: Shop TH: Teaching hospital
 N/A: Not analysed NS: No sample for dissolution SKB: SmithKline Beecham

ANNEX: 2C

Country: Ghana

Product: Sulphadoxine/pyrimethamine tablets

CENQAM LAB RESULTS

CENQAM REF NO	Sample number	CP	Manu- facturer	Dissolution test				Active ingredient content						
				Mean dissol- ution	% RSD (n=6)	Low fail <65%	Pass >65%	1st value	2nd value	3rd value	Mean value	Low fail <90%	High fail >110%	Pass 90- 110%
20010503-P	GH/SPT/SH118	S	Uni-med, India	0.19	223.61	0.19	-	90.27	93.33	92.79	92.13	-	-	92.13
20010503-S	GH/SPT/SH118	S	Uni-med, India	5.61	6.36	5.61	-	92.19	94.47	93.32	93.33	-	-	93.33
20010504-P	GH/SPT/PH17	P	Kinapharma Accra	16.89	9.89	16.89	-	92.23	95.82	94.62	94.22	-	-	94.22
20010504-S	GH/SPT/PH17	P	Kinapharma Accra	97.79	2.20	-	97.79	98.81	99.18	98.87	98.95	-	-	98.95
20010505-P	GH/SPT/HH72	H	Unknown	NS	-	-	-	93.48	99.08	-	96.28	-	-	96.28
20010505-S	GH/SPT/HH72	H	Unknown	NS	-	-	-	-	-	-	NSX	-	-	-
20010506-P	GH/SPT/HH70	H	Dannex Ltd, Accra	NS	-	-	-	81.80	83.00	-	82.40	82.40	-	-
20010506-S	GH/SPT/HH70	H	Dannex Ltd, Accra	NS	-	-	-	71.07	71.45	-	71.26	71.26	-	-
20010507-P	GH/SPT/DS05	DMS	Farmitalia, Italy	NS	-	-	-	-	-	-	NP	-	-	-
20010507-S	GH/SPT/DS05	DMS	Farmitalia, Italy	NS	-	-	-	-	-	-	IDS	-	-	-
20010508-P	GH/SPT/DH06	DH	Farmitalia, Italy	NS	-	-	-	-	-	-	NP	-	-	-
20010508-S	GH/SPT/DH06	DH	Farmitalia, Italy	NS	-	-	-	-	-	-	IDS	-	-	-
20010509-P	GH/SPT/PH13	P	Colorama, UK	NS	-	-	-	97.92	101.64	95.68	98.41	-	-	98.41
20010509-S	GH/SPT/PH13	P	Colorama, UK	NS	-	-	-	97.80	100.20	95.61	97.87	-	-	97.87
20010510-P	GH/SPT/PH112	P	Dannex Ltd, Accra	14.78	14.15	14.78	-	90.41	89.63	87.97	89.34	89.34	-	-
20010510-S	GH/SPT/PH112	P	Dannex Ltd, Accra	88.01	1.92	-	88.01	94.34	95.27	94.57	94.72	-	-	94.72
20010511-P	GH/SPT/HH40	H	Unknown	NS	-	-	-	98.92	92.48	-	95.70	-	-	95.70
20010511-S	GH/SPT/HH40	H	Unknown	NS	-	-	-	-	-	-	NSX	-	-	-
20010512-P	GH/SPT/PH114	P	Colorama Pharm Ltd, India	13.49	10.87	13.49	-	90.27	84.93	83.91	86.37	86.37	-	-
20010512-S	GH/SPT/PH114	P	Colorama Pharm Ltd, India	75.25	3.65	-	75.25	93.25	94.40	96.07	94.57	-	-	94.57
20010525-P	GH/SPT/PH019	P	Ajanta Pharm, Mauritius	68.19	6.07	-	68.19	105.58	105.66	101.28	104.17	-	-	104.17
20010525-S	GH/SPT/PH019	P	Ajanta Pharm, Mauritius	102.60	4.37	-	102.60	104.73	106.14	104.74	105.21	-	-	105.21

REF NO: Reference number RSD: Related standard deviation CP: Collection point
 DH: District hospital DMS: District medical stores H: Household S: Shop

P: Pharmacy P: Pyrimethamine S: Sulphadoxine NS: No sample (number of units for testing insufficient)
 IDS: Identity of the sulphadoxine questionable NP: No pyrimethamine detected
 NSX: No sulphadoxine detected

ANNEX: 3A

Country: Kenya
Product: Chloroquine syrup

CENQAM LAB RESULTS										
CENQAM REF NO	Sample number	CP	Manu- facturer	Active ingredient content						
				1st value	2nd value	3rd value	Mean value	Low fail <90%	High fail >110%	Pass 90 - 110%
20010626	KE/CQS/DS01	DMS	Novelty Mfg. Ltd, Kenya	102.53	104.47	105.26	104.09	-	-	104.09
20010630	KE/CQS/TH06	TH	-	97.06	96.51	96.55	96.71	-	-	96.71
20010631	KE/CQS/PV01	-	Medivet Products Ltd, Kenya	95.94	97.76	93.19	95.63	-	-	95.63
20010632	KE/CQT/CS01	CMS	-	109.38	112.07	107.79	109.75	-	-	109.75
20010635	KE/CQS/PH01	P	Biodeal Lab. Ltd, Kenya	87.89	87.57	87.73	87.73	87.73	-	-
20010636	KE/CQS/PH04	P	Sphinx Pharm. Ltd, Kenya	108.50	108.30	104.52	107.11	-	-	107.11
20010637	KE/CQS/PH02	P	Pharmaceutical Products Ltd, Kenya	107.40	112.89	106.10	108.80	-	-	108.80
20010638	KE/CQS/HC03	HC	Cosmos Ltd, Kenya	104.36	111.17	108.49	108.01	-	-	108.01
20010639	KE/CQS/DH02	DH	Laboratory & Allied Ltd, Kenya	77.82	77.82	74.18	76.64	76.64	-	-

REF NO: Reference number CP: Collection point CMS: Central medical stores
 DH: District hospital DMS: District medical stores HC: Health centre
 P: Pharmacy TH: Teaching hospital

