NATIONAL DRUG SURVEY 2014 - 2016

Chapter 10

Survey Results and Analysis

SURVEY RESULTS AND ANALYSIS

INTRODUCTION

This chapter presents how the samples were drawn, the results of sample collections, results of laboratory tests and the estimates of extent of NSQ and Spurious drugs. It has been found from the survey, that out of the 47,012 samples tested, 13 samples (0.0245%) were Spurious and 1,850 samples (3.16%) were NSQ. Besides, presenting the main results, the estimates of extent of NSQ and Spurious drugs, various issues in connection with this survey are presented and discussed. Some of the issues include:

- Source wise and location wise distribution of samples drawn under survey
- Batch consistency
- Hit rates
- Inclusion probabilities of molecule IDs
- Contribution of tests to failure of samples
- Analysis of date expired samples
- NSQ percentages for molecules and manufacturing units etc.

In the process, some interesting metrics are derived and the results on them are presented. For example, instead of simply looking at whether a sampled formulation has crossed its expiry date, one can examine the distribution of remaining shelf life, that is, the time from the date of sample collection to the expiry date. One of the purposes of this chapter is to provide supplementary information on the type of issues that may arise in conducting massive surveys like this. Such knowledge will be useful in conducting future surveys of this nature.

Analysis of the survey data was performed keeping in mind a variety of questions with regard to two aspects. One aspect deals with issues related to conduct of the survey and quality of data collected. The other aspect deals with results of laboratory tests and estimates of the extent of NSQ and Spurious drugs. The analysis was planned by first writing down a series of questions relating to

above mentioned aspects. A quick glance at these questions, listed below, will serve as a good preamble for the contents of this chapter.

Questions on Conduct of the Survey

These questions are related to conduct and performance of the survey and its design.

- What is the Source for drawing samples?
- What are the targeted and achieved sample sizes?
- Are the samples drawn from the selected sources? If not, what is the extent of deviation?
- Survey is aimed at collecting 6 samples from each Source. What is the distribution of number of samples collected from each Source?
- How good is the representation of samples? Do they cover the entire country?
- How well are the States and districts represented by the samples?
- How are the locations such as corporations, metropolitan cities, municipal towns, taluk headquarters and villages represented in the samples?
- What is the coverage of selected molecules?
- What is the coverage of dosage forms?

Questions on Quality of Drugs

These questions are related to quality of drugs based on laboratory test results.

- What is the extent of NSQ and Spurious drug estimates?
- What is the distribution of number of laboratory tests which contributed to NSQ samples?
- What is the quality of samples from the same batches collected from different geographic locations across the country?
- What are the main sources of NSQ or Spurious drugs?
- How is the time to expiry (gap between date of sample collection and expiry date) distributed?

We explored the answers to the questions listed above and summarized the results. The survey was aimed at analyzing the three sources - retail outlets,

Government sources and Ports separately. Some aspects were common to the three sources and some of the queries needed specific answers to each Source separately. The data were analyzed accordingly.

SAMPLING

Based on the outcome of the pilot study, the data collection form was used in the pilot study was modified and finalized. This form was used for the retail outlets and Government sources. For the Ports, a slightly modified sampling procedure had to be adopted because unlike the first two sources, samples had to be drawn from imported medicines from airports and sea ports. The form for data collection for Ports differed from that for other two sources mainly in the selection of molecules and formulations. For Ports, a sample was drawn from each formulation, of each molecule, of each batch number, of every consignment, provided that the molecule was in the list of the 224 molecules. As per the sampling design, for retail outlets and Government sources, selection of samples was made in three stages.

In the first stage selection of sources (a Source is either from retail outlets or Government i.e. State Government Medical Store Depots, CGHS, ESI Dispensaries and Civil Hospital Stores) was made using simple random sampling from the list of all registered sources. In the second stage, molecules were selected from each selected Source using the random list of molecules generated for each selected Source and included in Part-C of the Data form. In the third stage, one formulation was selected from each selected molecule using the prescribed method of random sampling using Part-D of the Data Form.

Selection of sources

In order to draw the first stage samples from Retail outlets and Government sources, the list of all registered sources was needed. The States/UTs provided the lists of 4,24,525 registered retail outlets in 572 districts out of 676 districts in the country. For the remaining 104 districts, the States/UTs were able to provide only the number of registered outlets i.e. 32,978, without any information in respect of Address of outlets, Licensing details etc. Even for those retail outlets where the information was made available, the quality of the data on registered outlets was inadequate.

States/UTs of Bihar, Dadra and Nagar Haveli, Daman and Diu, Meghalaya and Uttarakhand, provided only district-wise number of Retail outlets i.e. 32,978. Therefore, notional IDs for these 32,978 Retail outlets were generated for each of the districts of the above States/UTs for the purpose of sample selection. Thus, making the total number of retail outlets including the ones

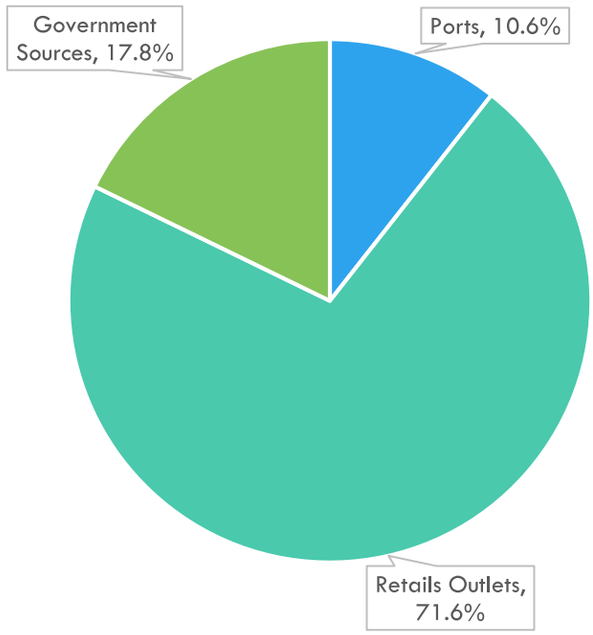
with notional IDs for stage one sampling was 4,57,503 (4,24,525+32,978). Of these, 6,081 retail outlets were selected using simple random sampling and the R-software package. The addresses for retail outlets with notional IDs were obtained through Google for the respective districts.

With regard to Government sources, the total number was 10,555 but the complete information was available only for 3,060 sources. The total targeted sample size was 1,507. It was decided that there should be at least one sample from each district. For selection of Government sources to be sampled, the three stage procedure similar to retail outlets was adopted.

Distribution of Samples

A total of 47,954 samples were drawn by 945 trained drug inspectors. Henceforth, drug inspectors are referred to as Sample Drawing Officers (SDOs). Each SDO was accompanied by either a representative of Civil Society or Pharmacy Council of India to ensure that the samples were drawn in an unbiased manner. Six formulations from six different molecules were planned to be drawn from each Source. The survey deployed 936 SDOs for drawing samples from Retail outlets and Government sources. Samples from Ports were drawn by 9 SDOs. Out of the 47,954 samples drawn under the survey, 47,012 samples drawn from 1421 Government sources and 5717 retail outlets

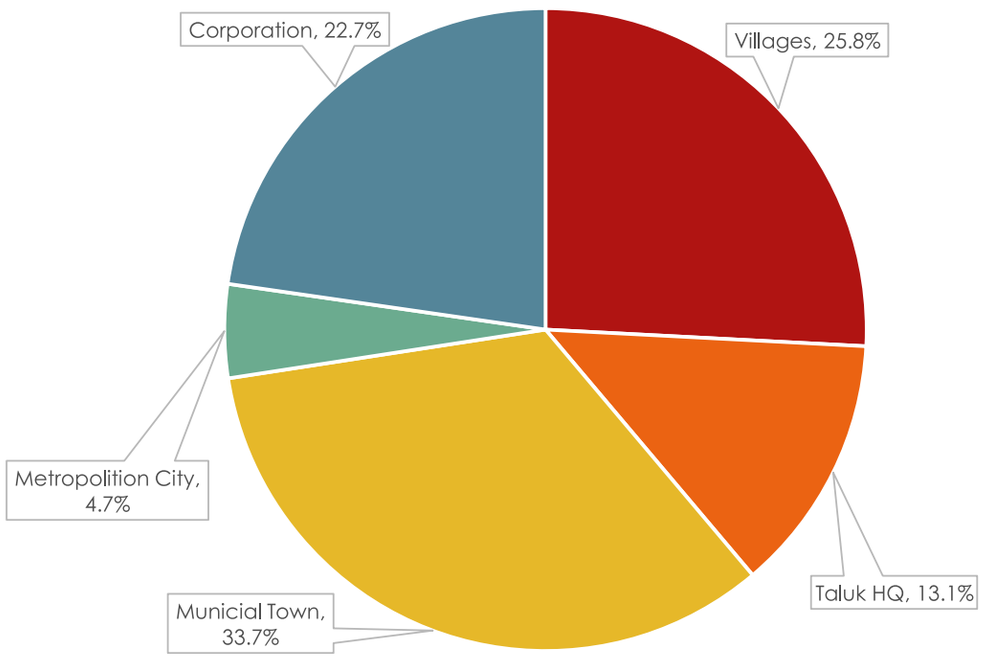
Exhibit 10.1
Source wise distribution of samples drawn under the survey



were subjected to laboratory test and analysis. Of these 33,656 were from retail outlets, 8,369 were from Government sources and 4,987 were from Ports (See Exhibit 10.1)

The 47,012 samples were from 1719 manufacturing units, however, 80% of these samples came from 197 manufacturing units. With respect to molecules, 47,012 samples were from 183 molecules and of these 80% of the samples came from 46 molecules. The samples from retail outlets and Government sources (42,025 samples) came from different types of locations. The location wise distribution of these samples is given in Exhibit 10.2. It may be noted that 38.8% of samples were drawn from rural areas (Villages & Taluk Hq).

Exhibit 10.2
Location wise distribution of samples drawn under the survey



Selection of Formulations

According to the sampling procedure, it was required to list all formulations available in adequate quantity under a selected molecule in Part-D of the data form and select one randomly with the specified procedure. For Ports this was not necessary as in that case samples had been drawn from every consignment.

Analysis of date expired samples

Five of the sampled formulations had expired at the time of sampling (see Exhibit 10.3.) Of these five, 3 were from retail outlets and 2 from Government sources. These samples had come from various locations.

