

# **Annual Drug Quality Monitoring and Surveillance Report 2021**



**National Drug Testing Laboratory  
Royal Centre for Disease Control  
Ministry of Health  
Thimphu, Bhutan**

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## 1. Introduction

According to research from WHO in 2017, it is estimated that 1 in 10 medical products circulating in low- and middle-income countries is either substandard or falsified, which indicated that people are taking medicines that fail to treat or prevent disease(1). Apart from increased morbidity and mortality from substandard and falsified medicines, it is also a financial loss to individuals and health systems that purchase these products(1,2). As the COVID-19 pandemic strains health systems worldwide, there is growing concern about its potential impact on the supply chain for medical products in low- and middle-income countries (LMICs)(3). As country borders closed and countries dependent on imports for essential medicines were left empty-handed, substandard and falsified (SF) products began proliferating in LMIC markets, further threatening public health and imperiling other ongoing health programs.(3). Quality medicines makes an essential contribution towards the effective management and treatment of illnesses(4).

National Drug Testing Laboratory (NDTL) was established under Royal Centre for Disease Control (RCDC) in 2013 as the National Quality Control Laboratory for medicinal products. The laboratory has been officially recognized as the reference laboratory for Drug Regulatory Authority (DRA) by the Bhutan Medicines Board. To enhance and ensure the quality of medicines, the quality monitoring and surveillance of medicines was strengthened by development of Medicinal Product Quality Monitoring System (MPQMS) and Substandard and Falsified Medical Product Reporting System (SFPRS) in collaboration with Drug Regulatory Authority.

## 2. Methodology:

### 2.1 Sampling

The types of samples NDTL collects and receives are of 3 categories;

- I. Surveillance – these categories of samples are collected quarterly from surveillance sites for drug quality monitoring in the country. The samples are collected by RCDC and DRA.
- II. Complain – these are the samples referred by other agencies based on complains received on the quality of the samples/ adverse drug reactions.
- III. Registration – these are the samples referred by DRA for registration of medicinal products.

The samples are further pharmacologically categorized into 30 groups as per the National Essential Medicine list 2018 (Annexure V). Further the samples are identified based on their formulation which is classified into 25 categories (Annexure IV). Presently NDTL has 4 surveillance sites from where samples are collected quarterly to monitor the quality of medicinal products. The surveillance sites are;

- I. Jigme Dorji Wangchuck National Referral Hospital, Thimphu,
- II. Mongar Eastern Regional Referral Hospital, Mongar
- III. Gelephu Central Regional Referral Hospital, Gelephu
- IV. Medical Supply & Distribution Division, Phuentsholing.

In addition, the NDTL also receives samples from DRA, Ministry of Health, Bhutan Narcotics Control Authority and other agencies.

### 2.2 Testing of Samples

The samples are analysed as per their pharmacopeia claim and availability of reference standards. If the prescribed pharmacopeia method is not achievable, the selection of method follows the order mentioned in Figure 1.

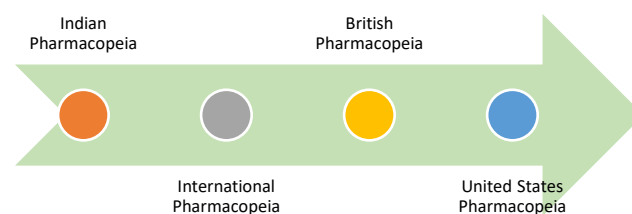


Figure 1: Flowchart for selection of methods

Primary reference standards from IPC (IPRS), USP, French Reference Standard, European Pharmacopoeia (Ph. Eur.) were used for the analysis of samples.

Table 1: List of Physical parameters

Physical Parameters	Equipment Used
Identification Test	Fourier-Transform Infrared Spectroscopy (FTIR)
Average Weight	Analytical Balance
Average volume	Analytical Balance
Uniformity of weight	Analytical Balance
Friability Test	Friability Apparatus
Disintegration Test	Disintegration Apparatus
pH	pH meter
Sterility Test	Safety Cabinet, Incubator

Table 2: List of chemical parameters

Chemical Parameters	Equipment Used
Assay	UV- Visible Spectrophotometer, High Performance Liquid Chromatography (HPLC), Titrator
Dissolution Test	Dissolution Apparatus
Microbiological Assay	Safety Cabinet, Incubator
Uniformity of Content	UV- Visible Spectrophotometer, HPLC, Titrator

2.3 Data Analysis

Data was generated from Medicinal Product Quality Monitoring System (MPQMS) and was imported into



Figure 2: Sample collection sites

the MS excel 2019 and Epi Info v.7 (CDC, USA) for analysis.

3. Results

3.1 Total Samples Analysed

3.1.1 Collection Site

In 2021, a total of 448 samples were collected from 23 sites of which 269 were referred by DRA and 173 were collected by RCDC. Further Bhutan Narcotics Control Authority forwarded 4 samples for identification of unknown substances and 1 complain sample each from Bumthang Hospital and Punakha Hospital were received at NDTL.