ANNEX: 3B

Country: Kenya
Product: Chloroquine tablets

CENQAM LAB RESULTS

CENQAM REF NO	Sample number	CP	Manu- facturer	Dissolution test				Active ingredient content						
				Mean dissol ution	% RSD (n=6)	Low fail <80%	Pass >80%	1st value	2nd value	3rd value	Mean value	Low fail <93%	High fail >107%	Pass 93 - 107%
20010606	KE/CQT/SH03	S	Dawa Pharm Ltd, Kenya	67.25	31.44	67.25	-	94.69	94.02	93.75	94.15	-	-	94.15
20010611	KE/CQT/DS01	DMS	Pharmaceutical Products Ltd, Kenya	87.64	1.95	-	87.64	88.70	91.09	88.54	89.44	89.44	-	-
20010612	KE/CQT/PH02	P	Shanxi Medicines & Health Products, China	90.23	4.23	-	90.23	93.53	93.91	93.97	93.81	-	-	93.81
20010615	KE/CQT/PH01	P	Howse & McGeorge Ltd, Kenya	81.66	13.13	-	81.66	94.36	95.46	95.72	95.18	-	-	95.18
20010616	KE/CQT/SH01	S	Prime Pharma Tech. Ind. Ltd, India	126.17	14.06	-	126.17	142.06	141.46	149.55	144.36	-	144.36	-
20010617	KE/CQT/PH03	P	Novelty Mfg. Ltd, Kenya	90.10	2.77	-	90.10	90.15	90.78	90.77	90.57	90.57	-	-
20010619	KE/CQT/CS01	CMS	Cosmos Ltd, Kenya	79.38	5.91	79.38	-	94.75	95.75	95.59	95.36	-	-	95.36
20010621	KE/CQT/SH02	S	Beta Health Care Int. Ltd, Kenya	89.08	3.00	-	89.08	95.26	94.70	93.09	94.35	-	-	94.35
20010622	KE/CQT/HC01	HC	Alkaloida Chemical Co, Hungary	88.20	3.18	-	88.20	96.41	96.37	93.19	95.32	-	-	95.32
20010623	KE/CQT/TH01	TH	Cosmos Ltd, Kenya	91.10	1.54	-	91.10	92.72	91.09	91.23	91.68	91.68	-	-
20010624	KE/CQT/DH01	DH	Pharmamed Ltd, Malta	94.39	1.78	-	94.39	92.26	92.27	91.69	92.07	92.07	-	-

REF NO: Reference number RSD: Related standard deviation CP: Collection point
 CMS: Central medical stores DH: District hospital DMS: District medical stores
 HC: Health centre P: Pharmacy S: Shop TH: Teaching hospital

ANNEX: 3C

Country: Kenya

Product: Sulphadoxine/pyrimethamine tablets

CENQAM LAB RESULTS

CENQAM REF NO	Sample number	CP	Manu- facturer	Dissolution test				Active ingredient content						
				Mean dissol- ution	% RSD (n=6)	Low fail <65%	Pass >65%	1st value	2nd value	3rd value	Mean value	Low fail <90%	High fail >110%	Pass 90 - 110%
20010603-P	KE/SPT/PH02	P	Pharmaceutical Mfg Ltd, Kenya	18.86	22.90	18.86	-	95.86	93.41	93.39	94.22	-	-	94.22
20010603-S	KE/SPT/PH02	P	Pharmaceutical Mfg Ltd, Kenya	75.83	11.50	-	75.83	97.44	96.27	96.76	96.82	-	-	96.82
20010604-P	KE/SPT/PH03	P	Lupin Lab. Ltd, India	62.86	3.33	62.86	-	97.90	99.82	98.08	98.60	-	-	98.60
20010604-S	KE/SPT/PH03	P	Lupin Lab. Ltd, India	90.89	1.40	-	90.89	102.01	104.89	101.41	102.77	-	-	102.77
20010605-P	KE/SPT/PH01	P	Universal Pharmacy Ltd, Kenya	15.88	10.40	15.88	-	100.84	99.99	100.49	100.44	-	-	100.44
20010605-S	KE/SPT/PH01	P	Universal Pharmacy Ltd, Kenya	83.12	3.42	-	83.12	100.17	99.18	100.19	99.85	-	-	99.85
20010607-P	KE/SPT/DH01	DH	Dawa Pharm Ltd, Kenya	0.00	-	0.00	-	96.06	98.79	99.34	98.06	-	-	98.06
20010607-S	KE/SPT/DH01	DH	Dawa Pharm Ltd, Kenya	94.68	2.63	-	94.68	99.39	100.75	100.51	100.22	-	-	100.22
20010608-P	KE/SPT/SH8	S	-	55.25	2.54	55.25	-	96.22	94.76	94.80	95.26	-	-	95.26
20010608-S	KE/SPT/SH8	S	-	90.38	1.75	-	90.38	99.67	100.58	99.89	100.05	-	-	100.05
20010609-P	KE/SPT/HC01	HC	Torrent Pharm, India	21.81	9.18	21.81	-	102.42	104.80	99.62	102.28	-	-	102.28
20010609-S	KE/SPT/HC01	HC	Torrent Pharm, India	97.77	3.40	-	97.77	102.57	103.12	102.90	102.86	-	-	102.86
20010610-P	KE/SPT/SH02	S	IPCA Lab. Ltd, India	54.06	5.15	54.06	-	97.11	99.35	98.23	98.23	-	-	98.23
20010610-S	KE/SPT/SH02	S	IPCA Lab. Ltd, India	86.73	3.50	-	86.73	100.31	100.85	101.09	100.75	-	-	100.75
20010613-P	KE/SPT/DS01	DMS	Laboratory & Allied Ltd, Kenya	56.40	3.06	56.40	-	95.54	95.69	-	95.62	-	-	95.62
20010613-S	KE/SPT/DS01	DMS	Laboratory & Allied Ltd, Kenya	95.47	2.32	95.47	-	97.96	99.22	-	98.59	-	-	98.59
20010614-P	KE/SPT/CS01	DMS	Kenya Allied Ltd	17.04	11.70	17.04	-	92.87	89.67	88.61	90.38	-	-	90.38
20010614-S	KE/SPT/CS01	DMS	Kenya Allied Ltd	47.78	8.09	47.78	-	95.38	98.08	98.61	97.36	-	-	97.36
20010618-P	KE/SPT/TH01	TH	Elys Chemical, Kenya	52.03	3.08	52.03	-	100.29	99.43	101.14	100.29	-	-	100.29
20010618-S	KE/SPT/TH01	TH	Elys Chemical, Kenya	98.38	1.40	-	98.38	101.18	99.42	101.54	100.71	-	-	100.71
20010620-P	KE/SPT/VE01	SV	Laboratory & Allied Ltd, Kenya	45.42	2.12	45.42	-	100.18	104.28	99.59	101.35	-	-	101.35
20010620-S	KE/SPT/VE01	SV	Laboratory & Allied Ltd, Kenya	81.37	2.33	-	81.37	99.03	103.52	94.60	99.05	-	-	99.05
20010625-P	KE/SPT/SH03	S	Cosmos Ltd, Kenya	65.58	7.09	-	65.58	97.78	94.21	-	96.00	-	-	96.00
20010625-S	KE/SPT/SH03	S	Cosmos Ltd, Kenya	93.70	4.19	-	93.70	100.34	100.06	-	100.20	-	-	100.20

REF NO: Reference number RSD: Related standard deviation CP: Collection point

DH: District hospital HC: Health centre P: Pharmacy SV: Street vendor S: Shop

TH: Teaching hospital DMS: District medical stores P: Pyrimethamine S: Sulphadoxine