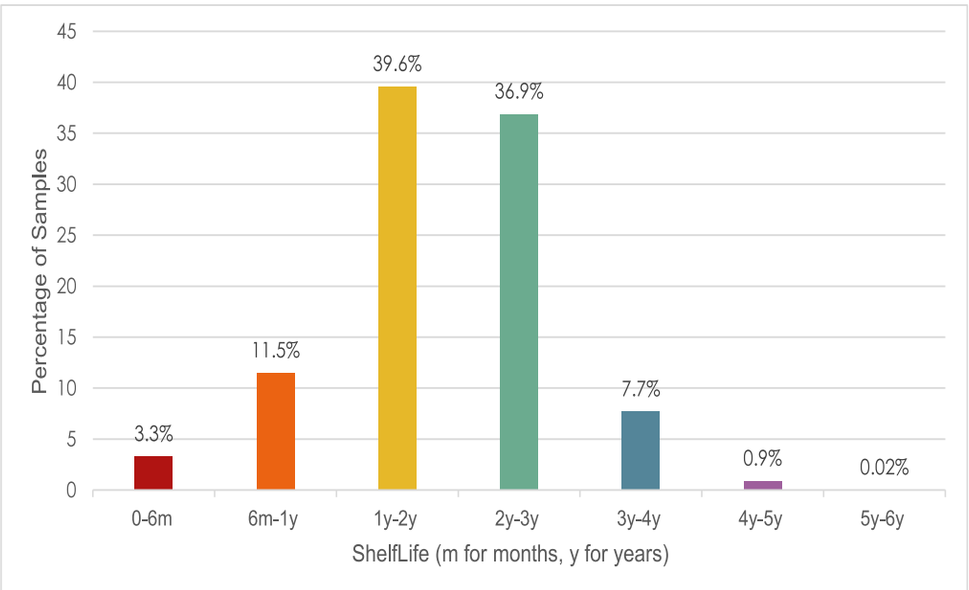
Exhibit 10.3
List of date expired samples drawn under the survey

S. No.	Generic Name	Dosage Form	Brand Name	Source	State	District	Place Type	Date of Sample Collection	Expiry Date
1.	Cephalexin	Capsules	Ceff 500	RO	Mizoram	Mamit	Taluk HQ	16-04-2015	Feb - 2015
2.	Ondansetron	Tablets	Rosetron-MD	RO	Himachal Pradesh	Sirmaur	Village	10-04-2015	March - 2015
3.	Pantoprazole	Tablets	Pentakind	RO	West Bengal	Howrah	Village	23-06-2015	March - 2015
4.	Misoprostol	Tablets	Misoclear	GS	Mizoram	Mamit	Taluk HQ	16-04-2015	Jan - 2015
5.	Oral Rehydration Salts	Oral Rehydration Salts	ORS	GS	Chattisgarh	Sukma	Municipal Town	13-04-2015	Feb - 2015

The distribution of shelf life of samples other than date expired is shown in Exhibit 10.4. About 14.8% of samples would have expired in less than one year and 76.5% of samples had remaining shelf life between 1 to 3 years. Also, about 8.62% of the samples had shelf life above 3 years.

Exhibit 10.4

Distribution of shelf life of samples (other than date expired)



Batch Consistency

In case of sampling from Ports, it was decided that three samples from each consignment would be drawn. This provided an opportunity to check batch consistency. For the other two sources i.e. retail outlets and government sources, this aspect could be inferred from the formulations that had come from:

- same batch number,
- same manufacturer,
- same molecule ID,
- same generic name or brand name,
- same dosage form and
- same strength

These formulations which had all these six fields common were called repeat samples. It was observed that from the retail outlets and Government sources, 9,262 samples were drawn from 3,854 repeat batches. That is, there were formulations with the same values for the six fields mentioned above. With regard to Port, 598 samples were drawn from 268 repeat batches. .

Hit Rates

SDOs were asked to draw samples from their assigned sources (the ones given to them with names and addresses). It was possible that samples were drawn from unassigned sources. This might have happened for various reasons such as: (i) the assigned Source was either non-existent or closed at the time of survey, (ii) the specified address was incorrect, (iii) location could not be reached due to weather conditions or other reasons, (iv) the SDO and/or the team members did not draw the samples from assigned outlets. According to the statistical principles, it is desirable that the percentage of assigned sources in the total samples drawn is high. We called this percentage as hit rate. Hit rate could be computed for each SDO or for a district or a State or for the entire set of drawn samples.

Out of the 5,717 retail outlets, 3,495 (61.3%) were the originally assigned and the balance 2222 (38.7%) were unassigned, i.e. hit rate for retail outlets was 61.3%. As per the sampling procedure, if an assigned outlet was not existent or closed at the time of survey visit, the SDOs were supposed to select a nearest retail outlet leaving the choice to the representative of Civil Society /Pharmacy Council of India as member of the team.

The procedure for drawing samples from the Ports was described in the chapter of main survey. Samples were drawn from all consignments pertaining to the 224 molecules. A total of 4,987 samples were collected from the ports by nine SDOs.

RETAIL OUTLETS

The survey data comprises mainly three parts:

Part-A data: This contains stage one data, namely,

- Outlet ID (outlet ID is identified uniquely by the Data Form number),
- State/UT,
- District and type of location of the outlet,
- ID of the SDO who visited the outlet, outlet address,

- Whether the outlet visited was the assigned one or not, if the outlet was not the assigned one then the reason for choosing the unassigned one, and
- Sample collection date.

Part-B data: In part-B data, the particulars of the collected sample were captured. It contained:

- Sample ID,
- Serial Number of the molecule (from list of molecules in Part C of the Data Form),
- Molecule ID,
- Generic and brand names,
- Batch number of the sample,
- Name, license number, address and country of the manufacturer of the sample,
- Date of manufacturing, expiry date and the date of drawl of sample,
- Sample dosage form,
- Total quantity of the sample available in the outlet,
- Quantity of sample drawn,
- Number of formulations with adequate quantity under the molecule ID of the sample.

Laboratory Data: For each sampled formulation, laboratory data provides data on:

- Sample ID,
- Lab ID where the test is performed,
- Results of various tests performed,
- Protocol ID for the tests, and
- Whether the sampled formulation was NSQ or not.

For all tests performed, the test results provided were binary in nature, that is, it was only mentioned whether a sampled formulation passed (complied) or not (not complied) in a particular test.

Analysis of Part-A Data

Coverage of Outlets and Hit Rates

Samples from 5,717 retail outlets across the country were collected by 899 SDOs. The 5,717 outlets were from 640 districts. The location-wise break-up of the 5,717 outlets is given Exhibit 10.5. Exhibit 10.6 summarizes some important parameters of the sample collection.

Exhibit 10.5
Location wise percentages of samples for Retail Outlets

S. No.	Place Type	No. of Outlets	Percentage
1.	Corporation	1387	24.26
2.	Metropolitan Cities	291	5.09
3.	Municipal Towns	1782	31.17
4.	Taluk Headquarters	686	12.00
5	Villages	1571	27.48
	Total	**5717**	**100.00**

Exhibit 10.6
State wise summary of information captured in Part A of data form from Retail Outlets

S. No.	State	Outlets in State	Outlets Sampled	No. of SDOs involved	Assigned Outlets	Hit Rate
1	Andaman and Nicobar Islands	63	6	1	3	50
2	Andhra Pradesh	33656	579	47	118	20.4
3	Arunachal Pradesh	725	24	4	15	62.5
4	Assam	5156	60	16	41	68.3
5	Bihar	28651	288	43	154	53.5
6	Chandigarh	492	7	2	4	57.1
7	Chattisgarh	7755	93	18	65	69.9
8	Dadra and Nagar Haveli	95	3	1	2	66.7
9	Daman and Diu	66	6	1	4	66.7
10	Delhi	10331	77	11	42	54.5

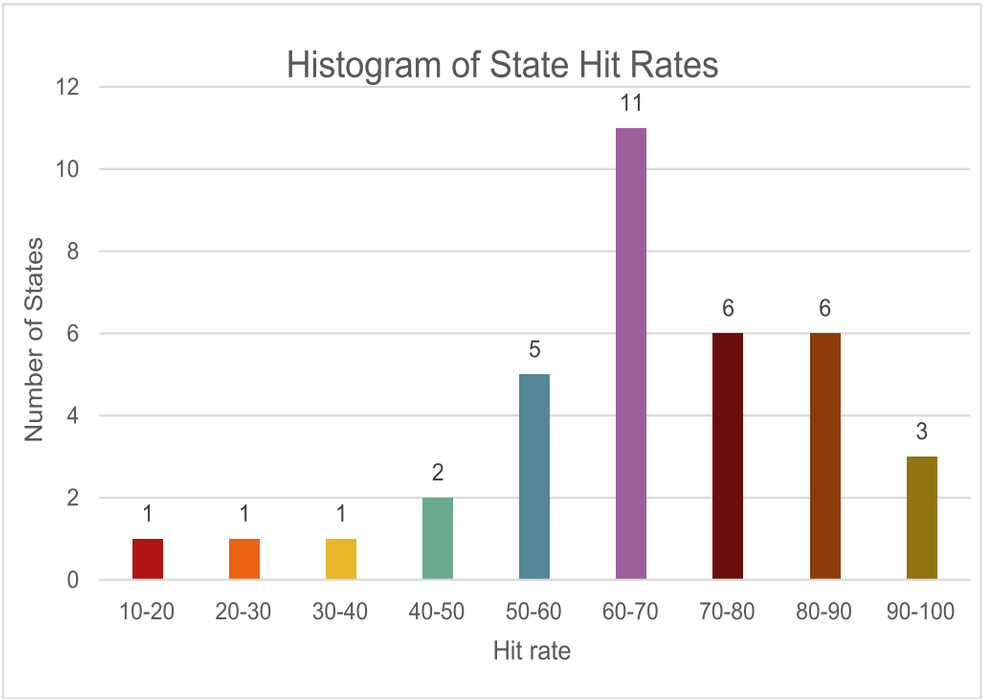
S. No.	State	Outlets in State	Outlets Sampled	No. of SDOs involved	Assigned Outlets	Hit Rate
11	Goa	536	6	2	4	66.7
12	Gujarat	17213	230	56	199	86.5
13	Haryana	10931	142	20	108	76.1
14	Himachal Pradesh	2688	27	9	24	88.9
15	Jammu and Kashmir	7699	74	21	50	67.6
16	Jharkhand	8319	387	28	223	59.9
17	Karnataka	22595	276	49	234	84.8
18	Kerala	27520	256	38	209	81.6
19	Lakshadweep	1	1	1	1	100
20	Madhya Pradesh	18654	144	34	108	75
21	Maharashtra	48558	652	88	513	78.7
22	Manipur	1840	13	4	2	15.4
23	Meghalaya	208	15	6	14	93.3
24	Mizoram	325	17	7	11	64.7
25	Nagaland	245	22	6	18	81.8
26	Orissa	13218	160	40	118	73.8
27	Puducherry	428	13	5	12	92.3
28	Punjab	13078	117	31	87	74.4
29	Rajasthan	18515	249	55	171	68.7
30	Sikkim	236	5	2	2	40
31	Tamilnadu	27296	340	69	235	69.1
32	Telangana	29223	367	55	168	45.8
33	Tripura	316	16	4	13	81.3
34	Uttar Pradesh	51890	497	72	338	68
35	Uttarakhand	3958	42	4	32	76.2
36	West Bengal	45023	506	50	153	30.2
	Total	**457503**	**5717**	**899**	**3495**	**61.3**

Hit Rates

Out of 6,081 retail outlets targeted, samples were drawn from 5,717 retail outlets. Of these 5,717 retail outlets from which samples were drawn, 3,495 were the assigned retail outlets and the balance 2,222 retail outlets were unassigned ones. Barring Lakshadweep which had only one assigned outlet, the overall hit rate is 61.3%. The hit rates of the States/UTs varied from 15.4 to 93.3 percent. Hit rates of States/UTs can be seen in Exhibit 10.6. Fifty percent of the States/UTs had hit rate above 68% and 75 percent of the states have

hit rate above 57%. Hit rates were very high (>80%) for Gujarat, Himachal Pradesh, Kerala, Karnataka, Lakshadweep, Meghalaya, Nagaland, Puducherry and Tripura. Distribution of hit rate of States/UTs is shown in Exhibit 10.7. Hit rate in 11 States/UTs was between 60-70% and 3 States/UTs had a hit rate between 90-100%. One State each had a hit rate between 10-20%, 20-30% and 30-40% respectively. The data show that 26 States/UTs (72.2%) out of 36 had a hit rate of more than 60%.