Maximum number of samples were collected from JDWNRH comprising of 33.04 %, followed by samples from Paro Hospital and Wangdue Hospital with 8.93 % and 7.59 % respectively.

Table 3: Distribution of samples collected by different agencies

Collected by	No. of samples	Frequency (%)
Drug Regulatory Authority	269	60.045
Royal Centre for Disease Control	173	38.616
Bhutan Narcotics Control Authority	4	0.893
Bumthang Hospital	1	0.223
Punakha Hospital	1	0.223

In 2021, the highest number of samples were tested from October - December constituting 48.21 %, followed by July - September with 28.57 % which coincides with the delivery of supplies by the seller in supply chain of the procurement.

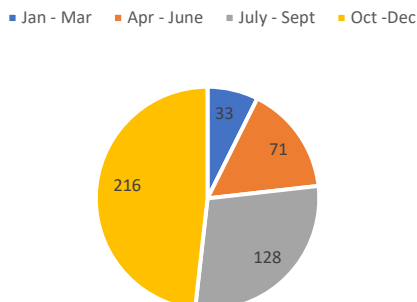


Figure 3: Distribution of samples analysed quarterly

Further, the number of samples collected and tested at NDTL has gradually increased from 2018 to 2021 with an exception in year 2020 due to disruption in the sample collection owing to the pandemic.

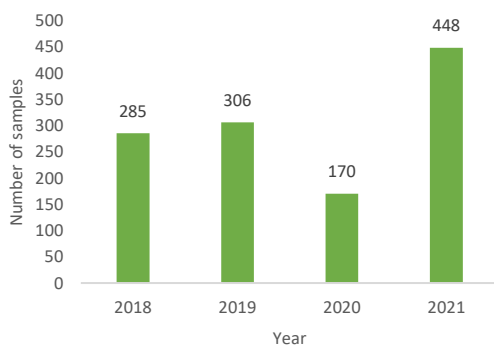


Figure 4: Distribution of samples analysed yearly

#### 1.1.1 Category of samples

A total of 448 samples were analysed in 2021 comprising of 21 complain samples and 427 surveillance samples.

Table 5: Number of samples analysed as per the category

Test Category	No. of samples	Percent
Complain	21	4.69 %
Surveillance	427	95.31 %
Total	448	

A total of 21 samples (4.69%) analysed in 2021 were found to be substandard; of which 3.57% (n=16) were medicines and other 1.12% (n=5) were medical devices. From the 21 substandard samples, griseofulvin tablets constituted 23.8 % (n=5) followed by chloroquine tablet at 14.29 % (n=3).

Table 6: List of non-compliance samples

Medicines	Frequency	Percent
Amiodarone 200mg tablet	1	4.76
Chloroquine 150mg tablet	3	14.29
Dicyclomine 10mg tablet	1	4.76
Griseofulvin 250mg tablet	5	23.81
Phenytoin 100mg tablet	2	9.52
Spironolactone 25mg tablet	1	4.76
Thyroxine 100 mcg tablet	1	4.76
Vitamin C 250mg tablet	2	9.52
<b>Medical Devices</b>		
Sterile Powdered Latex Surgical Gloves Size 7.0	1	4.76
Sterile Powdered Latex Surgical Gloves Size 7.5	1	4.76
Sterile Powdered Latex Surgical Gloves Size 8.0	1	4.76
IV Cannula with Wings & Injection Port Size 16G	1	4.76
Suction Catheter Size FG 12	1	4.76

#### 1.1.2 Category of formulation

The types of samples are categorized into 25 formulations. Presently tablets are the most frequently tested samples at NDTL with a proportion of 83.26 %, followed by other formulations which included medical devices with a proportion of 7.81 %.

Table 7: Distribution of samples tested as per Formulation

Formulation	Frequency	Percent
Tablets	373	83.26
Capsules	25	5.58
Powders for injection	3	0.67
Concentrated solutions for injection	1	0.22

Injections	6	1.34
Oral powders	5	1.12
Medical devices	35	7.81
Total	448	

### 1.1.3 Test Parameters

A total of 10 parameters were tested in 2021. A total of 38.84 % (n= 174) samples were analysed for both physical as well as chemical parameters and 61.16 % (n= 274) samples were analysed for only physical parameters.

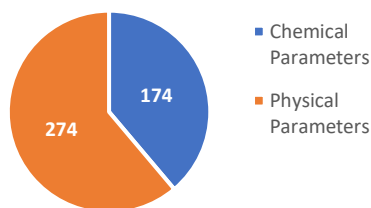


Figure 5: Number of samples analysed for Chemical and Physical Parameters

Table 8: List of test parameters analysed

Parameters	Total
Assay	174
Average Volume	1
Average Weight	402
Disintegration	367
Dissolution	12
Friability	216
Identification Test	12
pH	8
Sterility Test	45
Uniformity of Weight	403

### 1.1.4 Pharmacological category

The samples are broadly categorized into 30 pharmacological categories as per the National Essential Medicines List 2018. Samples belonging to 19 various categories were analysed. The most frequently tested samples were Cardiovascular medicines constituting 17.19 % (n=77), followed by anti-infectives medicines at 15.63 % (70).