ANNEX: 4A

Country: Mali

Product: Chloroquine syrup

CENQAM LAB RESULTS										
CENQAM REF NO	Sample number	CP	Manufacturer	Active ingredient content						
				1st value	2nd value	3rd value	Mean value	Low fail <90%	High fail >110%	Pass 90 - 110%
200104111	MA/CQS/HH14	H	UMPP, Bamako, Mali	86.70	88.68	87.14	88.68	88.68	-	-
200104112	MA/CQS/HH15	H	N/A	-	-	-	TLS	-	-	-
200104113	MA/CQS/PH05	P	UMPP, Bamako, Mali	79.56	103.90	-	91.73	-	-	91.73
200104114	MA/CQS/VE09	SV	UMPP, Bamako, Mali	-	-	-	TLS	-	-	-
200104115	MA/CQS/DH04	DH	UMPP, Bamako, Mali	-	-	-	TLS	-	-	-
200104116	MA/CQS/HH12	H	UMPP, Bamako, Mali	-	-	-	TLS	-	-	-
200104117	MA/CQS/VE11	SV	UMPP, Bamako, Mali	83.76	-	-	83.76	83.76	-	-
200104118	MA/CQS/PH07	P	Unknown	-	-	-	TLS	-	-	-
200104119	MA/CQS/VE08	SV	UMPP, Bamako, Mali	-	-	-	TLS	-	-	-
200104120	MA/CQS/HC03	HC	UMPP, Bamako, Mali	-	-	-	TLS	-	-	-
200104121	MA/CQS/PH06	P	UMPP, Bamako, Mali	-	-	-	TLS	-	-	-
200104122	MA/CQS/SH17	S	N/A	77.88	-	-	77.88	77.88	-	-
200104123	MA/CQS/VE10	SV	UMPP, Bamako, Mali	-	-	-	TLS	-	-	-
200104124	MA/CQS/HH13	H	UMPP, Bamako, Mali	80.89	-	-	80.89	80.89	-	-
200104125	MA/CQS/CS02	CMS	RP Rorer, Senegal	105.35	-	-	105.35	-	-	105.35

REF NO: Reference number

DH: District hospital

P: Pharmacy

TLS: Too little sample

CP: Collection point

H: Household

SV: Street vendor

CMS: Central medical stores

HC: Health centre

S: Shop

ANNEX: 4B

Country: Mali
Product: Chloroquine tablets

CENQAM LAB RESULTS

CENQAM REF NO	Sample number	CP	Manu- facturer	Dissolution test				Active ingredient content						
				Mean dissol- ution	% RSD (n=6)	Low fail <80%	Pass >80%	1st value	2nd value	3rd value	Mean value	Low fail <93%	High fail >107%	Pass 93 - 107%
200104126	MA/CQT/DS01	DMS	RP Rorer, Senegal	93.76	1.60	-	93.76	95.39	95.40	98.51	96.43	-	-	96.43
200104128	MA/CQT/HC03	HC	UMPP, Bamako, Mali	91.63	2.77	-	91.63	94.05	92.12	90.88	92.35	92.35	-	-
200104135	MA/CQT/VE10	SV	UMPP, Bamako, Mali	89.51	2.81	-	89.51	90.37	89.97	90.21	90.18	90.18	-	-
200104136	MA/CQT/VE11	SV	UMPP, Bamako, Mali	93.09	1.74	-	93.09	91.99	93.71	92.99	92.90	92.90	-	-
200104137	MA/CQT/HH12	H	UMPP, Bamako, Mali	91.40	2.76	-	91.40	94.07	91.50	93.59	93.05	-	-	93.05
200104138	MA/CQT/SH13	S	UMPP, Bamako, Mali	88.51	0.87	-	88.51	89.58	86.41	83.16	86.38	86.38	-	-
200104139	MA/CQT/SH14	S	UMPP, Bamako, Mali	87.61	2.74	-	87.61	106.46	105.51	106.42	106.13	-	-	106.13
200104140	MA/CQT/SH15	S	UMDP, Bamako, Mali	88.60	1.61	-	88.60	89.85	92.25	91.68	91.26	91.26	-	-
200104141	MA/CQT/TH16	TH	UMPP, Bamako, Mali	88.15	1.62	-	88.15	89.11	91.64	90.85	90.53	90.53	-	-
200104142	MA/CQT/HH17	H	N/A	87.81	4.61	-	87.81	92.44	95.08	93.87	93.80	-	-	-
200104143	MA/CQT/HH18	H	N/A	87.10	2.92	-	87.10	92.42	90.76	103.23	95.47	-	-	95.47
200104144	MA/CQT/HH19	H	N/A	85.23	6.16	-	85.23	94.34	94.71	93.67	94.24	-	-	94.24
200104145	MA/CQT/HH20	H	N/A	85.43	4.00	-	85.43	90.81	90.46	90.41	90.56	90.56	-	-
200104159	MA/CQT/CS02	CMS	RP Rorer, Senegal	81.17	5.57	-	81.17	85.26	84.90	88.67	86.28	86.28	-	-
200104160	MA/CQT/DH04	DH	UMPP, Bamako, Mali	88.31	1.34	-	88.31	95.70	94.35	93.28	94.44	-	-	94.44
200104161	MA/CQT/PH05	P	UMPP, Bamako, Mali	96.33	3.35	-	96.33	93.51	93.41	93.38	93.43	-	-	93.43
200104162	MA/CQT/PH06	P	UMPP, Bamako, Mali	83.12	5.34	-	83.12	92.39	92.84	92.78	92.67	92.67	-	-
200104163	MA/CQT/PH07	P	Unknown	57.05	2.41	-	57.05	58.99	59.94	60.45	59.79	59.79	-	-
200104164	MA/CQT/VE08	SV	Robert's Pharm, Nigeria	98.53	2.67	-	98.53	89.73	91.90	89.77	90.47	90.47	-	-
200104165	MA/CQT/VE09	SV	UMPP, Bamako, Mali	90.95	5.62	-	90.95	92.46	92.28	92.76	92.50	92.50	-	-

REF NO: Reference number RSD: Related standard deviation CP: Collection point
DH: District hospital DMS: District medical stores CMS: Central medical stores
HC: Health centre H: Household P: Pharmacy S: Shop SV: Street vendor
TH: Teaching hospital

ANNEX: 4C

Country: Mali

Product: Sulphadoxine/pyrimethamine tablets

CENQAM LAB RESULTS

CENQAM REF NO	Sample number	CP	Manu- facturer	Dissolution test				Active ingredient content						
				Mean dissol- ution	% RSD (n=6)	Low fail <65%	Pass >65%	1st value	2nd value	3rd value	Mean value	Low fail <90%	High fail >110%	Pass 90 - 110%
200104127-P	MA/SPT/CS02	CMS	Ajanta Pharm, Maurice	50.08	9.91	50.08	-	95.66	107.06	107.83	103.52	-	-	103.52
200104127-S	MA/SPT/CS02	CMS	Ajanta Pharm, Maurice	96.89	2.78	-	96.89	107.47	105.18	106.42	106.36	-	-	106.36
200104129-P	MA/SPT/PH04	P	Umedica Lab, India	0.47	101.94	0.47	-	93.11	103.50	103.90	100.17	-	-	100.17
200104129-S	MA/SPT/PH04	P	Umedica Lab, India	30.87	78.06	30.87	-	97.25	100.68	101.54	99.82	-	-	99.82
200104130-P	MA/SPT/PH05	P	Gracure Pharm Ltd, India	11.57	10.39	11.57	-	97.95	86.03	105.27	96.42	-	-	96.42
200104130-S	MA/SPT/PH05	P	Gracure Pharm Ltd, India	66.08	7.31	66.08	-	98.80	100.70	99.53	99.68	-	-	99.68
200104131-P	MA/SPT/PH06	P	Gracure Pharm Ltd, India	17.42	8.14	17.42	-	89.59	93.61	89.09	90.77	-	-	90.77
200104131-S	MA/SPT/PH06	P	Gracure Pharm Ltd, India	74.45	1.82	-	74.45	101.47	101.51	100.67	101.22	-	-	101.22
200104132-P	MA/SPT/SH07	S	N/A	39.24	3.15	39.24	-	88.35	99.87	101.35	96.53	-	-	96.53
200104132-S	MA/SPT/SH07	S	N/A	96.53	3.08	-	96.53	100.75	99.65	99.30	99.90	-	-	99.90
200104133-P	MA/SPT/TH08	TH	Ajanta Pharm, Maurice	56.32	6.76	56.32	-	86.78	102.30	104.63	97.90	-	-	97.90
200104133-S	MA/SPT/TH08	TH	Ajanta Pharm, Maurice	100.39	1.54	-	100.39	99.82	101.66	103.06	101.52	-	-	101.52
200104134-P	MA/SPT/VE09	SV	UMPP, Bamako, Mali	20.68	9.52	20.68	-	100.10	99.72	100.98	100.27	-	-	100.27
200104134-S	MA/SPT/VE09	SV	UMPP, Bamako, Mali	78.54	4.03	-	78.54	100.20	100.05	102.08	100.78	-	-	100.78