Exhibit 10.7
Hit rate distribution of 36 States/UTs for Retail Outlets



Analysis of Part-B Data

In Part-B, data on each sampled formulation was captured. From the 5,717 retail outlets, a total of 33,656 samples were drawn from 177 different molecules (79%) out of the 224. This means that 47 of the 224 molecules could not be drawn in the survey. List of molecules for which samples were drawn in the survey is given in Exhibit 10.8.

Exhibit 10.8
List of molecules for which samples were drawn from retail outlets under the survey

S.No.	ID	Drug Molecule
1	M001	25% Dextrose
2	M003	5-Fluorouracil
3	M006	Acetyl Salicylic Acid
4	M007	Acyclovir
5	M008	Adrenaline Bitartrate
6	M009	Albendazole
7	M010	Allopurinol
8	M011	Alprazolam
9	M012	Aluminium Hydroxide+Magnesium Hydroxide
10	M013	Amikacin
11	M014	Amiodarone
12	M015	Amitriptyline
13	M016	Amlodipine
14	M017	Amlodipine+Losartan Potassium
15	M018	Amoxicillin
16	M019	Amoxicillin+Clavulinic Acid
17	M020	Ampicillin
18	M022	Aspirin+Caffeine
19	M023	Atenolol
20	M024	Atorvastatin
21	M025	Atracurium Besylate
22	M027	Azathioprine
23	M028	Azithromycin
24	M029	Beclomethasone Dipropionate
25	M030	Benzathine Benzylpenicillin
26	M031	Bisacodyl

S.No.	ID	Drug Molecule
27	M034	Carbamazepine
28	M035	Carbidopa+Levodopa Tablets
29	M036	Carbimazole
30	M037	Cefixime
31	M038	Cefotaxime
32	M039	Ceftazidime
33	M040	Ceftriaxone
34	M041	Cephalexin
35	M042	Cetirizine
36	M044	Chloroquine Phosphate
37	M045	Chlorpheniramine Maleate
38	M046	Chlorpromazine Hydrochloride
39	M048	Ciprofloxacin Hydrochlorid
40	M051	Clindamycin
41	M052	Clofazimine
42	M053	Clomiphene Citrate
43	M054	Clopidogrel
44	M055	Clotrimazole
45	M058	Colchicine
46	M060	Compound Sodium Chloride+Dextrose Injection
47	M062	Concentrated Vitamin A+D Solution
48	M063	Cyclophosphamide
49	M064	Danazol
50	M065	Dapsone
51	M067	Dexamethasone
52	M068	Dexchlorpheniramine Maleate
53	M069	Dextromethorphan
54	M070	Dextrose Injection

S.No.	ID	Drug Molecule
55	M073	Dextrose+Sodium Chloride Injection (5% & 0.9%)
56	M074	Dextrose+Sodium Chloride Injection
57	M075	Diazepam
58	M076	Diclofenac
59	M077	Dicyclomine Hydrochloride
60	M079	Diethylcarbamazine Citrate
61	M080	Digoxin
62	M082	Diltiazem
63	M083	Dobutamine
64	M084	Domperidone
65	M085	Dopamine Hydrochloride
66	M086	Doxycycline
67	M087	Efavirenz
68	M088	Efavirenz+Emtricitabine+Tenofovir
69	M091	Enalapril Maleate
70	M092	Erythromycin Estolate
71	M093	Ethambutol
72	M094	Ethambutol+Isoniazid
73	M095	Ethambutol+Isoniazid+Pyrazinamide+ Rifampicin
74	M096	Ethambutol+Isoniazid+Rifampicin
75	M097	Ethinylestradiol
76	M098	Ethinylestradiol+Levonorgesterol
77	M099	Ethinylestradiol+Norethisterone
78	M100	Etophylline+Theophylline Prolonged-release
79	M101	Etoposide
80	M102	Famotidine
81	M103	Fluconazole

S.No.	ID	Drug Molecule
82	M104	Fluoxetine Hydrochloride
83	M105	Flutamide
84	M106	Folic Acid+Iron
85	M108	Furosemide
86	M109	Gentamicin
87	M110	Glibenclamide
88	M111	Glyceryl Trinitrate
89	M112	Griseofulvin
90	M113	Haloperidol
91	M114	Hydrochlorothiazide+Irbesartan
92	M115	Hydrochlorothiazide+Losartan Potassium
93	M116	Hydrochlorothiazide+Ramipril
94	M117	Hydrochlorothiazide+Valsartan
95	M118	Hydrochlorthiazide
96	M120	Hydrocortisone Sodium Succinate
97	M122	Hyoscine Butyl Bromide
98	M123	Ibuprofen
99	M124	Imatinib
100	M125	Imipramine
101	M127	Iodine
102	M128	Isoniazid
103	M129	Isoniazid+Pyrazinamide+Rifampicin
104	M130	Isoniazid+Rifampicin
105	M132	Isosorbide Mononitrate/Dinitrate
106	M133	Lamivudine
107	M134	Lamivudine+Nevirapine+Stavudine
108	M135	Lamivudine+Nevirapine+Zidovudine
109	M136	Lamivudine+Stavudine

S.No.	ID	Drug Molecule
110	M138	Lamivudine+Zidovudine
111	M139	Levothyroxine
112	M140	Lignocaine + Adrenaline Injection
113	M141	Lignocaine Hydrochloride
114	M142	Lithium Carbonate
115	M143	Lopinavir+Ritonavir
116	M144	Lorazepam
117	M145	Losartan Potassium
118	M146	Magnesium Sulphate
119	M147	Mannitol
120	M148	Medroxy Progesterone Acetate
121	M152	Mesna
122	M153	Metformin
123	M154	Methotrexate
124	M155	Methyl Prednisolone
125	M156	Methyldopa
126	M157	Methylergometerin
127	M158	Metoclopramide
128	M159	Metoprolol
129	M160	Metronidazole
130	M161	Mifepristone
131	M162	Misoprostol
132	M164	Neostigmine
133	M166	Nifedipine
134	M167	Nitrofurantoin
135	M168	Norethisterone
136	M170	Ofloxacin
137	M171	Olanzapine

S.No.	ID	Drug Molecule
138	M172	Omeprazole
139	M173	Ondansetron
140	M174	Oral Rehydration Salts
141	M175	Oxytocin
142	M176	Pantoprazole
143	M177	Paracetamol
144	M179	Pheniramine Maleate
145	M180	Phenobarbitone
146	M181	Phenytoin Sodium
147	M182	Piperazine
148	M183	Potassium Chloride Injection
149	M185	Prednisolone
150	M186	Primaquine
151	M189	Promethazine
152	M190	Pyrazinamide
153	M191	Pyridostigmine
154	M193	Pyrimethamine+Sulfadoxine
155	M194	Quinine Sulphate
156	M196	Ranitidine
157	M197	Rifampicin
158	M198	Ringer Lactate Injection
159	M199	Ritonavir
160	M200	Salbutamol Sulphate
161	M203	Sodium Bicarbonate Injection
162	M204	Sodium Chloride Injection
163	M206	Sodium Valproate
164	M207	Spironolactone
165	M209	Streptomycin Sulphate

S.No.	ID	Drug Molecule
166	M211	Sulfasalazine
167	M212	Sulphadiazine
168	M213	Sulphamethoxazole+Trimethoprim
169	M214	Tamoxifen Citrate
170	M215	Terbutaline Sulphate
171	M216	Testosterone
172	M217	Tramadol
173	M218	Vecuronium Bromide
174	M219	Verapamil
175	M222	Water for Injection
176	M223	Zidovudine
177	M224	Zinc Sulfate

Distribution of Number of Samples in retail outlets

Six samples were targeted from each retail outlet. Out of 5,717 retail outlets, 6 samples were drawn from each of 5,232 retail outlets, 5 samples were drawn from each of 383 retail outlets and 4 or fewer samples were drawn from each of 102 retail outlets. Out of the 5,717 retail outlets, samples were drawn from different molecule IDs in 5,710 retail outlets. Only in 7 retail outlets, more than one formulation from the same molecule ID were drawn. The results for these 7 retail outlets are listed in Exhibit 10.9.

Exhibit 10.9
Seven outlets in which more than one formulation was selected from same molecule

S. No.	Form No.	Molecule ID	No. Formulation sampled	State	SDO ID
1.	F1195	M019	3	Jammu and Kashmir	335
1.	F1195	M103	2	Jammu and Kashmir	335
2.	F2225	M028	2	Karnataka	86
3.	F2825	M160	2	West Bengal	1001
4.	F3865	M048	2	Uttar Pradesh	514
5.	F4029	M037	2	Haryana	43
6.	F4259	M160	2	Delhi	664
7.	F4789	M145	2	Kerala	658

Inclusion Probabilities of Molecule IDs

The sampling procedure provided equal opportunity to all the 224 molecules for inclusion in the sample. However, the selection depended on the availability of molecules in the outlets. In all, 177 molecules got included in the sampled formulations from retail outlets. From the sampled data, we could compute the chance of molecule inclusion in the sample. This chance varied from 0 to 6 percent. Some of the molecules along with their inclusion chances (specified as percentage) are shown in Exhibit 10.10 List of 47 molecules which were not picked up during sampling is presented in Exhibit 10.11.