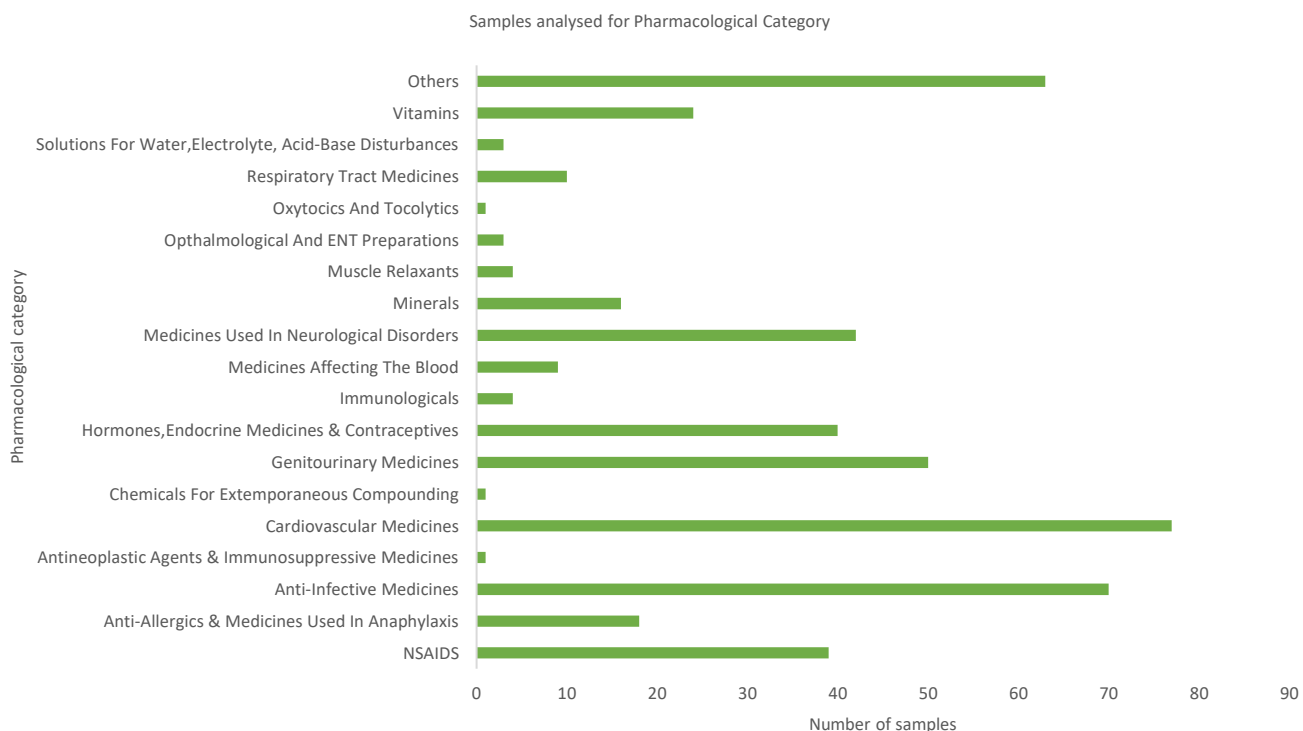


Figure 6: Distribution of samples analysed as per their Pharmacological category

## 1.2 Non - compliance

### 1.2.1 Collection Site

In 2021, samples from 23 different health centres were tested. Out of the 23 health centres, samples from 11 health centres were found to be non-compliant. The highest percent of non-compliance was 16.67 % for Dewathang Hospital and Tsimalakha Hospital. However, more samples from this hospital needs to be tested to ascertain any conclusion. JDWNRH had 9 samples which were non-compliant from the 148 tested with % non-compliance at 6.08 %.

The non-compliance trend shows a steady increase in the absolute number of samples found to be substandard from 2019 till 2021.