REF NO: Reference number
 CMS: Central medical stores
 TH: Teaching hospital

RSD: Related standard deviation CP: Collection point
 P: Pharmacy SV: Street vendor
 S: Shop P: Pyrimethamine S: Sulphadoxine

ANNEX: 5A

Country: Mozambique
Product: Chloroquine syrup

CENQAM LAB RESULTS										
CENQAM REF NO	Sample number	CP	Manu- facturer	Active ingredient content						
				1st value	2nd value	3rd value	Mean value	Low fail <90%	High fail >110%	Pass 90 - 110%
20010405	MO/CQS/PH15	P	Simrone Pharm, India	102.59	102.48	-	102.53	-	-	102.53
20010406	MO/CQS/PH19	P	Simrone Pharm, India	104.64	107.07	105.24	105.65	-	-	105.65
20010412	MO/CQS/PH001	P	Simrone Pharm, India	108.74	112.66	106.22	109.21	-	-	109.21
20010409	MO/CQS/PH/01	P	Simrone Pharm, India	108.38	112.02	106.42	108.94	-	-	108.94
20010413	MO/CQS/PH03	P	Simrone Pharm, India	108.77	104.29	114.04	109.03	-	-	109.03
20010459	MO/CQS/TH27	TH	Pharco Pharm, Alexandria	98.24	99.86	-	99.05	-	-	99.05
20010458	MO/CQS/TH001	TH	Pharco Pharm, Alexandria	99.33	100.69	-	100.01	-	-	100.01
20010424	MO/CQS/PH04	P	Pharco Pharm, Alexandria	96.04	101.04	101.42	99.50	-	-	99.50
200104103	MO/CQS/CS02	CMS	Pharm Indus Lab, Sudan	119.69	118.61	119.29	119.20	-	119.20	-
200104105	MO/CQS/CS03	CMS	Pharma Danica	107.73	109.60	-	108.67	-	-	108.67
200104108	MO/CQS/PH02	P	Belta Pharma, Italy	121.05	121.87	118.28	120.40	-	120.40	-
200104156	MO/CQS/CS01	CMS	Ulticare-Lyka, Nigeria	117.8	-	-	117.8	-	117.8	-

REF NO: Reference number
 CMS: Central medical stores

CP: Collection point
 P: Pharmacy

TH: Teaching hospital

ANNEX: 5B

Country: Mozambique
Product: Chloroquine tablets

CENQAM LAB RESULTS

CENQAM REF NO	Sample number	CP	Manu- facturer	Dissolution test				Active ingredient content						
				Mean dissol- ution	% RSD (n=6)	Low fail <80%	Pass >80%	1st value	2nd value	3rd value	Mean value	Low fail <93%	High fail >107%	Pass 93 - 107%
20010432	MO/CQT/TH002	TH	Bayer Vital, Germany	96.28	2.31	-	96.28	97.17	95.87	94.62	95.89	-	-	95.89
20010438	MO/CQT/HC001	HC	South West No2, China	93.28	0.90	-	93.28	93.38	93.30	93.15	93.28	-	-	93.28
20010443	MO/CQT/TH001	TH	South West No2, China	93.63	2.21	-	93.63	85.58	84.09	82.95	84.20	84.20	-	-
20010446	MO/CQT/VE005	SV	N/A	91.61	2.01	-	91.61	93.57	91.40	94.41	93.12	-	-	93.12
20010448	MO/CQT/HC01	HC	Chong Quing, China	96.57	2.06	-	96.57	94.84	94.89	96.20	95.31	-	-	95.31
20010451	MO/CQT/VE002	SV	N/A	-	-	-	-	-	-	-	-	-	-	-
20010452	MO/CQT/DS001	DMS	Nordia Pharm, Denmark	90.60	3.12	-	90.60	90.87	88.68	89.99	89.85	89.85	-	-
20010455	MO/CQT/PH001	P	Colorama Pharm, India	94.28	2.47	-	94.28	94.28	93.73	94.76	94.26	-	-	94.26
20010456	MO/CQT/HH002	H	N/A	93.69	1.43	-	93.69	96.40	97.02	96.32	96.58	-	-	96.58
20010461	MO/CQT/CS07	CMS	Labialfarma	62.18	16.22	62.18	-	93.13	94.71	91.02	92.95	92.95	-	-
200104146	MO/CQT/PH03	P	Shangai, China	90.36	0.80	-	90.36	89.54	89.41	89.66	89.54	89.54	-	-
200104147	MO/CQT/CS7	CMS	Shangai, China	88.22	2.91	-	88.22	93.18	92.03	90.72	91.97	91.97	-	-
200104148	MO/CQT/PH04	P	Shangai, China	90.93	3.27	-	90.93	95.59	92.85	95.35	94.60	-	-	94.60
200104149	MO/CQT/TH8	TH	Propharma, Denmark	90.13	3.40	-	90.13	92.99	93.84	94.96	93.93	-	-	93.93
200104152	MO/CQT/CS4	CMS	Chong Quing, China	93.62	1.61	-	93.62	106.38	105.51	106.19	106.03	-	-	106.03
200104154	MO/CQT/HC13	HC	Maneesh Pharma, India	90.83	4.43	-	90.83	91.45	94.72	93.34	93.17	-	-	93.17

REF NO: Reference number RSD: Related standard deviation CP: Collection point
 DH: District hospital DMS: District medical stores CMS: Central medical stores
 HC: Health centre H: Household P: Pharmacy SV: Street vendor
 TH: Teaching hospital