Exhibit 10.10
Molecule inclusion chances for retail outlets

Some of the Molecules with high chance					Some of the Molecules with low chance				
S. No.	ID	Generic Name	No. of Formulations in the Sample	Inclusion Chances	S. No.	ID	Generic Name	No. of Formulations in the Sample	Inclusion Chances
1.	M177	Paracetamol	1956	5.81	1.	M183	Potassium Chloride Injection	5	0.01
2.	M196	Ranitidine	1886	5.60	2.	M058	Colchicine	9	0.03
3.	M042	Cetirizine	1425	4.23	3.	M064	Danazol	9	0.03
4.	M172	Omeprazole	1059	3.15	4.	M085	Dopamine Hydrochloride	9	0.03
5.	M160	Metronidazole	1049	3.12	5.	M203	Sodium Bicarbonate Injection	9	0.03
6.	M185	Prednisolon	1039	3.09	6.	M215	Terbutaline Sulphate	9	0.03
7.	M067	Dexamethasone	1036	3.08	7.	M077	Dicyclomine Hydrochloride	10	0.03
8.	M016	Amlodipine	1024	3.04	8.	M162	Misoprostol	12	0.04
9.	M170	Ofloxacin	800	2.38	9	M074	Dextrose+ Sodium Chloride Injection	14	0.04

Exhibit 10.11
List of molecules which were not picked up during sampling

S.No.	ID	Drug Moleule
1.	M002	5-Amino Salicylic Acid (5-ASA)
2.	M004	Abacavir+Lamivudine Tablets
3.	M005	Abacavir+Lamivudine+Zidovudine Tablets
4.	M021	Artesunate+Pyrimethamine+Sulfadoxine
5.	M026	Atropine+Morphine Injection
6.	M032	Busulphan
7.	M033	Calcium Folinate Injection
8.	M043	Chlorambucil
9.	M047	Cilastatin+Imipenem Injection
10.	M049	Cisplatin
11.	M050	Clavulanic Acid+Ticarcillin Injection
12.	M056	Cloxacillin
13.	M057	Codeine Phosphate
14.	M059	Colchicine+Probenicid Tablets
15.	M061	Compound Sodium Lactate+Dextrose Injection
16.	M066	Daunorubicin
17.	M071	Dextrose+Half strength Compound Sodium Lactate Injection
18.	M072	Dextrose+Modified Compound Sodium Lactate Injection
19.	M078	Didanosine
20.	M081	Diloxanide Furoate
21.	M089	Efavirenz+Lamivudine +Tenofovir+Dipivoxil Fumarate Tablets
22.	M090	Emtricitabine+Tenofovir Tablets
23.	M107	Fructose+Sodium Chloride Injection
24.	M119	Hydrocortisone Ointment+Quiniodochlor
25.	M121	Hydroxychloroquine Phosphate

S.No.	ID	Drug Moleule
26.	M126	Indinavir
27.	M131	Isoniazid+Thiacetazone Tablets
28.	M137	Lamivudine+Tenofovir Tablets
29.	M149	Mefloquine
30.	M150	Melphalan Tablet Only
31.	M151	Mercaptopurine
32.	M163	Nelfinavir
33.	M165	Nevirapine
34.	M169	Nystatin
35.	M178	Pentamidine Isothionate
36.	M184	Praziquantel
37.	M187	Procainamide Hydrochloride
38.	M188	Procaine and Adrenaline Injection
39.	M192	Pyrimethamine
40.	M195	Raloxifene
41.	M201	Salicylic Acid Paste+Zinc Oxide
42.	M202	Saquinavir
43.	M205	Sodium Nitroprusside
44.	M208	Stavudine
45.	M210	Succinyl Choline Chloride
46.	M220	Vinblastine Sulphate
47.	M221	Vincristine

Coverage of Dosage Forms

Most of the formulations in the samples collected were in the form of tablets. See Exhibit 10.12 for the Pareto picture of the dosage form distribution. Complete list of dosage forms is given in Exhibit 10.13.

Exhibit 10.12
Dosage form distribution of the samples

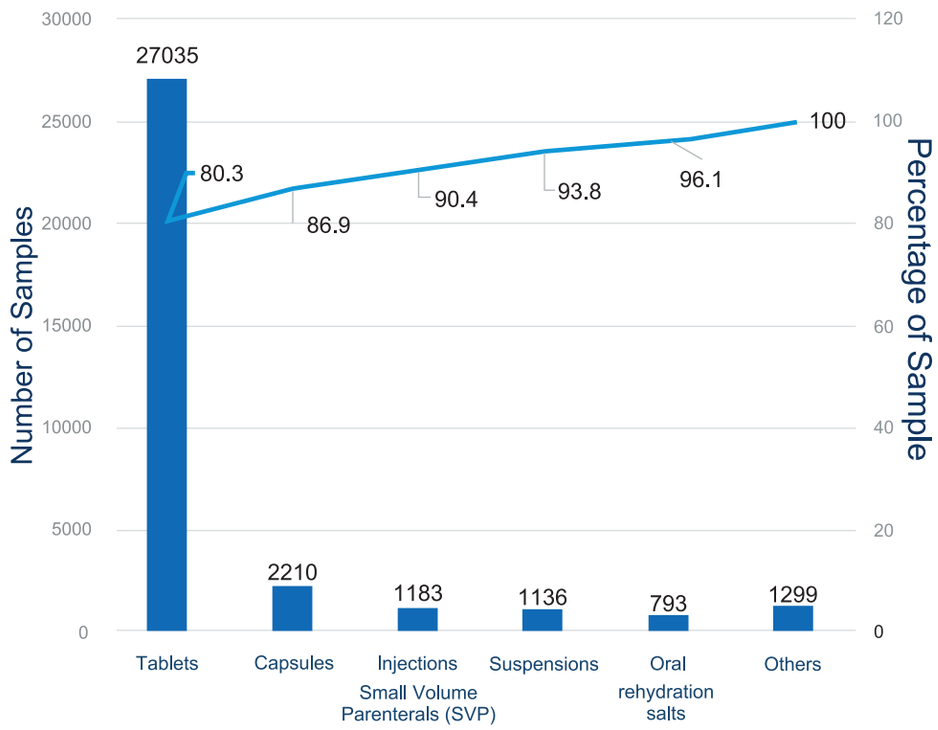


Exhibit 10.13
Summary of dosage forms in the samples from retail outlets

S.No.	Dosage Form	Count	Percentage
1	Tablets	27035	80.33
2	Capsules	2210	6.57
3	Injections Small Volume Parenterals (SVP)	1183	3.52
4	Suspensions	1136	3.38
5	Oral Rehydration Salts	793	2.36
6	Liquids	473	1.41
7	Injections Large Volume Parenterals (LVP)	305	0.91
8	Powder for Injections	134	0.4

S.No.	Dosage Form	Count	Percentage
9	Dispersible Tablets	97	0.29
10	Powder for Oral Liquids	70	0.21
11	Cream (non-sterile)	48	0.14
12	Gel (non-sterile)	47	0.14
13	Eye Drop	42	0.12
14	Ointment (Non-sterile)	28	0.08
15	Granules (Non-sterile)	11	0.03
16	Gel (sterile)	10	0.03
17	Ointment (sterile)	8	0.02
18	Paste (Non-sterile)	8	0.02
19	Bulk Drugs	6	0.02
20	Inhalers	3	0.01
21	Lozenges	3	0.01
22	Suppositories	3	0.01
23	Antacids Sachets	1	0
24	Ear Drops	1	0
25	Orally Disintegrating Strips	1	0

Analysis of Lab Data

In this section the results on quality of medicines are presented with respect to two aspects viz. the shelf life and the results of lab tests.

Lab Test Results and NSQ Proportions

The samples drawn under survey were subjected to test/analysis at 10 Central/ State Government Drug Testing Laboratories. A total of 69 different tests were performed on samples in the labs. Not all the 69 tests were applicable to all formulations. Samples from retail outlets failed in one or more of the 28 out of these 69 tests. The list of these 28 tests and the number of tests that samples failed in each of these 28 tests are summarized in Exhibit 10.14. From this figure, it can be seen that in case of retail outlets, failure due to dissolution test contributed to 33.6% of non-compliance. Failure in assay contributed to 22.6% of non-compliance and failure in description contributed to 11.9% of non-compliance, and so on.

Exhibit 10.14
Contribution of tests to failure of samples from Retail Outlets

S.No.	Tests performed on samples	No. of tests not complied	Percentage of non-compliance
1	Dissolution	420	33.6
2	Assay	283	22.6
3	Description	149	11.9
4	Related Substances	89	7.1
5	Particulate matter	72	5.8
6	Uniformity of Content	35	2.8
7	Water Content	32	2.6
8	Disintegration Test	28	2.2
9	Clarity of Solution	23	1.8
10	Sterility	22	1.8
11	pH	16	1.3
12	Bacterial Endotoxin Test	14	1.1
13	Uniformity of Weight	13	1
14	Other tests	11	0.9
15	Seal Test	5	0.4
16	Free Salicylic Acid	5	0.4
17	Extractable Volume	5	0.4
18	Loss on Drying	4	0.3
19	Uniformity of filled Weight	4	0.3
20	Particulate contamination	4	0.3
21	Identification by IR	4	0.3
22	Uniformity of Dispersion	3	0.2
23	Identification by HPLC	3	0.2
24	Identification by TLC	2	0.2
25	Impurity	2	0.2
26	Uniformity of Volume	1	0.1
27	Weight per ML	1	0.1
28	Appearance of Solution	1	0.1
	Total	**1251**	**100**

Out of the 33,656 samples tested from retail outlets, 1011 failed in one or more of the 28 tests and were declared as NSQ. This information is summarized in Exhibit 10.15. The break-up of the results for the 1011 samples is presented in Exhibit 10.16.