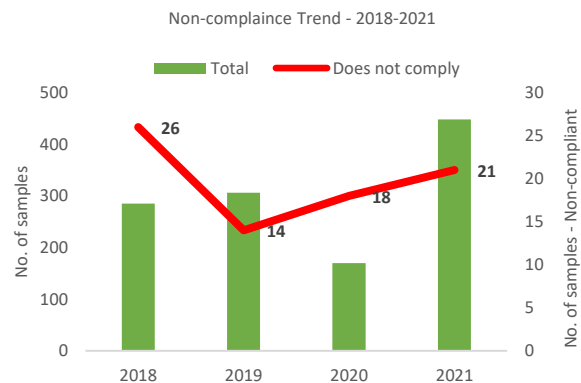


Figure 7: Non-compliance trend 2018 - 2021

### Non-compliance rate for health centres

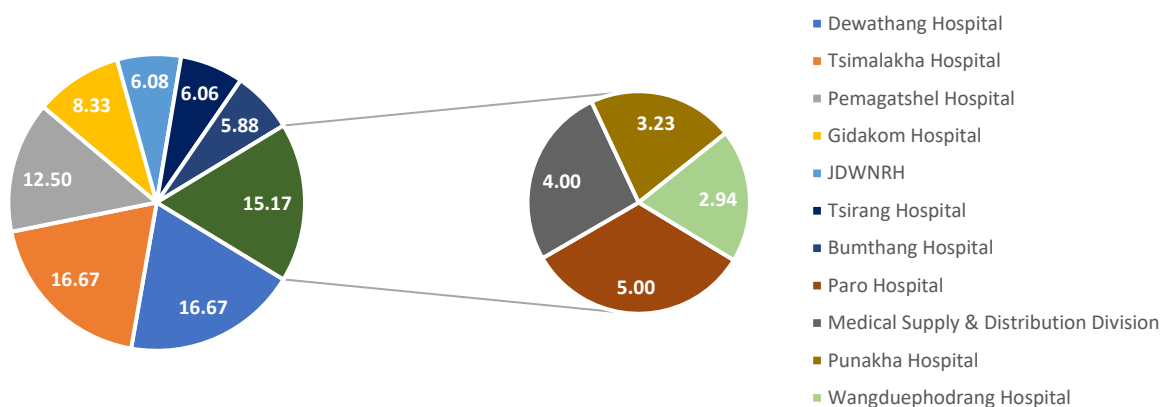


Figure 8: Percent non-compliance - Collection Site

### 1.2.2 Category of samples

The percent of non-compliance for complain samples was 9.52 % and for surveillance samples was 4.45 %. Overall, the percentage of non-compliance was 4.69 % in 2021.

Table 9: Non-compliance rate as per the category of samples

Category of samples	Does not comply	Total	% Non-compliance
Complain	2	21	9.52
Surveillance	19	427	4.45
Total	21	448	4.69

Table 10 shows the list of samples which did not comply as per the requirements of the monograph against the following parameters which comprises of 8 types of medicines and 5 types of medical devices.

Table 10: List of non-compliance samples against test parameters

Sample	Parameters
Amiodarone 200mg tablet	Friability Test
Chloroquine 150mg tablet	Assay
Dicyclomine 10mg tablet	Friability Test
Griseofulvin 250mg tablet	Friability Test
Phenytoin 100mg tablet	Assay
Spirolactone 25mg tablet	Dissolution Test
Thyroxine 100 mcg tablet	Friability Test
Vitamin C 250mg tablet	Friability Test
Sterile Powdered Latex Surgical Gloves Size 7.0	Sterility Test
Sterile Powdered Latex Surgical Gloves Size 7.5	Sterility Test
Sterile Powdered Latex Surgical Gloves Size 8.0	Sterility Test
I.V Cannula with Wings & Injection Port Size 16G	Sterility Test
Suction Catheter Size FG 12	Sterility Test

1.2.3 Category of formulation

At present tablets are the most frequently tested samples at NDTL followed by capsules and other types of samples. From these 16 tablets and 5 samples of medical devices did not comply with the requirements of the monograph or the standard methods and the percent of non-compliance was 4.29 % and 14.29 % respectively.

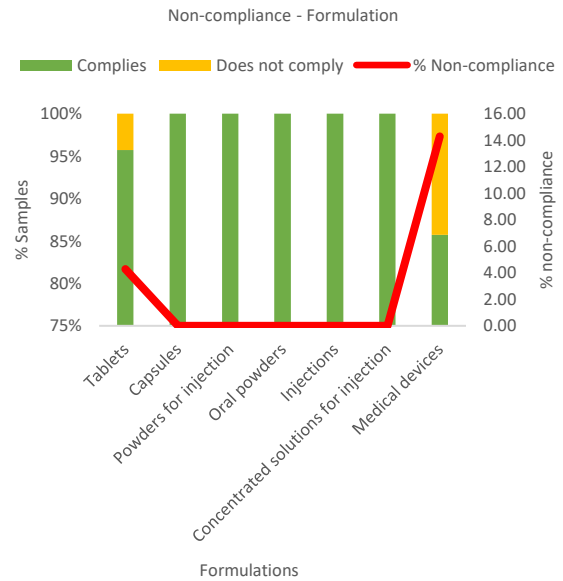


Figure 9: Percent non-compliance as per the formulation

1.2.4 Test Parameters

The non-compliance rate for the samples tested for physical parameters, sterility and both physical and chemical parameters were 3.28 % (n=9), 11.11 % (n=5) and 6.90 % (n=12) respectively. Furthermore, the content of active pharmaceutical ingredient was found unacceptable in 6.89 % (n=12) from 174 samples tested for assay.