ANNEX: 5C

Country: Mozambique
Product: Sulphadoxine/pyrimethamine tablets

CENQAM LAB RESULTS

CENQAM REF NO	Sample number	CP	Manu- facturer	Dissolution test				Active ingredient content						
				Mean dissol- ution	% RSD (n=6)	Low fail <65%	Pass >65%	1st value	2nd value	3rd value	Mean value	Low fail <90%	High fail >110%	Pass 90 - 110%
20010425-P	MO/SPT/PH002	P	Gracure pharm	25.70	2.89	25.70	-	94.70	99.08	-	96.89	-	-	96.89
20010425-S	MO/SPT/PH002	P	Gracure pharm	73.34	1.06	-	73.34	99.59	94.95	-	97.27	-	-	97.27
20010437-P	MO/SPT/TH002	TH	Duopharma, Malaysia	22.50	30.47	22.50	-	99.42	96.47	-	97.95	-	-	97.95
10010437-S	MO/SPT/TH002	TH	Duopharma, Malaysia	94.48	4.89	-	94.48	96.79	97.19	-	96.99	-	-	96.99
20010439-P	MO/SPT/CS001	CMS	Pharmanova, Malawi	14.48	33.04	14.48	-	97.32	98.84	-	98.08	-	-	98.08
20010439-S	MO/SPT/CS001	CMS	Pharmanova, Malawi	49.56	3.81	49.56	-	98.13	TLS	-	98.13	-	-	98.13
20010440-P	MO/SPT/HC002	HC	Limassol, Cyprus	45.82	21.00	45.82	-	96.75	98.01	-	97.38	-	-	97.38
20010440-S	MO/SPT/HC002	HC	Limassol, Cyprus	87.40	10.39	-	87.40	98.68	97.42	-	98.05	-	-	98.05
20010441-P	MO/SPT/HC001	HC	Alferez Pvt Ltd, India	4.97	40.52	4.97	-	96.06	93.47	-	94.76	-	-	94.76
20010441-S	MO/SPT/HC001	HC	Alferez Pvt Ltd, India	41.61	17.23	41.61	-	98.20	99.37	-	98.78	-	-	98.78
20010442-P	MO/SPT/HC003	HC	Pharmanova, Malawi	12.68	0.00	12.68	-	103.03	98.45	-	100.74	-	-	100.74
20010442-S	MO/SPT/HC003	HC	Pharmanova, Malawi	46.44	2.51	46.44	-	93.37	94.42	-	93.89	-	-	93.89
20010444-P	MO/SPT/DS001	DMS	Pharmamed, Malta	50.70	15.39	50.70	-	89.10	96.48	-	92.79	-	-	92.79
20010444-S	MO/SPT/DS001	DMS	Pharmamed, Malta	92.29	1.46	-	92.29	98.24	100.10	-	99.17	-	-	99.17
20010445-P	MO/SPT/VE/02	SV	N/A	27.98	9.55	27.98	-	104.68	103.92	-	104.30	-	-	104.30
20010445-S	MO/SPT/VE/02	SV	N/A	65.03	6.61	-	65.03	99.74	98.90	-	99.32	-	-	99.32
20010447-P	MO/SPT/TH001	TH	Nordia, Dinamarca	21.94	31.34	21.94	-	100.15	TLS	-	100.15	-	-	100.15
20010447-S	MO/SPT/TH001	TH	Nordia, Dinamarca	94.15	3.11	-	94.15	101.74	101.13	-	101.43	-	-	101.43
20010449-P	MO/SPT/VE001	SV	No information	12.68	0.00	12.68	-	80.69	78.91	-	79.80	79.80	-	-
20010449-S	MO/SPT/VE001	SV	No information	44.22	3.44	44.22	-	98.14	100.01	-	99.08	-	-	99.08
20010450	MO/SPT/VE/01	SV	No information*	-	-	-	-	-	-	-	-	-	-	-
20010453-P	MO/SPT/PH003	P	Remedica, Cyprus	53.53	12.61	53.53	-	103.33	102.75	103.61	103.23	-	-	103.23
20010453-S	MO/SPT/PH003	P	Remedica, Cyprus	75.75	6.26	-	75.75	102.66	104.16	103.20	103.34	-	-	103.20
20010454-P	MO/SPT/HH001	H	N/A	12.68	0.00	12.68	-	97.49	97.93	-	97.71	-	-	97.71
20010454-S	MO/SPT/HH001	H	N/A	47.88	1.93	47.88	-	99.18	98.13	-	98.66	-	-	98.66
20010457-P	MO/SPT/PH/05	P	Duopharma, Malaysia	15.06	18.02	15.06	-	97.49	97.93	-	97.71	-	-	97.71

Continued on page 48

20010457-S	MO/SPT/PH/05	P	Duopharma, Malaysia	93.52	4.09	-	93.52	99.18	98.13	-	98.66	-	-	98.66
20010490-P	MO/SPT/PH/03	P	Alison SPRL, Belgium	31.01	43.16	43.16	-	101.91	98.85	102.59	101.12	-	-	101.12
20010490-S	MO/SPT/PH/03	P	Alison SPRL, Belgium	56.81	50.95	50.95	-	100.82	98.95	97.19	98.99	-	-	98.99
200104150-P	MO/SPT/TH/01	TH	Duopharma, Malaysia	17.68	30.05	17.68	-	98.39	102.61	101.53	100.84	-	-	100.84
200104150-S	MO/SPT/TH/01	TH	Duopharma, Malaysia	96.15	4.66	-	96.15	100.10	102.47	100.01	100.86	-	-	100.86
200104151-P	MO/SPT/CS/04	CMS	Duopharma, Malaysia	23.11	8.54	23.11	-	TLS	105.40	107.10	106.25	-	-	105.25
200104151-S	MO/SPT/CS/04	CMS	Duopharma, Malaysia	97.18	3.90	-	97.18	98.48	99.51	100.02	99.34	-	-	99.34
200104153-P	MO/SPT/CS/03	CMS	Limassol, Cyprus	55.43	5.97	55.43	-	110.07	110.30	109.49	109.95	-	-	109.95
200104153-S	MO/SPT/CS/03	CMS	Limassol, Cyprus	97.92	1.03	-	97.92	100.36	99.93	98.10	99.46	-	-	99.46
200104155-P	MO/SPT/PH5	P	Kopran Ltd, India	4.42	18.46	4.42	-	113.08	109.10	110.06	110.75	-	110.75	-
200104155-S	MO/SPT/PH5	P	Kopran Ltd, India	9.76	20.54	9.76	-	101.62	99.25	99.41	100.09	-	-	100.09

REF NO: Reference number **RSD:** Related standard deviation **CP:** Collection point
DMS: District medical stores **P:** Pharmacy **CMS:** Central medical stores
SV: Street vendor **TH:** Teaching hospital **P:** Pyrimethamine **S:** Sulphadoxine
HC: Health centre **H:** Household **TLS:** Too little sample (not enough tablets)
*: Probably counterfeit/incorrectly labelled