Exhibit 10.15
Contribution of tests to failures of samples from Retail Outlets

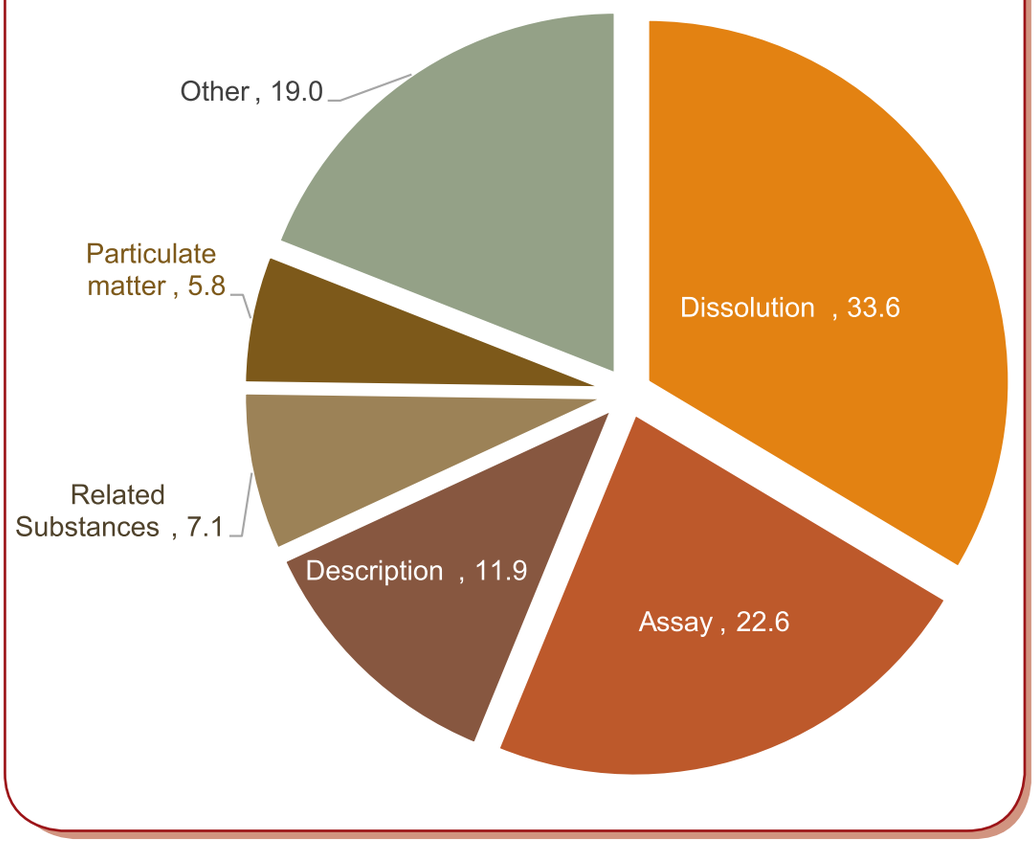


Exhibit 10.16
Break-up of 1011 NSQ samples from retail outlets that have failed in one or more tests

Number of tests not complied	1	2	3	4	Total
Number of sampled formulation	809	166	31	5	1011

The estimated NSQ percentage for retail outlets in India is 3% with the upper 95% confidence limit of 3.19%. The estimates were also obtained for each State. Exhibit 10.17 presents the estimated NSQ percentages with approximate upper and lower 95% confidence limits for the states.

Exhibit 10.17
Estimates of NSQ percentages for retail outlets with approximate upper and lower 95% confidence limit (CL)

S. No.	State*	No. of Formulations	Number of NSQ Samples	NSQ %	Lower 95% CL	Upper 95% CL
1	ANDAMAN AND NICOBAR ISLANDS	35	0	0.00	0.00	0.00
2	ANDHRA PRADESH	3437	132	3.84	3.20	4.48
3	ARUNACHAL PRADESH	128	3	2.34	0.00	4.96
4	ASSAM	348	10	2.87	1.12	4.63
5	BIHAR	1694	53	3.13	2.30	3.96
6	CHANDIGARH	40	1	2.50	0.00	7.34
7	CHATTISGARH	549	16	2.91	1.51	4.32
8	DADRA AND NAGAR HAVELI	18	0	0.00	0.00	0.00
9	DAMAN AND DIU	36	1	2.78	0.00	8.15
10	DELHI	453	7	1.55	0.41	2.68
11	GOA	36	0	0.00	0.00	0.00
12	GUJARAT	1372	65	4.74	3.61	5.86
13	HARYANA	842	33	3.92	2.61	5.23
14	HIMACHAL PRADESH	161	5	3.11	0.43	5.79
15	JAMMU AND KASHMIR	441	15	3.40	1.71	5.09
16	JHARKHAND	2294	40	1.74	1.21	2.28
17	KARNATAKA	1633	42	2.57	1.80	3.34
18	KERALA	1523	30	1.97	1.27	2.67
19	LAKSHADWEEP	6	1	16.67	0.00	46.49
20	MADHYA PRADESH	853	19	2.23	1.24	3.22
21	MAHARASHTRA	3803	121	3.18	2.62	3.74
22	MANIPUR	76	4	5.26	0.24	10.28

S. No.	State*	No. of Formulations	Number of NSQ Samples	NSQ %	Lower 95% CL	Upper 95% CL
23	MEGHALAYA	84	5	5.95	0.89	11.01
24	MIZORAM	102	9	8.82	3.32	14.33
25	NAGALAND	117	8	6.84	2.26	11.41
26	ORISSA	954	35	3.67	2.48	4.86
27	PUDUCHERRY	78	4	5.13	0.23	10.02
28	PUNJAB	691	29	4.20	2.70	5.69
29	RAJASTHAN	1483	44	2.97	2.10	3.83
30	SIKKIM	29	1	3.45	0.00	10.09
31	TAMILNADU	2013	77	3.83	2.99	4.66
32	TELANGANA	2137	62	2.90	2.19	3.61
33	TRIPURA	96	5	5.21	0.76	9.65
34	UTTAR PRADESH	2871	85	2.96	2.34	3.58
35	UTTARAKHAND	231	7	3.03	0.82	5.24
36	WEST BENGAL	2992	42	1.40	0.98	1.83
	All Retail Outlets	**33656**	**1011**	**3.00**	**2.83**	**3.19**

National average of NSQ from retail Sources is 3.00%. Rows in Pink have NSQ percentage above National average and Rows in green have NSQ percentages below National average.

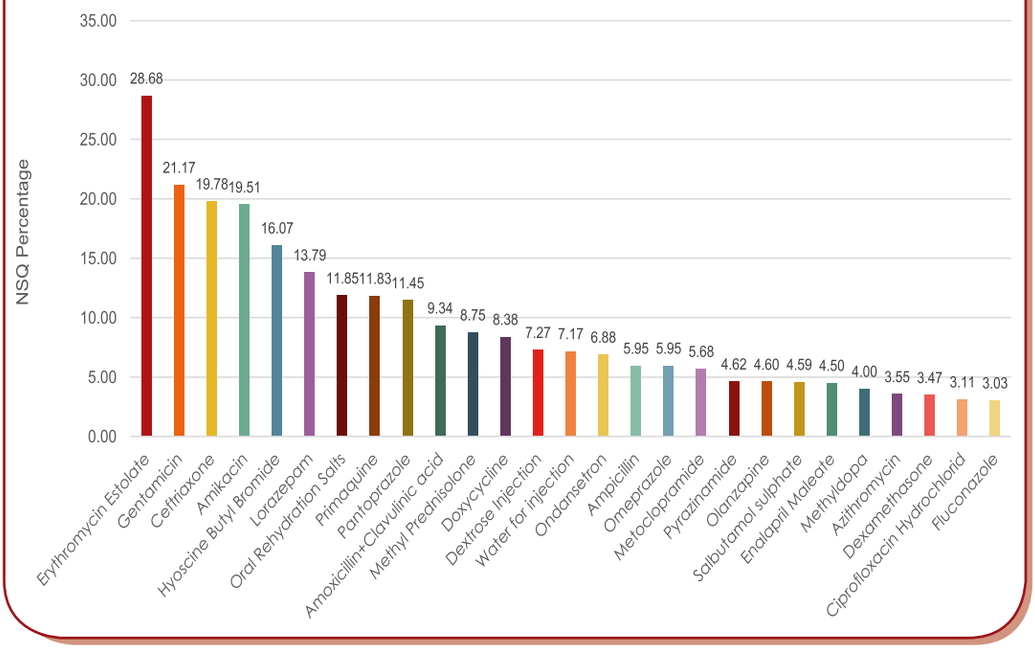
Note: When proportions are estimated, larger sample sizes yield more precise estimates. The precision is expressed in terms of confidence intervals. When the sample is large, we have narrow confidence interval, and when the sample size is small we have wide confidence interval. For instance, NSQ of 3.84% for Andhra Pardesh has a confidence interval of 3.2 - 4.48 based on the sample size of 3437 whereas NSQ of 16.67% for Lakshadweep has confidence interval of 0 - 46.49 based on a sample size of 6. Thus the estimate NSQ percentage is more precise for Andhra Pradesh compared to that of Lakshdweep.

The NSQ percentages were also estimated for molecules with at least 100 samples from retail outlets. These are shown in Exhibit 10.18. Few examples are hereunder:

- Erythromycin Estolate: 39 (28.68%) out of 136 samples drawn from retail outlets under the survey were declared NSQ upon laboratory testing.
- Gentamicin: 29 (21.17%) out of 137 samples drawn from retail outlets under the survey were declared NSQ upon laboratory testing.
- Amikacin: 32 (19.51%) out of 164 samples drawn from retail outlets under the survey were declared NSQ upon laboratory testing.

- Oral Rehydration Salts: 94 (11.85%) out of 793 samples drawn from retail outlets under the survey were declared NSQ upon laboratory testing.

Exhibit 10.18
Molecules with more than 3% NSQ samples (total samples ≥ 50)



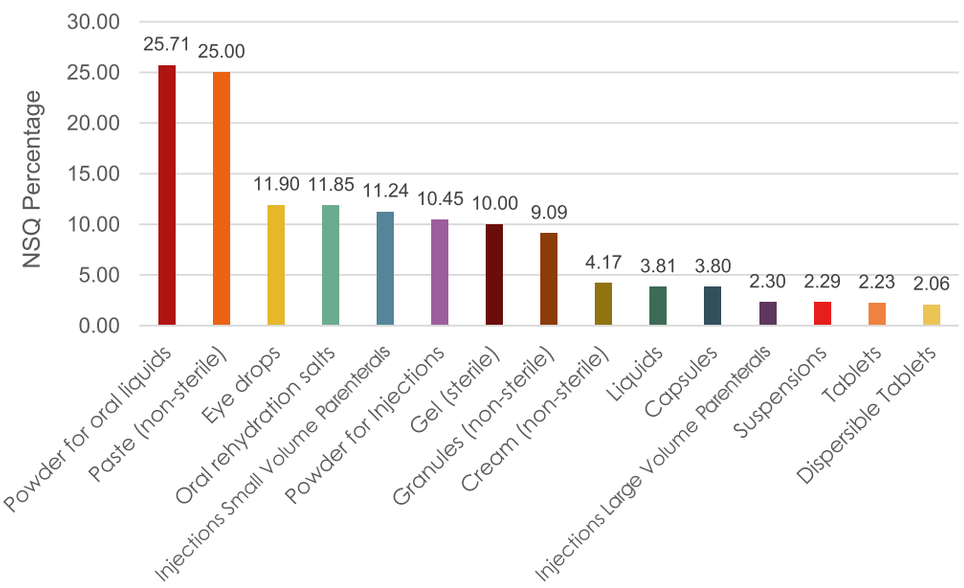
The NSQ percentages with respect to dosage forms (with at least 1 NSQ samples) from retail outlets are shown in Exhibit 10.19. Again it can be inferred that NSQ percentage for some dosage forms were generally very high, as shown hereunder:

Powder for oral liquids: 18 (25.71%) out of 70 samples drawn from retail outlets under the survey were declared NSQ upon laboratory testing.

Paste (non-sterile): 2 (25%) out of 8 samples drawn from retail outlets under the survey were declared NSQ upon laboratory testing.