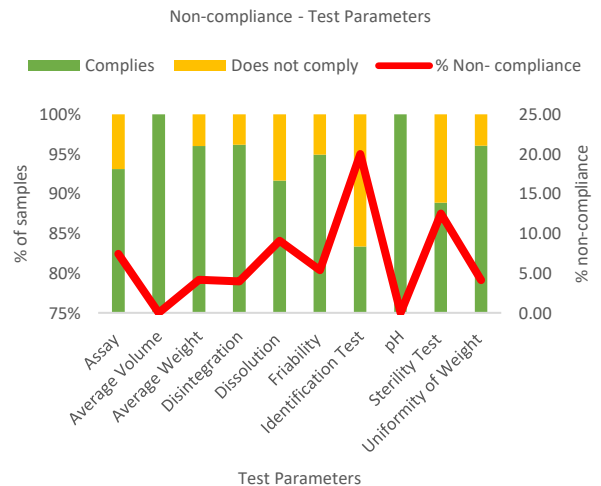


Figure 10: Non-compliance as per Test Parameters.



### 1.2.5 Pharmacological Category

Cardiovascular medicines and anti-infective medicines were the two highest category of samples analysed in 2021. Analgesics, Antipyretics & Non-Steroidal Anti-Inflammatory Medicines (NSAIDs) had the maximum percent non-compliance at 10.26 % (n=4). Anti-infective medicines, others category and vitamins had 7.14 % (n=5), 9.52 % (6) and 8.33% (n=2) of non-compliance respectively which is rather high and alarming.

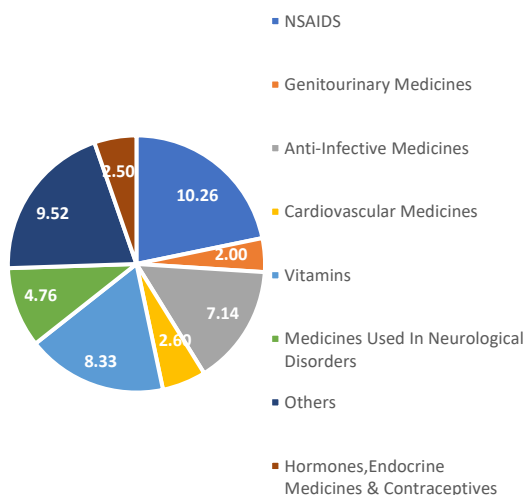


Figure 11: Non-compliance as per Pharmacological Category

## 2. Discussion

In 2021, 448 samples were analysed at NDTL comprising of 427 surveillance samples and 21 complain samples. Drug Regulatory Authority referred 60.045 % of samples and 38.57 % were collected by RCDC. The samples were collected from 23 different health centres. Identical to previous years highest number of samples were collected from JDWNRH with 33.04% (n=148) of the proportion.

National Drug Testing Laboratory received and analysed 76.69 % (n=344) of samples from July to December 2021, which coincides with the receipt of supplies by Ministry of Health in the procurement cycle. This has benefited in providing timely intervention in identifying substandard and falsified medicines. From the 448 samples, 38.84 % of samples were analysed for both physical and chemical

parameters whereas 61.16 % of samples were analysed for only physical parameters.

Cardiovascular medicines, Anti-infective medicines and Genitourinary medicines were the highest number of samples analysed constituting 17.19 %, 15.63 % and 11.16 % respectively. However, the rate of non-compliance was high for NSAIDs, Vitamins and Anti-infectives medicines with rate of non-compliance of 10.26 %, 8.33% and 7.14 % respectively. Furthermore, the content of active pharmaceutical ingredient was found unacceptable in 6.89 % (n=12) from 174 samples tested for assay.

Even though the yearly rate of non-compliance from 2018 to 2021 shows no alarming indication, it is important to discuss increase in the absolute number of non-compliant sample.

The overall non-compliance rate for 2021 was 4.69 %. Surveillance samples had 4.52 % of non-compliance rate and complain samples had 9.52 % of non-compliance rate. To ascertain any conclusion on the higher rate of non-compliance for complain samples, more complain samples needs to be analysed in future.

Medical devices which included surgical gloves, IV cannula, catheter etc had a no-compliance rate of 14.29 % from the 35 analysed for sterility test. Thus, more attention must be accorded to medical devices too.

## 3. Conclusion and Way forward

With the slow increase in the non-compliance trend, there is a need to strengthen Drug Quality Monitoring and Surveillance in the country. Further there is an urgent need to institute a mechanism to test the medicinal products at the point of entry and distribution centre prior to distribution of the products to health centres.

### Way Forward:

- Increase the number of surveillance sites.
- Timely field monitoring and evaluation to provide recommendations and suggestions.
- Encourage active participation from health centres to ensure the quality of medicines.