ANNEX: 6A

Country: Sudan
Product: Chloroquine syrup

CENQAM LAB RESULTS

CENQAM REF NO	Sample number	CP	Manu- facturer	Active ingredient content						
				1st value	2nd value	3rd value	Mean value	Low fail <90%	High fail >110%	Pass 90 - 110%
20020523	SU/CQS/TH01	TH	Sigma Tau	99.61	98.78	101.11	99.83	-	-	99.83
20020524	SU/CQS/DH02	DH	Amipharma	-	-	-	SUSP	-	-	-
20020525	SU/CQS/DS03	DMS	IPCA	79.25	79.48	77.25	78.66	78.66	-	-
20020526	SU/CQS/CS04	CMS	SKB	-	-	-	-	-	-	-
20020527	SU/CQS/HC05	HC	Elie	98.10	102.41	103.49	101.33	-	-	101.33
20020528	SU/CQS/PH06	P	SPIC	119.29	122.04	116.26	119.20	-	119.20	-
20020529	SU/CQS/PH07	P	Bells	99.51	98.96	98.67	99.05	-	-	99.05
20020530	SU/CQS/PH08	S	Kharachi Chemical	101.54	103.39	104.92	103.28	-	-	103.28
20020531	SU/CQS/SH09	S	Purna Pharmaceutical	103.66	103.38	-	103.52	-	-	103.52
20020532	SU/CQS/SH10	S	Rosemont	97.68	97.00	-	97.34	-	-	97.34
20020533	SU/CQS/SH11	S	Sigma Tau	112.93	106.63	110.72	110.09	-	110.09	-
20020534	SU/CQS/VE12	V	Jordanian Pharmaceutical	109.80	-	-	109.80	-	-	109.80
20020535	SU/CQS/VE13	V	Rivo Pharma SA	111.23	108.77	-	110.00	-	-	110.00
20020536	SU/CQS/VE14	V	Rivoharm S.A 6928 Manne	-	-	-	SUSP	-	-	-
20020537	SU/CQS/VE15	V	Sigma Tau	105.85	103.46	108.72	106.01	-	-	106.01
20020538	SU/CQS/HH16	H	Jordian Pharmaceutical Co	109.61	-	-	109.61	-	-	109.61
20020539	SU/CQS/HH17	H	IPCA	111.58	-	-	111.58	-	111.58	-
20020540	SU/CQS/HH18	H	Rivoharm S.A 6928 Manne	109.84	109.05	111.83	109.44	-	-	109.44
20020541	SU/CQS/HH19	H	Sigma Tau	111.71	100.49	110.10	107.43	-	-	107.43
20020542	SU/CQS/HH20	H	Amipharma	-	-	-	SUSP	-	-	-

REF NO: Reference number CP: Collection point CMS: Central medical stores
 DH: District hospital DMS: District medical stores H: Household HC: Health centre
 P: Pharmacy S: Shop V: Vendor TH: Teaching hospital P: Pyrimethamine
 S: Sulphadoxine SKB: Smith Kline Beecham SUSP: Suspension

ANNEX: 6B

Country: Sudan
Product: Chloroquine tablets

CENQAM LAB RESULTS

CENQAM REF NO	Sample number	CP	Manu- facturer	Dissolution test				Active ingredient content						
				Mean dissol- ution	% RSD (n=6)	Low fail <80%	Pass >80%	1st value	2nd value	3rd value	Mean value	Low fail <93%	High fail >107%	Pass 93 - 107%
20020503	SU/CQT/TH01	TH	Efroze	90.06	4.94	-	90.06	94.26	92.49	93.69	93.48	-	-	93.48
20020504	SU/CQT/DH02	DH	Amipharma	91.53	1.61	-	91.53	94.06	92.73	96.45	94.41	-	-	94.41
20020505	SU/CQT/DS03	DMS	IPCA	62.82	23.70	62.82	-	92.67	96.97	96.31	95.32	-	-	95.32
20020506	SU/CQT/CS04	CMS	Plethico	97.71	1.62	-	97.71	94.57	96.67	94.59	95.28	-	-	95.28
20020507	SU/CQT/HC05	HC	Remedica	100.50	4.84	-	100.50	105.00	95.89	92.65	97.85	-	-	97.85
20020508	SU/CQT/PH06	P	Elie	101.65	9.94	-	101.65	97.95	100.60	97.93	98.83	-	-	98.83
20020509	SU/CQT/PH07	P	Zeneca	99.35	1.41	-	99.35	98.59	99.52	102.18	100.09	-	-	100.09
20020510	SU/CQT/PH08	P	General Medicines	102.76	0.90	-	102.76	103.06	104.07	104.46	103.87	-	-	103.87
20020511	SU/CQT/SH09	S	Pharmamed	96.00	1.22	-	96.00	95.35	96.75	90.83	94.31	-	-	94.31
20020512	SU/CQT/SH10	S	Shifa	99.96	2.18	-	99.96	97.06	97.21	94.90	96.39	-	-	96.39
20020513	SU/CQT/SH11	S	Amipharma	99.34	2.60	-	99.34	97.44	100.24	97.12	98.27	-	-	98.27
20020514	SU/CQT/VE12	V	Pharmamed	100.31	3.84	-	100.31	96.35	99.40	95.89	97.21	-	-	97.21
20020515	SU/CQT/VE13	V	Amipharma	96.35	2.53	-	96.35	92.02	93.93	96.55	94.17	-	-	94.17
20020516	SU/CQT/VE14	V	General Medicines	98.67	1.65	-	98.67	106.64	106.14	106.34	106.37	-	-	106.37
20020517	SU/CQT/VE15	V	Efroze	94.31	1.92	-	94.31	97.44	96.86	98.78	97.69	-	-	97.69
20020518	SU/CQT/HH16	H	IPCA	71.35	0.40	71.35	-	95.01	92.20	97.75	94.99	-	-	94.99
20020519	SU/CQT/HH17	H	Unknown	NS	-	-	-	210.01	202.22	-	206.12	-	206.12	-
20020520	SU/CQT/HH18	H	Al Shifa	NS	-	-	-	92.15	-	-	92.15	92.15	-	-
20020521	SU/CQT/HH19	H	General Medicines	NS	-	-	-	106.71	105.77	-	106.24	-	-	106.24
20020522	SU/CQT/HH20	H	Amipharma	NS	-	-	-	99.27	101.55	97.84	99.56	-	-	99.56

REF NO: Reference number RSD: Related standard deviation CP: Collection point
 CMS: Central medical stores DH: District hospital DMS: District medical stores
 H: Household HC: Health centre P: Pharmacy S: Shop V: Vendor
 TH: Teaching hospital P: Pyrimethamine S: Sulphadoxine NS: Not enough tablets
 received to perform dissolution test