Eye Drops: 5 (11.90%) out of 42 samples drawn from retail outlets under the survey were declared NSQ upon laboratory testing.

Exhibit 10.19
The NSQ percentages for dosage forms with at least 1 NSQ sample



NSQ percentages for manufacturing units are shown in Exhibit 10.20 and 10.21 . It can also be inferred from data that drugs supplied by some of the manufacturing units had very high NSQ percentages as shown hereunder:

HALEWOOD LABORATORIES PVT LTD.: 46 (64.79%) out of 71 samples of the manufacturer drawn from retail outlets under the survey were declared NSQ upon laboratory testing.

SHIVA BIOGENETIC PHARMACEUTICALS PVT LTD.: 25 (40.32%) out of 62 samples of the manufacturer drawn from retail outlets under the survey were declared NSQ upon laboratory testing.

RIDLEY LIFE SCIENCE PVT LTD.: 11 (21.15%) out of 52 samples of the manufacturer drawn from retail outlets under the survey were declared NSQ upon laboratory testing.

INDCHEMIE HEALTH SPECIALITIES PVT LTD.: 19 (19%) out of 100 samples of the manufacturer drawn from retail outlets under the survey were declared NSQ upon laboratory testing.

Exhibit 10.20
Manufacturing units with sample size more than 50 and NSQ Percentage above retail average of 3.00%

S. No.	Manufacturing Unit	State	No. of samples	No. of NSQ Samples	% NSQ
1	HALEWOOD LABORATORIES PVT LTD	GUJARAT	71	46	64.79
2	SHIVA BIOGENETIC PHARMACEUTICALS PVT LTD	HIMACHAL PRADESH	62	25	40.32
3	RIDLEY LIFE SCIENCE PVT LTD	DELHI	52	11	21.15
4	INDCHEMIE HEALTH SPECIALITIES PVT LTD	SIKKIM	100	19	19.00
5	NOEL PHARMA INDIA PVT LTD	HIMACHAL PRADESH	73	12	16.44
6	SCOTT EDIL PHAMACIA LTD	HIMACHAL PRADESH	127	20	15.75
7	ZEE LABORATORIES LTD	HIMACHAL PRADESH	56	8	14.29
8	CRESCENT THERAPEUTICS LTD	HIMACHAL PRADESH	100	13	13.00
9	LABORATE PHARMACEUTICALS INDIA LTD	HIMACHAL PRADESH	85	10	11.76
10	NITIN LIFESCIENCES LTD	HARYANA	61	6	9.84
11	R.K. LABORATORIES PVT LTD	HIMACHAL PRADESH	52	5	9.62
12	BIOCHEM PHARMACEUTICALS INDUSTRIES LTD	DAMAN AND DIU	67	5	7.46
13	SKYMAP PHARMACEUTICALS LTD	UTTARAKHAND	84	5	5.95
14	G S PHARMACEUTICALS PVT LTD	UTTARAKHAND	79	4	5.06
15	INNOVA CAPTAB PVT LTD	HIMACHAL PRADESH	67	3	4.48
16	ALEMBIC PHARMACEUTICALS LTD	HIMACHAL PRADESH	231	9	3.90
17	CIPLA LTD	DAMAN AND DIU	114	4	3.51
18	PARENTERAL DRUGS INDIA LTD	HIMACHAL PRADESH	122	4	3.28

Fig 10.21
Manufacturing units with sample size between 25-49 and NSQ Percentage above retail average of 3.00%

	Manufacturing Unit	State	No. of samples	NSQ Samples	%NSQ
1	ACME DIET CARE PVT LTD	GUJARAT	32	29	90.63
2	VINTOCHEM PHARMACEUTICALS	MADHYA PRADESH	35	21	60.00
3	PFIZER LIMITED	MAHARASHTRA	46	26	56.52
4	KORTEN PHAMACEUTICALS PVT LTD	MAHARASHTRA	29	10	34.48
5	EG PHARMACEUTICALS	HIMACHAL PRADESH	27	5	18.52
6	SAITECH MEDICARE PVT LTD	HIMACHAL PRADESH	31	4	12.90
7	TIRUPATI MEDICARE LTD	HIMACHAL PRADESH	32	4	12.50
8	BIOGENETIC DRUGS PVT LTD	HIMACHAL PRADESH	36	3	8.33
9	COTEC HEALTHCARE PVT LTD	UTTARAKHAND	25	2	8.00
10	PURE & CARE HEALTHCARE PVT LTD	UTTARAKHAND	38	3	7.89
11	BRD MADILABS	HIMACHAL PRADESH	27	2	7.41
12	MEPROMAX LIFESCIENCES PVT LTD	UTTARAKHAND	30	2	6.67
13	SUN PHARMA LABORATORIES LTD	GUJARAT	30	2	6.67
14	NEON LABORATORIES LTD	MAHARASHTRA	42	2	4.76
15	PREET REMEDIES PVT LTD	HIMACHAL PRADESH	47	2	4.26

	Manufacturing Unit	State	No. of samples	NSQ Samples	%NSQ
16	PARENTERAL DRUGS INDIA LTD	MADHYA PRADESH	28	1	3.57
17	SHINE PHARMACEUTICALS LTD	GUJARAT	28	1	3.57
18	SIRMOUR REMEDIES PVT LTD	HIMACHAL PRADESH	28	1	3.57
19	ANKUR DRUGS AND PHARMA LTD	HIMACHAL PRADESH	29	1	3.45
20	TORRENT PHRAMACEUTICALS LTD	GUJARAT	29	1	3.45
21	MAPRA LABORATORIES PVT LTD	DAMAN AND DIU	32	1	3.13
22	SHIVALIK REMEDIES PVT LTD	UTTARAKHAND	32	1	3.13

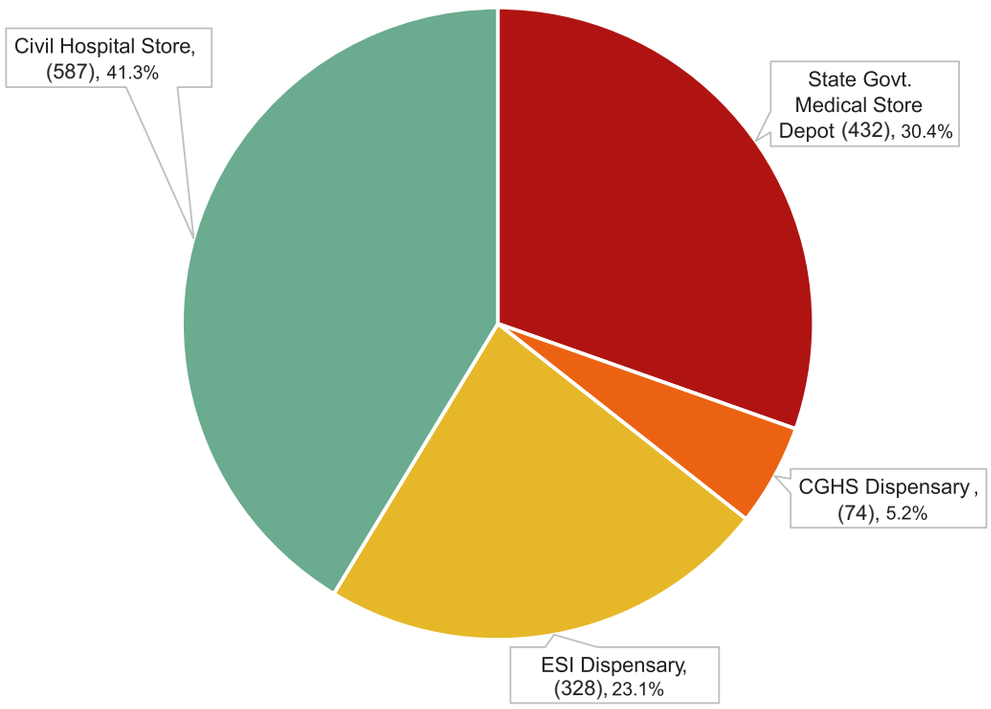
GOVERNMENT SOURCES

Analysis of Part-A Data

Coverage of outlets and hit rates

In case of Government sources a total of 1,507 sources were targeted for sample drawing. However, a total of 8,554 samples were drawn out of which 8,369 samples drawn from 1,421 Government sources were subjected to test/ analysis. The break-up of 1,421 Government sources i.e. State Government Medical Stores Depots (432), CGHS Dispensaries (74), Civil Hospital Stores (587), and ESI Dispensaries (328) is shown in Exhibit 10.22.

Exhibit 10.22
Composition of Government sources



The state wise break-up along with particulars of number of sources from which samples were drawn, the number and percentage of assigned ones in them, hit rate, the number of SDOs involved in the drawl of samples, are given in Exhibit 10.23. Samples were collected from 619 districts. The distribution of number of sampled Government sources per district is presented in Exhibit 10.24. The overall hit rate achieved for Government sources was 92.4%.

Exhibit 10.25 presents the location type wise distribution of Government sources. 44.2% percent of the sources were from municipal towns, 18.5% were from villages and 17.3% were from taluk headquarters. Hence, in case of Government sources 35.8% of the samples were drawn from rural areas.