#### 4. Reference

1. 1 in 10 medical products in developing countries is substandard or falsified [Internet]. [cited 2022 Jan 18]. Available from: <https://www.who.int/news/item/28-11-2017-1-in-10-medical-products-in-developing-countries-is-substandard-or-falsified>
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3. Stronger Medical Product Quality Assurance Systems Respond During the COVID-19 Pandemic [Internet]. [cited 2022 Jan 18]. Available from: <https://www.usp.org/global-public-health/promoting-quality-of-medicines/medical-quality-assurance-systems-covid-19>
4. Ozawai S, Higgins CR, Yemeke TT, Nwokike JI, Evans L, Hajjou M, et al. Importance of medicine quality in achieving universal health coverage. PLoS ONE. 2020 Jul 1;15(7 July).

## 5. Annexure

### Annexure I: List of samples tested in 2021

SN	Name	SN	Name
1.	Acetazolamide 250mg tablet	62.	Isosorbide dinitrate 10mg tablet
2.	Acyclovir 400mg tablet	63.	Isosorbide dinitrate 5mg sublingual tablet
3.	Albendazole 400mg tablet	64.	Lamotrigine 50mg tablet
4.	Allopurinol 100mg tablet	65.	Levetiracetam 500mg tablet
5.	Aluminium hydroxide 250mg + Magnesium hydroxide 400mg tablet	66.	Levodopa 250mg + Carbidopa 25mg tablet
6.	Amiodarone 200mg tablet	67.	Levofloxacin 250mg tablet
7.	Amitriptylline 25mg tablet	68.	Losartan 25mg tablet
8.	Amlodipine 5mg tablet	69.	Mefenamic acid 250mg tablet
9.	Amoxicillin Dispersable 250mg tablet	70.	Metformin 500mg tablet
10.	Ampicillin 500mg powder for injection	71.	Methotrexate 2.5mg tablet
11.	Aspirin 75mg enteric coated tablet	72.	Methyldopa 250mg tablet
12.	Atenolol 50mg tablet	73.	Methylergometrine 125mcg tablet
13.	Atorvastatin 10mg tablet	74.	Metoclopramide 10mg tablet
14.	Baclofen 10mg tablet	75.	Metronidazole 400mg tablet
15.	Benzoic acid powder (450g)	76.	Nifedipine 20mg sustained release tablet
16.	Betahistine dihydrochloride 16mg tablet	77.	Norfloxacin 400mg tablet
17.	Calcium lactate 300mg tablet	78.	Olanzapine 10mg tablet
18.	Carbamazepine 200mg tablet	79.	Omeprazole 20mg capsule
19.	Carbimazole 5mg tablet	80.	Ondansetron 4mg tablet
20.	Carvedilol 12.5mg tablet	81.	p-Aminosalicylate sodium 5.52 g powder for oral solution
21.	Carvedilol 3.125mg tablet	82.	Pantoprazole IP 40mg.
22.	Cetirizine 10mg tablet	83.	Paracetamol 500mg tablet
23.	Chloroquine 150mg tablet	84.	Phenoxymethylpenicillin 250mg tablet
24.	Chlorpromazine 100mg tablet	85.	Phenytoin 100mg tablet
25.	Cinnarizine 15mg tablet	86.	Phytomenadione (Vit. K) 10mg/mL injection (1mL)
26.	Ciprofloxacin 500mg tablet	87.	Potassium chloride 600mg tablet
27.	Clarithromycin 250mg tablet	88.	Prazosin Hydrochloride tablet
28.	Clobazam 5mg tablet	89.	Prednisolone 20mg tablet
29.	Clomiphene 50mg tablet	90.	Primaquine 7.5mg tablet
30.	Clonazepam 0.5mg tablet	91.	Promethazine hydrochloride 10mg tablet
31.	Clopidogrel 75mg tablet	92.	Propranolol 40mg tablet
32.	Cloxacillin 250mg capsule	93.	Pyrazinamide 400mg Tablet
33.	Codeine phosphate 15mg tablet	94.	Pyrazinamide 500mg tablet
34.	Cotrimoxazole (Sulphamethoxazole 400mg+Trimethoprim 80mg) tablet	95.	Pyridoxine (vitamin B6) 25mg tablet
35.	Cycloserine Capsules 250mg	96.	Quetiapine 50mg tablet
36.	Deflazacort 1mg tablet	97.	Ranitidine 150mg tablet
37.	Deflazacort 6mg tablet	98.	Retinol (vitamin A) 200,000IU capsule
38.	Dexamethasone 4mg tablet	99.	Rifampicin 150mg
39.	Dicyclomine 10mg tablet	100.	Rifampicin 300mg tablet
40.	Dicycloverine Hydrochloride 10mgg	101.	Salbutamol 4mg tablet
41.	Doxycycline 100mg capsule	102.	Senna 15mg tablet
42.	Enalapril 5mg tablet	103.	Sodium bicarbonate 500mg tablet