ANNEX: 6C

Country: Sudan

Product: Sulphadoxine/pyrimethamine tablets

CENQAM LAB RESULTS

CENQAM REF NO	Sample number	CP	Manu- facturer	Dissolution test				Active ingredient content						
				Mean dissol- ution	% RSD (n=6)	Low fail <65%	Pass >65%	1st value	2nd value	3rd value	Mean value	Low fail <90%	High fail >110%	Pass 90 - 110%
20020543-P	SU/SPT/TH01	TH	Lyka	43.91	2.07	43.91	-	95.38	96.74	97.10	96.41	-	-	96.41
20020543-S	SU/SPT/TH01	TH	Lyka	87.59	1.47	-	87.59	98.18	97.31	98.50	98.00	-	-	98.00
20020544-P	SU/SPT/DH02	D	General Medicine	18.79	10.06	18.79	-	-	94.55	98.49	96.52	-	-	96.52
20020544-S	SU/SPT/DH02	D	General Medicine	93.54	2.81	-	93.54	-	98.22	96.81	97.52	-	-	97.52
20020545-P	SU/SPT/DS03	DMS	IPCA	73.86	1.12	-	73.86	95.74	96.47	96.86	96.36	-	-	96.36
20020545-S	SU/SPT/DS03	DMS	IPCA	92.94	1.71	-	92.94	93.60	97.48	95.02	95.37	-	-	95.37
20020546-P	SU/SPT/CS04	CMS	General Medicine	12.74	14.49	12.74	-	91.04	97.48	93.85	94.12	-	-	94.12
20020546-S	SU/SPT/CS04	CMS	General Medicine	95.32	1.83	-	95.32	96.94	99.63	97.64	98.07	-	-	98.07
20020547-P	SU/SPT/HC05	HC	IPCA	52.46	6.77	52.46	-	98.79	98.60	99.25	98.88	-	-	98.88
20020547-S	SU/SPT/HC05	HC	IPCA	87.68	1.70	-	87.68	97.12	97.17	97.89	97.39	-	-	97.39
20020548-P	SU/SPT/PH06	P	Roche	46.47	3.46	46.47	-	103.22	108.64	103.36	105.07	-	-	105.07
20020548-S	SU/SPT/PH06	P	Efroze	95.10	0.49	-	95.10	100.44	103.48	97.10	100.34	-	-	100.34
20020549-P	SU/SPT/PH07	P	Efroze	9.74	19.31	9.74	-	107.44	104.84	103.59	105.29	-	-	105.29
20020549-S	SU/SPT/PH07	P	Efroze	83.17	5.76	-	83.17	97.03	91.94	94.17	94.38	-	-	94.38
20020550-P	SU/SPT/PH08	P	Elie	50.88	4.11	50.88	-	95.66	97.25	97.72	96.88	-	-	96.88
20020550-S	SU/SPT/PH08	P	Elie	95.69	1.88	-	95.69	95.47	96.87	96.73	96.36	-	-	96.36
20020551-P	SU/SPT/SH09	S	Amipharma	14.90	1.77	14.90	-	99.03	98.59	98.30	98.64	-	-	98.64
20020551-S	SU/SPT/SH09	S	Amipharma	95.18	0.88	-	95.18	100.33	100.27	99.85	100.15	-	-	100.15
20020552-P	SU/SPT/SH10	S	General Medicine	19.10	7.31	19.10	-	105.21	98.73	104.05	102.66	-	-	102.66
20020552-S	SU/SPT/SH10	S	General Medicine	99.21	4.44	-	99.21	101.56	95.73	100.61	99.30	-	-	99.30
20020553-P	SU/SPT/SH11	S	Amipharma	15.45	13.81	15.45	-	99.57	95.99	96.83	97.46	-	-	97.46
20020553-S	SU/SPT/SH11	S	Amipharma	103.75	3.52	-	103.75	101.39	97.90	99.36	99.55	-	-	99.55
20020554-P	SU/SPT/VE12	V	IPCA	58.92	2.92	58.92	-	96.42	97.37	102.11	98.63	-	-	98.63
20020554-S	SU/SPT/VE12	V	IPCA	83.30	4.53	-	83.30	96.74	95.62	-	96.18	-	-	96.18
20020555-P	SU/SPT/VE13	V	Not known	66.26	8.04	-	66.26	102.65	103.37	107.35	104.46	-	-	104.46
20020555-S	SU/SPT/VE13	V	Not known	92.89	11.06	-	92.89	101.83	102.71	103.07	102.54	-	-	102.54
20020556-P	SU/SPT/VE14	V	IPCA	72.08	1.03	-	72.08	99.08	100.48	101.00	100.19	-	-	100.19
20020556-S	SU/SPT/VE14	V	IPCA	97.40	1.31	-	97.40	100.56	101.44	101.91	101.30	-	-	101.30

Continued on page 52

20020557-P	SU/SPT/VE15	V	Amipharma	15.76	10.81	15.76	-	101.58	102.22	106.94	103.58	-	-	103.58
20020557-S	SU/SPT/VE15	V	Amipharma	99.77	0.79	-	99.77	102.74	102.11	105.59	103.48	-	-	103.48
20020558-P	SU/SPT/HH16	H	Not known	NS	-	-	-	99.16	-	-	-	-	-	99.16
20020558-S	SU/SPT/HH16	H	Not known	NS	-	-	-	100.86	-	-	-	-	-	100.86
20020559-P	SU/SPT/HH17	H	Not known	NS	-	-	-	99.24	-	-	-	-	-	99.24
20020559-S	SU/SPT/HH17	H	Not known	NS	-	-	-	103.21	-	-	-	-	-	103.21
20020560-P	SU/SPT/HH18	H	Not known	NS	-	-	-	100.90	99.85	-	100.37	-	-	100.37
20020560-S	SU/SPT/HH18	H	Not known	NS	-	-	-	101.96	101.21	-	101.59	-	-	101.59
20020561-P	SU/SPT/HH19	H	Not known	NS	-	-	-	101.44	100.96	-	101.20	-	-	101.20
20020561-S	SU/SPT/HH19	H	Not known	NS	-	-	-	102.28	101.65	-	101.96	-	-	101.96
20020562-P	SU/SPT/HH20	H	Not known	NS	-	-	-	104.05	102.12	-	103.08	-	-	103.08
20020562-S	SU/SPT/HH20	H	Not known	NS	-	-	-	104.09	102.30	-	103.19	-	-	103.19

REF NO: Reference number RSD: Related standard deviation CP: Collection point
 CMS: Central medical stores DH: District hospital DMS: District medical stores
 H: Household HC: Health centre P: Pharmacy S: Shop V: Vendor
 TH: Teaching hospital P: Pyrimethamine S: Sulphadoxine NS: Not enough tablets received to perform dissolution test

ANNEX: 7A

Country: Zimbabwe
Product: Chloroquine syrup

CENQAM LAB RESULTS

CENQAM REF NO	Sample number	CP	Manu- facturer	Active ingredient content						
				1st value	2nd value	3rd value	Mean value	Low fail <90%	High fail >110%	Pass 90 - 110%
20010491	ZI/CQS/DH7	DH	CAPS	93.65	90.50	96.10	93.42	-	-	93.42
20010492	ZI/CQS/HC24	HC	CAPS	91.05	91.01	84.82	88.86	88.96	-	-
20010493	ZI/CQS/HC8	HC	CAPS	105.02	105.75	105.03	105.27	-	-	105.27
20010494	ZI/CQS/DH3	DH	CAPS	89.98	93.02	93.92	92.31	-	-	92.31
20010495	ZI/CQS/HH21	H	N/A	85.17	87.75	85.66	86.19	86.19	-	-
20010496	ZI/CQS/TH19	TH	CAPS	99.26	99.52	-	99.39	-	-	99.39
20010497	ZI/CQS/HH25	H	N/A	94.88	95.27	95.23	95.13	-	-	95.13
20010498	ZI/CQS/HC22	HC	CAPS	95.55	88.46	95.47	93.16	-	-	93.16
20010499	ZI/CQS/HC13	HC	CAPS	90.67	-	-	90.67	-	-	90.67
200104100	ZI/CQS/DH6	DH	CAPS	90.86	89.05	-	89.96	-	-	89.96
200104101	ZI/CQS/DH12	DH	CAPS	96.47	93.99	-	95.23	-	-	95.23
200104106	ZI/CQS/PH26	P	CAPS	100.58	96.58	-	98.58	-	-	98.58
200104107	ZI/CQS/SH14	S	CAPS	102.04	99.80	-	100.92	-	-	100.92
200104109	ZI/CQS/HH16	H	CAPS	99.05	-	-	99.05	-	-	99.05
200104110	ZI/CQS/SH15	S	CAPS	88.60	90.45	91.25	90.10	-	-	90.10

REF NO: Reference number CP: Collection point DH: District hospital
 HC: Health centre H: Household P: Pharmacy
 S: Shop TH: Teaching hospital