Exhibit 10.23
State wise break up of Govt. Sources

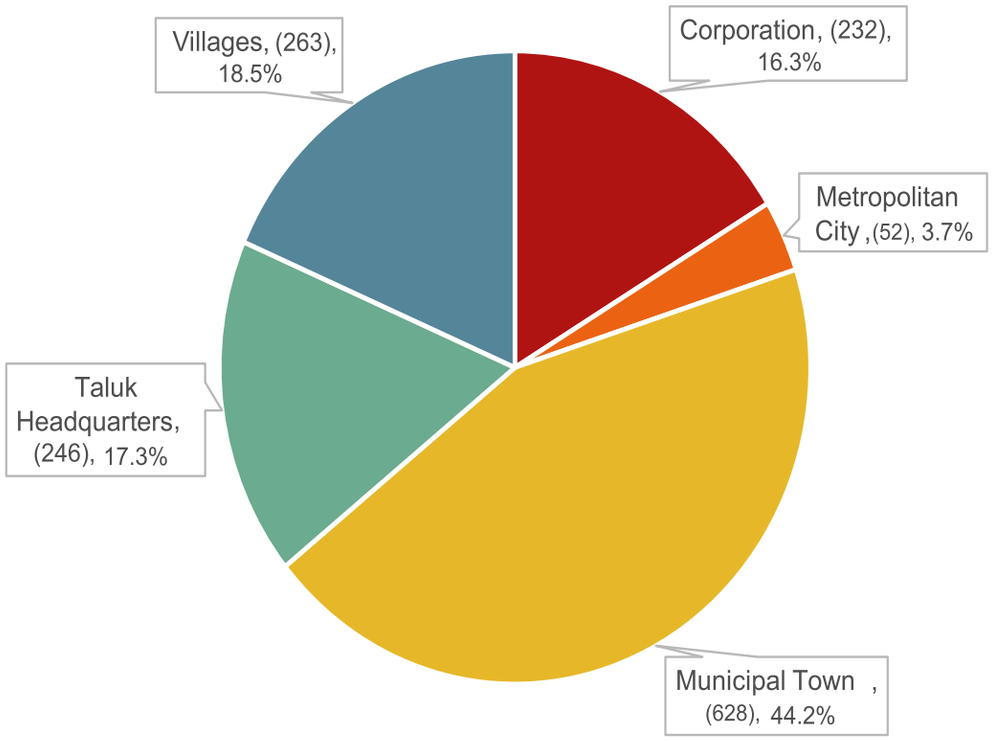
State	sources in Population	No. of Outlets Sampled	Assigned	Hit Rate	Number of SDOs
Andaman and Nicobar Islands	2	2	2	100.0	1
Andhra Pradesh	1461	16	15	93.8	12
Arunachal Pradesh	19	18	13	72.2	4
Assam	65	48	44	91.7	16
Bihar	709	41	37	90.2	25
Chandigarh	8	1	1	100.0	1
Chattisgarh	323	47	38	80.9	17
Dadra and Nagar Haveli	2	1	1	100.0	1
Daman and Diu	3	2	2	100.0	1
Delhi	132	7	7	100.0	2
Goa	11	2	2	100.0	2
Gujarat	161	62	57	91.9	30
Haryana	132	34	32	94.1	19
Himachal Pradesh	53	18	18	100.0	9
Jammu and Kashmir	21	34	34	100.0	20
Jharkhand	22	36	29	80.6	19
Karnataka	181	68	57	83.8	33
Kerala	1438	159	158	99.4	31
Lakshadweep	1	1	1	100.0	1
Madhya Pradesh	50	96	94	97.9	31
Maharashtra	236	75	70	93.3	35
Manipur	7	23	23	100.0	4
Meghalaya	11	12	12	100.0	6
Mizoram	9	15	15	100.0	7
Nagaland	22	18	18	100.0	6
Orissa	237	44	40	90.9	29

State	sources in Population	No. of Outlets Sampled	Assigned	Hit Rate	Number of SDOs
Puducherry	79	7	6	85.7	4
Punjab	169	62	58	93.5	22
Rajasthan	737	78	65	83.3	29
Sikkim	6	4	4	100.0	2
Tamilnadu	1391	98	92	93.9	34
Telangana	900	28	19	67.9	11
Tripura	19	16	16	100.0	4
Uttar Pradesh	305	188	175	93.1	70
Uttarakhand	10	22	20	90.9	4
West Bengal	1623	38	38	100.0	19
Total	10555	1421	1313	92.4	560

Exhibit 10.24
Distribution of number of sampled Government sources in districts

No. of sources	1	2	3	4	5	6	8	9	11	12	13	14	15	16	20	Total
No. of Districts	205	246	105	36	5	6	1	3	1	4	1	1	1	3	1	619
Percent	33.1	39.7	17	5.8	0.8	1	0.2	0.5	0.2	0.6	0.2	0.2	0.2	0.5	0.2	100

Exhibit 10.25
Location type wise distribution of Government sources



Six samples were targeted from each Government source. Out of 1421 Government sources 6 samples were drawn from each of 1297 (91.3%) of the Government sources, 5 samples were drawn from each of 104 (7.3%) of the Government. sources and 4 or fewer samples were drawn from remaining 20 (1.4%) of Government sources. The distribution is shown in Exhibit 10.26.

Exhibit 10.26
Distribution of number of samples drawn from Government source

No. Samples	1	2	3	4	5	6	Total
No. sources	3	1	2	14	104	1297	1421
Percentage	0.2	0.1	0.1	1	7.3	91.3	100

Analysis of Part-B Data of Government sources

Coverage of Molecules

Total 8,369 samples from 158 molecules were covered from Government sources under the survey. Exhibit 10.27 shows the list of molecules for which samples were drawn from Government sources under the survey. Fifty-six molecules contributed to 80% of the samples drawn from Government sources. Paracetamol was the most frequently sampled molecule. Exhibit 10.28 shows molecule inclusion chances from Government sources.

Exhibit 10.27
lists the molecule sampled from Government sources

S.No.	Molecule ID	Generic Name
1	M001	25% Dextrose
2	M002	5-Amino Salicylic Acid (5-ASA)
3	M006	Acetyl Salicylic Acid
4	M007	Acyclovir
5	M008	Adrenaline Bitartrate
6	M009	Albendazole
7	M010	Allopurinol
8	M011	Alprazolam
9	M012	Aluminium Hydroxide+Magnesium Hydroxide
10	M013	Amikacin
11	M014	Amiodarone
12	M015	Amitriptyline
13	M016	Amlodipine
14	M017	Amlodipine+Losartan Potassium
15	M018	Amoxicillin
16	M019	Amoxicillin+Clavulinic Acid
17	M020	Ampicillin
18	M023	Atenolol
19	M024	Atorvastatin

S.No.	Molecule ID	Generic Name
20	M025	Atracurium Besylate
21	M027	Azathioprine
22	M028	Azithromycin
23	M029	Beclomethasone Dipropionate
24	M030	Benzathine Benzylpenicillin
25	M031	Bisacodyl
26	M034	Carbamazepine
27	M035	Carbidopa+Levodopa
28	M036	Carbimazole
29	M037	Cefixime
30	M038	Cefotaxime
31	M039	Ceftazidime
32	M040	Ceftriaxone
33	M041	Cephalexin
34	M042	Cetrizine
35	M044	Chloroquine Phosphate
36	M045	Chlorpheniramine Maleate
37	M046	Chlorpromazine Hydrochloride
38	M048	Ciprofloxacin Hydrochlorid
39	M051	Clindamycin
40	M052	Clofazimine
41	M053	Clomiphene Citrate
42	M054	Clopidogrel
43	M055	Clotrimazole
44	M056	Cloxacillin
45	M060	Compound Sodium Chloride+Dextrose Injection
46	M062	Concentrated Vitamin A+D Solution
47	M063	Cyclophosphamide
48	M064	Danazol
49	M067	Dexamethasone

S.No.	Molecule ID	Generic Name
50	M068	Dexchlorpheniramine Maleate
51	M069	Dextromethorphan
52	M070	Dextrose Injection
53	M074	Dextrose+Sodium Chloride Injection
54	M073	Dextrose+Sodium Chloride Injection (5% and 0.9%)
55	M075	Diazepam
56	M076	Diclofenac
57	M077	Dicyclomine Hydrochloride
58	M079	Diethylcarbamazine Citrate
59	M080	Digoxin
60	M082	Diltiazem
61	M083	Dobutamine
62	M084	Domperidone
63	M085	Dopamine Hydrochloride
64	M086	Doxycycline
65	M087	Efavirenz
66	M091	Enalapril Maleate
67	M092	Erythromycin Estolate
68	M093	Ethambutol
69	M097	Ethinylestradiol
70	M098	Ethinylestradiol+Levonorgesterol
71	M100	Etophylline+Theophylline Prolonged-release
72	M102	Famotidine
73	M103	Fluconazole
74	M104	Fluoxetine Hydrochloride
75	M106	Folic Acid+Iron
76	M108	Furosemide
77	M109	Gentamicin
78	M110	Glibenclamide

S.No.	Molecule ID	Generic Name
79	M111	Glyceryl Trinitrate
80	M112	Griseofulvin
81	M113	Haloperidol
82	M115	Hydrochlorothiazide+Losartan Potassium
83	M116	Hydrochlorothiazide+Ramipril
84	M118	Hydrochlorthiazide
85	M120	Hydrocortisone Sodium Succinate
86	M122	Hyoscine Butyl Bromide
87	M123	Ibuprofen
88	M125	Imipramine
89	M127	Iodine
90	M128	Isoniazid
91	M132	Isosorbide Mononitrate/Dinitrate
92	M134	Lamivudine+Nevirapine+Stavudine
93	M135	Lamivudine+Nevirapine+Zidovudine
94	M136	Lamivudine+Stavudine
95	M138	Lamivudine+Zidovudine
96	M141	Lignocaine Hydrochloride
97	M140	Lignocaine+Adrenaline Injection
98	M142	Lithium Carbonate
99	M143	Lopinavir+Ritonavir
100	M144	Lorazepam
101	M145	Losartan Potassium
102	M146	Magnesium Sulphate
103	M147	Mannitol
104	M148	Medroxy Progesterone Acetate
105	M149	Mefloquine
106	M153	Metformin
107	M154	Methotrexate
108	M155	Methyl Prednisolone

S.No.	Molecule ID	Generic Name
109	M156	Methyldopa
110	M157	Methylergometerin
111	M158	Metoclopramide
112	M159	Metoprolol
113	M160	Metronidazole
114	M161	Mifepristone
115	M162	Misoprostol
116	M164	Neostigmine
117	M166	Nifedipine
118	M167	Nitrofurantoin
119	M168	Norethisterone
120	M170	Ofloxacin
121	M171	Olanzapine
122	M172	Omeprazole
123	M173	Ondansetron
124	M174	Oral Rehydration Salts
125	M175	Oxytocin
126	M176	Pantoprazole
127	M177	Paracetamol
128	M179	Pheniramine Maleate
129	M180	Phenobarbitone
130	M181	Phenytoin Sodium
131	M182	Piperazine
132	M183	Potassium Chloride Injection
133	M185	Prednisolone
134	M186	Primaquine
135	M189	Promethazine
136	M190	Pyrazinamide
137	M193	Pyrimethamine+Sulfadoxine
138	M194	Quinine Sulphate

S.No.	Molecule ID	Generic Name
139	M196	Ranitidine
140	M197	Rifampicin
141	M198	Ringer Lactate Injection
142	M200	Salbutamol Sulphate
143	M203	Sodium Bicarbonate Injection
144	M204	Sodium Chloride Injection
145	M206	Sodium Valproate
146	M207	Spironolactone
147	M209	Streptomycin Sulphate
148	M210	Succinyl Choline Chloride
149	M211	Sulfasalazine
150	M212	Sulphadiazine
151	M213	Sulphamethoxazole+Trimethoprim
152	M214	Tamoxifen Citrate
153	M215	Terbutaline Sulphate
154	M217	Tramadol
155	M218	Vecuronium Bromide
156	M219	Verapamil
157	M222	Water for injection
158	M224	Zinc Sulfate

Exhibit 10.28
Molecule inclusion chances for Government sources

S. No.	Molecule ID	Generic Name	Count	Inclusion Chances	S. No.	Molecule ID	Generic Name	Count	Inclusion Chances
1	M177	Paracetamol	316	3.78	1	M134	Lamivudine + Nevirapine + Stavudine	1	0.01
2	M076	Diclofenac	266	3.18	2	M135	Lamivudine + Nevirapine + Zidovudine	1	0.01
3	M048	Ciprofloxacin Hydrochlorid	252	3.01	3	M136	Lamivudine + Stavudine	1	0.01
4	M018	Amoxicillin	243	2.9	4	M138	Lamivudine + Zidovudine	1	0.01
5	M160	Metro-nidazole	219	2.62	5	M143	Lopinavir + Ritonavir	1	0.01

Dosage Forms

Like in retail outlets, majority of the samples drawn from Government sources were tablets. Exhibit 10.29 gives the break-up of dosage forms.