43.	Erythromycin stearate 250mg tablet	104.	Sodium valproate 200mg tablet
44.	Ethambutol 275mg + Isoniazid 75mg + Pyrazinamide 400mg + Rifampicin 150mg tablet	105.	Spirolactone 25mg tablet
45.	Ethambutol 400mg tablet	106.	Streptomycin 1g powder for injection
46.	Ethionamide 250mg tablet	107.	Suxamethonium 50mg/mL injection (2mL)
47.	Fenofibrate Capsule 200mg	108.	Tamsulosin 0.4mg tablet
48.	Ferrous sulphate 60mg + Folic acid 0.40mg tablet	109.	Theophylline 69mg + Etophylline 231mg retard tablet
49.	Finasteride 5mg tablet	110.	Thiamine 75mg tablet
50.	Fluconazole 150mg tablet	111.	Thyroxine 100 mcg tablet
51.	Fluoxetine 20mg tablet	112.	Thyroxine 25 mcg tablet
52.	Furosemide 40mg tablet	113.	Trihexyphenidyl 2mg tablet
53.	Gentamicin 40mg/mL injection (2mL)	114.	Verapamil 40mg tablet
54.	Glipizide 5mg tablet	115.	Vildagliptin 50mg tablet
55.	Griseofulvin 250mg tablet	116.	Vitamin B complex tablet
56.	Hydralazine 25mg tablet	117.	Vitamin C 250mg tablet
57.	Hydrochlorothiazide 25mg tablet	118.	Warfarin 1mg tablet
58.	Ibuprofen 400mg tablet	119.	Warfarin 3mg tablet
59.	Indomethacin 25mg capsule	120.	Warfarin 5mg tablet
60.	Isoniazid 300mg tablet	121.	Water for Injection 1ml
61.	Isoniazid 75mg + Rifampicin 150mg tablet	122.	Zinc sulphate 20mg tablet

Annexure II: List of medical devices

SN	Name	SN	Name
1.	Bio-Flon I.V Cannula with Wings & Injection Port Size 16G	17.	IV Cannula with Wings & Injection Port Size 26G
2.	Catheter (Nasogastric Tube) Size 14FG	18.	IV Cannula with Luber Lock, Wings & Injection Port Size 18G
3.	Catheter (Nasogastric Tube) Size 16FG	19.	IV Cannula with Luber Lock, Wings & Injection Port Size 20G
4.	Catheter (Nasogastric Tube) Size 18FG	20.	IV Cannula with Luber Lock, Wings & Injection Port Size 22G
5.	Disposable Surgical Rubber Gloves Size 6.5	21.	IV Cannula with Wings & Injection Port Size 16G
6.	Disposable Surgical Rubber Gloves Size 7.0	22.	Mr.Inject Insulin Syringe 1ml
7.	Disposable Syringe 1ml	23.	Naso-Gastric Tube Size FG-14
8.	Disposable Syringe 50ml	24.	Sterile Latex Surgical Gloves-Powdered Size 6.5
9.	Disposable Syringe with Needle 10ml	25.	Sterile Powdered Latex Surgical Gloves Size 7.0
10.	Disposable Syringe with Needle 2ml	26.	Sterile Powdered Latex Surgical Gloves Size 7.5
11.	Disposable Syringe with Needle 5ml	27.	Sterile Powdered Latex Surgical Gloves Size 8.0
12.	Hi-flon I.V Cannula Size 14G	28.	Suction Catheter Size FG 12
13.	Infant Feeding Tube Size FG-6	29.	Suction Catheter Size FG 18
14.	Infusion Set Size 21G	30.	Suction Catheter Size FG 6
15.	IV Cannula with Wings & II.V Cannula with Wings & Injection Port Size 26G	31.	Suction Catheter with Thumb Control Size FG 6
16.	IV Cannula with Wings & Injection Port Size 24G		