ANNEX: 7B

Country: Zimbabwe
Product: Chloroquine tablets

CENQAM LAB RESULTS

CENQAM REF NO	Sample number	CP	Manu- facturer	Dissolution test				Active ingredient content						
				Mean dissol- ution	% RSD (n=6)	Low fail <80%	Pass >80%	1st value	2nd value	3rd value	Mean value	Low fail <93%	High fail >107%	Pass 93- 107%
20010464	ZI/CQT/PH21	P	CAPS	86.34	6.61	-	86.34	84.74	85.93	84.55	85.05	85.05	-	-
20010466	ZI/CQT/HH18	H	CAPS	88.86	6.71	-	88.86	90.18	89.46	89.49	89.71	89.71	-	-
20010467	ZI/CQT/DH7	DH	Varichem	85.96	6.53	-	85.96	66.02	64.63	65.78	65.47	65.47	-	-
20010471	ZI/CQT/SH26	S	Datlabs	93.44	2.85	-	93.44	66.72	68.49	68.82	68.01	68.01	-	-
20010474	ZI/CQT/HH19	H	Datlabs	65.21	21.69	65.21	-	91.14	91.47	91.48	91.36	91.36	-	-
20010476	ZI/CQT/HC13	HC	Varichem	93.31	3.07	-	93.31	91.92	91.89	93.40	92.40	92.40	-	-
20010478	ZI/CQT/SH27	S	Pharmanova	98.60	1.84	-	98.60	94.44	93.18	93.64	93.75	-	-	93.75
20010479	ZI/CQT/HC10	HC	Varichem	91.93	2.10	-	91.93	93.62	94.55	92.97	93.71	-	-	93.71
20010480	ZI/CQT/TH24	TH	CAPS	93.13	3.83	-	93.13	92.79	90.42	90.83	91.34	91.34	-	-
20010482	ZI/CQT/HH20	H	Datlabs	87.46	1.33	-	87.46	91.72	92.70	-	92.21	92.21	-	-
20010483	ZI/CQT/DH8	DH	CAPS	95.36	1.59	-	95.36	91.28	92.79	93.01	92.36	92.36	-	-
20010484	ZI/CQT/TH23	TH	Varichem	87.56	4.47	-	87.56	93.07	94.59	92.49	93.38	-	-	93.38
20010486	ZI/CQT/HC12	HC	Varichem	89.90	2.82	-	89.90	93.83	93.49	93.37	93.56	-	-	93.56
20010487	ZI/CQT/HC2	HC	Varichem	88.61	3.63	-	88.61	91.23	90.90	91.88	91.33	91.33	-	-
20010488	ZI/CQT/DH4	DH	Varichem	82.23	4.58	-	82.23	95.71	94.14	93.98	94.61	-	-	94.61

REF NO: Reference number RSD: Related standard deviation CP: Collection point
 DH: District hospital HC: Health centre H: Household P: Pharmacy S: Shop
 TH: Teaching hospital

ANNEX: 7C

Country: Zimbabwe

Product: Sulphadoxine/pyrimethamine tablets

CENQAM LAB RESULTS

CENQAM REF NO	Sample number	CP	Manu- facturer	Dissolution test				Active ingredient content						
				Mean dissol- ution	% RSD (n=6)	Low fail <65%	Pass >65%	1st value	2nd value	3rd value	Mean value	Low fail <90%	High fail >110%	Pass 90 - 110%
20010460-P	ZI/SPL/PH19	P	Roche	SYRUP	-	-	-	TLS	-	-	-	-	-	-
20010460-S	ZI/SPL/PH19	P	Roche	SYRUP	-	-	-	TLS	-	-	-	-	-	-
20010465-P	ZI/SPT/PH10	P	Pharm	5.97	14.91	5.97	-	93.58	90.27	-	91.92	-	-	91.92
20010465-S	ZI/SPT/PH10	P	Pharm	57.47	5.29	57.47	-	95.26	95.04	-	95.15	-	-	95.15
20010468-P	ZI/SPT/HC18	HC	Pharm	5.85	16.93	5.85	-	93.08	-	-	93.08	-	-	93.08
20010468-S	ZI/SPT/HC18	HC	Pharm	55.87	4.53	55.87	-	98.72	-	-	98.72	-	-	98.72
20010469-P	ZI/SPT/TH7	TH	Pharm	9.58	25.58	9.58	-	101.32	-	-	101.32	-	-	101.32
20010469-S	ZI/SPT/TH7	TH	Pharm	61.89	23.26	61.89	-	98.36	-	-	98.36	-	-	98.36
20010470-P	ZI/SPT/DH16	DH	Pharm	15.39	27.88	15.39	-	107.83	107.48	-	107.65	-	-	107.65
20010470-S	ZI/SPT/DH16	DH	Pharm	66.65	8.76	-	66.65	101.00	102.31	-	101.66	-	-	101.66
20010472-P	ZI/SPT/TH6	TH	Pharm	3.41	47.29	3.41	-	72.03	76.02	71.75	73.26	73.26	-	-
20010472-S	ZI/SPT/TH6	TH	Pharm	66.34	17.95	-	66.34	97.75	98.59	98.33	98.22	-	-	98.22
20010473-P	ZI/SPT/HC14	HC	Pharm	26.58	92.18	26.58	-	105.39	105.25	88.43	99.69	-	-	99.69
20010473-S	ZI/SPT/HC14	HC	Pharm	71.30	12.92	-	71.30	100.90	98.93	105.31	101.71	-	-	101.71
20010475-P	ZI/SPT/PH11	P	Roche	47.64	41.20	47.64	-	101.54	110.09	101.05	104.23	-	-	104.23
20010475-S	ZI/SPT/PH11	P	Roche	82.40	37.54	-	82.40	102.97	111.04	102.31	105.44	-	-	105.44
20010477-P	ZI/SPT/HC8	HC	Pharm	14.16	117.08	14.16	-	89.27	104.98	88.84	94.36	-	-	94.36
20010477-S	ZI/SPT/HC8	HC	Pharm	64.44	15.72	64.44	-	103.41	89.45	97.84	96.90	-	-	96.90
20010481-P	ZI/SPT/HC20	HC	Pharm	6.61	71.50	6.61	-	102.96	98.41	91.31	97.56	-	-	97.56
20010481-S	ZI/SPT/HC20	HC	Pharm	56.03	8.61	56.03	-	100.60	99.62	101.29	100.50	-	-	100.50
20010485-P	ZI/SPT/DH1	DH	Pharm	6.55	31.88	6.55	-	90.11	102.16	96.82	96.36	-	-	96.36
20010485-S	ZI/SPT/DH1	DH	Pharm	56.58	17.34	56.58	-	102.39	97.41	97.45	99.08	-	-	99.08
20010489-P	ZI/SPT/HC12	HC	Pharm	7.51	6.42	7.51	-	100.49	98.51	101.93	100.31	-	-	100.31
20010489-S	ZI/SPT/HC12	HC	Pharm	45.41	5.91	45.41	-	98.72	97.28	100.23	98.74	-	-	98.74

REF NO: Reference number RSD: Related standard deviation CP: Collection point

DH: District hospital HC: Health centre P: Pharmacy TH: Teaching hospital

P: Pyrimethamine S: Sulphadoxine

TLS: Too little sample Pharm: Pharmanova

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