Annexure III: List of Samples tested for full parameters

SN	Name	SN	Name
1.	Acetazolamide 250mg tablet	44.	Isoniazid 300mg tablet
2.	Acyclovir 400mg tablet	45.	Isoniazid 50mg + Pyrazinamide 150mg + Rifampicin 75mg tablet
3.	Albendazole 400mg tablet	46.	Isoniazid 75mg + Rifampicin 150mg tablet
4.	Allopurinol 100mg tablet	47.	Labetalol 5mg/mL injection (20mL)
5.	Amitriptyline 25mg tablet	48.	Lamivudine 150mg tablet
6.	Amlodipine 5mg tablet	49.	Lamotrigine 50mg tablet
7.	Amoxicillin 250mg capsule	50.	Levofloxacin 250mg tablet
8.	Amoxicillin 25mg/mL syrup (60mL)	51.	Losartan 25mg tablet
9.	Amoxycillin Dispersible tablet 250mg	52.	Metformin 500mg tablet
10.	Ampicillin 500mg powder for injection	53.	Methotrexate 2.5mg tablet
11.	Aspirin 75mg enteric coated tablet	54.	Metoclopramide 10mg tablet
12.	Atenolol 50mg tablet	55.	Metoprolol succinate 25mg tablet
13.	Atorvastatin 10mg tablet	56.	Metoprolol Succinate Extended-Release Tablet 47.5mg
14.	Baclofen 10mg tablet	57.	Metronidazole 400mg tablet
15.	Benzoic acid powder (450g)	58.	Nevirapine 200mg tablet
16.	Calcium lactate 300mg tablet	59.	Nifedipine 20mg sustained release tablet
17.	Carbamazepine 200mg tablet	60.	Nitrofurantoin 100mg tablet
18.	Carbimazole 5mg tablet	61.	Olanzapine 10mg tablet
19.	Cephalexin 250mg tablet (Blister pack)	62.	Omeprazole 20mg capsule
20.	Cetirizine 10mg tablet	63.	p-Aminosalicylate sodium 5.52 g powder for oral solution
21.	Chloroquine 150mg tablet	64.	Paracetamol 500mg tablet
22.	Chlorpromazine 100mg tablet	65.	Phenytoin 100mg tablet
23.	Chlorpromazine 25mg/mL injection (2mL)	66.	Prednisolone 20mg tablet
24.	Ciprofloxacin 500mg tablet	67.	Prednisolone 5mg tablet
25.	Clomiphene 50mg tablet	68.	Primaquine 7.5mg tablet
26.	Cloxacillin 250mg capsule	69.	Promethazine hydrochloride 10mg tablet
27.	Cycloserine 250mg capsule	70.	Propranolol 40mg tablet
28.	Cycloserine 250mg tablet	71.	Pyrazinamide 400mg tablet
29.	Dexamethasone 4mg tablet	72.	Pyrazinamide 500mg tablet
30.	Diazepam 5mg tablet	73.	Pyridoxine (vitamin B6) 25mg tablet
31.	Digoxin 250mcg tablet	74.	Quetiapine 50mg tablet
32.	Enalapril 5mg tablet	75.	Quinine 300mg tablet
33.	Ethambutol 275mg + Isoniazid 75mg + Pyrazinamide 400mg + Rifampicin 150mg tablet	76.	Ranitidine 150mg tablet
34.	Ethambutol 400mg tablet	77.	Rifampicin 150mg capsule
35.	Ethionamide 250mg tablet	78.	Sodium bicarbonate 500mg tablet
36.	Finasteride 5mg tablet	79.	Spironolactone 25mg tablet
37.	Fluconazole 150mg tablet	80.	Tenofovir 300mg tablet
38.	Fluoxetine 20mg tablet	81.	Thiamine 75mg tablet
39.	Folic acid 5mg tablet	82.	Thyroxine 100 mcg tablet
40.	Furosemide 40mg tablet	83.	Thyroxine 25mcg tablet
41.	Glipizide 5mg tablet	84.	Verapamil 40mg tablet
42.	Griseofulvin 250mg tablet	85.	Verapamil Injection 5mg
43.	Hydrochlorothiazide 25mg tablet	86.	Vitamin C 250mg tablet

Annexure IV: Category of Formulation

<b>SN</b>	<b>Formulation</b>	<b>SN</b>	<b>Formulation</b>
1	Capsules	13	Nasal drops, solutions and sprays
2	Concentrated solutions for injection	14	Nasal powder
3	Creams	15	Nasal Preparations
4	Ear drops	16	Ointments
5	Eye drops	17	Oral liquids
6	Gels	18	Oral powders
7	Granules	19	Parenteral preparations
8	Infusions	20	Pessaries
9	Inhalation preparations	21	Powders for injection
10	Injections	22	Suppositories
11	Insulin preparations	23	Tablets
12	Liposomal preparations	24	Others

Annexure V: Pharmacological Category of Medicines

<b>SN</b>	<b>Name of Category</b>	<b>SN</b>	<b>Name of Category</b>
1	Anesthetics	16	Medicines for Soft Tissue Inflammation
2	Analgesics, Antipyretics & Non-Steroidal Anti-Inflammatory Medicines (NSAIDS)	17	Medicines for Use in Chemotherapy
3	Anti-Allergics & Medicines Used in Anaphylaxis	18	Medicines for Use in Hemodialysis
4	Anti-Dotes & Substances Used in Poisoning	19	Medicines for Use In ICU
5	Anti-Infective Medicines	20	Medicines Used in Neurological Disorders
6	Antineoplastic Agents & Immunosuppressive Medicines	21	Minerals
7	Blood Products and Blood Substitutes	22	Muscle Relaxants
8	Cardiovascular Medicines	23	Ophthalmological and ENT Preparations
9	Chemicals for Extemporaneous Compounding	24	Oxytocic and Tocolytics
10	Dermatological Medicines	25	Parenteral Nutrition
11	Diagnostic Agents	26	Respiratory Tract Medicines
12	Genitourinary Medicines	27	Solutions for Water, Electrolyte, Acid-Base Disturbances
13	Hormones, Endocrine Medicines & Contraceptives	28	Vitamins
14	Immunologicals	29	Traditional Medicines
15	Medicines Affecting the Blood	30	Others