Exhibit 10.29
Distribution of dosage forms in the sampled formulations

S.No.	Dosage Forms	Number of Samples	Percent
1	Tablets	5676	67.82
2	Injections Small Volume Parenterals (SVP)	851	10.17
3	Capsules	698	8.34
4	Injections Large Volume Parenterals (LVP)	260	3.11
5	Suspensions	210	2.51
6	Oral rehydration salts	198	2.37
7	Powder for Injections	160	1.91
8	Liquids	120	1.43
9	Cream (non-sterile)	68	0.81
10	Gel (non-sterile)	30	0.36
11	Eye drops	25	0.3
12	Ointment (Non-sterile)	22	0.26
13	Gel (sterile)	20	0.24
14	Powder for oral liquids	12	0.14
15	Suppositories	7	0.08
16	Cream (sterile)	3	0.04
17	Ear drops	3	0.04
18	Ointment (sterile)	3	0.04
19	Pessaries	2	0.02
20	Dispersible Tablets	1	0.01

Expired Formulations

Among the 8,369 samples drawn from Government sources 90.16% of them had remaining shelf life of more than 6 months on the date of drawing of samples. The histogram of the remaining shelf life is shown Exhibit 10.30. Only two samples drawn under the survey were already date expired. The list of the 2 samples along with dates of manufacturing, date of expiry and date of drawing of samples are presented in Exhibit 10.31.

Exhibit 10.30
Distribution of shelf life of formulations as on sample collection date

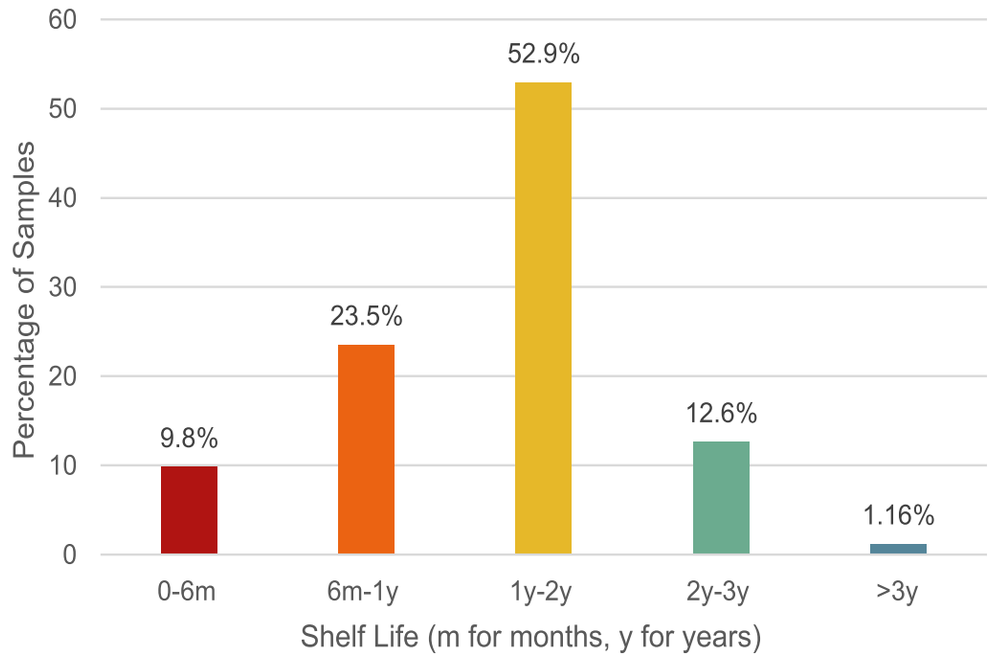


Exhibit 10.31
List of expired samples from Government sources

S. No.	Molecule ID	Generic Name	Dosage Form	Brand Name	State	District	Place Type	Date of Sample Collected	Expiry Date
1	M162	Misoprostol	Tablets	Misoclear	Mizoram	Mamit	Taluk HQ (3)	16-04-2015	31-01-2015
2	M174	Oral Rehydration Salts	Oral rehydration salts	ORS	Chattisgarh	Sukma	Municipal Town (2)	13-04-2015	31-01-2015

Lab Test Results and NSQ Proportion

The samples drawn under survey were subjected to test/analysis at 10 Central/ State Government Drug Testing Laboratories. The number of lab tests performed were 69. Not all the 69 tests were applicable to all formulations. Samples from Government sources failed in 27 out of these 69 tests. Out of the 8,369 samples tested from Government sources, 839 samples failed in one or more of the 27 tests and were declared as NSQ. The list of these 27 tests and the number of tests not complied are summarized in Exhibit 10.32 and 10.33.

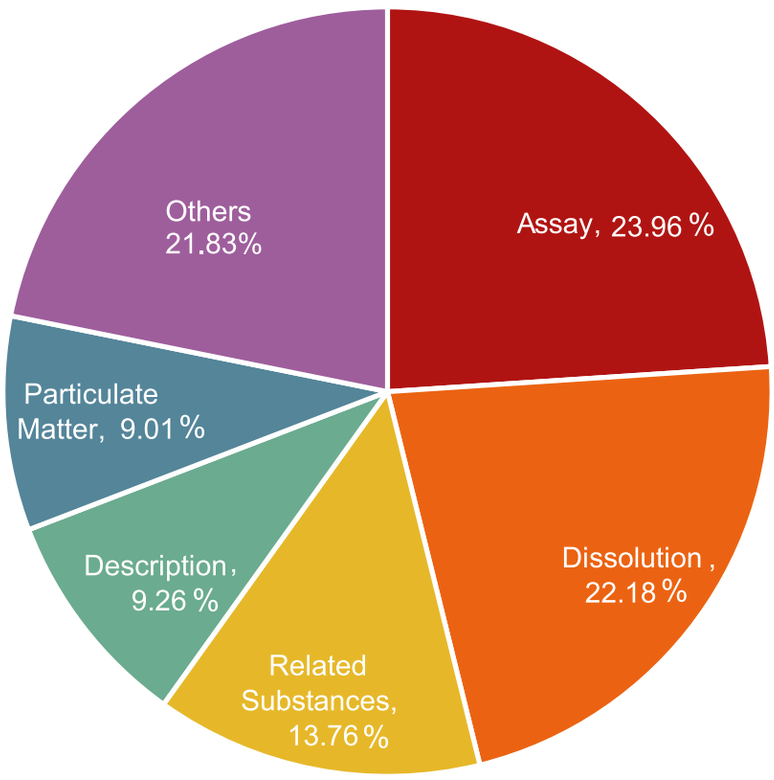
Exhibit 10.32
Contribution of tests to failure of samples from Government source

S. No.	Test performed	No. of test not complied	Percentage non-compliance
1	Assay	282	23.96
2	Dissolution	261	22.18
3	Related Substances	162	13.76
4	Description	109	9.26
5	Particulate matter	106	9.01
6	Uniformity Of Content	51	4.33
7	Clarity Of Solution	39	3.31
8	DisintegrationTest	35	2.97
9	Uniformity Of Dispersion	27	2.29
10	pH	24	2.04
11	Bacterial Endotoxin Test	18	1.53
12	Uniformity Of Filled Weight	10	0.85
13	Extractable Volume	10	0.85
14	Sterility	7	0.59
15	Uniformity Of Weight	6	0.51
16	Other test	6	0.51
17	Seal test	5	0.42
18	Identification HPLC	4	0.34

S. No.	Test performed	No. of test not complied	Percentage non-compliance
19	Loss on Drying	3	0.25
20	Particulate contamination	3	0.25
21	Free Salicylic Acid	2	0.17
22	Water	2	0.17
23	Identification by IR	1	0.08
24	Identification by TLC	1	0.08
25	Appearance of Solution	1	0.08
26	2-Chlorotritanol	1	0.08
27	Uniformity of dosage units	1	0.08
28	**Total**	**1177**	**100.00**

Exhibit 10.33

Contribution of tests to failures of samples from Government sources



From these figures, it can be seen that in case of Government sources, Failure in assay contributed to 23.96% of non-compliance, failure in dissolution contributed to 22.18% of non-compliance and failure in related substances contributed to 13.76% of non-compliance and so on. The estimate of NSQ proportion for Government sources is 10.02% and the approximate 95% confidence interval for the same is 09.38% to 10.68%. The estimates were also obtained for each State. Exhibit 10.34 presents the estimated NSQ percentages with approximate upper and lower 95% confidence limits for the states.

NSQ proportions were also estimated location wise. The NSQ proportions location wise along with number of samples are presented in Exhibit 10.35 and NSQ percentage estimates for various Government sources in Exhibit 10.36. It can be inferred from these figures that NSQ percentages were higher in municipal towns and Taluk headquarters.

Exhibit 10.34
State wise estimates of NSQ percentages for Government sources with approximate upper and lower 95% confidence limit

S. No.	State*	No. of Samples	No. of NSQ Samples	NSQ %	Lower 95% CL	Upper 95% CL
1	ANDAMAN AND NICOBAR ISLANDS	11	1	9.09	0.00	26.08
2	ANDHRA PRADESH	94	10	10.64	4.41	16.87
3	ARUNACHAL PRADESH	104	14	13.46	6.90	20.02
4	ASSAM	282	26	9.22	5.84	12.60
5	BIHAR	241	21	8.71	5.15	12.27
6	CHANDIGARH	6	0	0.00	0.00	0.00
7	CHATTISGARH	279	23	8.24	5.02	11.47
8	DADRA AND NAGAR HAVELI	5	0	0.00	0.00	0.00
9	DAMAN AND DIU	12	0	0.00	0.00	0.00
10	DELHI	39	1	2.56	0.00	7.52
11	GOA	12	1	8.33	0.00	23.97
12	GUJARAT	369	38	10.30	7.20	13.40
13	HARYANA	200	19	9.50	5.44	13.56
14	HIMACHAL PRADESH	108	10	9.26	3.79	14.73
15	JAMMU AND KASHMIR	203	17	8.37	4.56	12.18
16	JHARKHAND	208	22	10.58	6.40	14.76

S. No.	State*	No. of Samples	No. of NSQ Samples	NSQ %	Lower 95% CL	Upper 95% CL
17	KARNATAKA	406	35	8.62	5.89	11.35
18	KERALA	946	94	9.94	8.03	11.84
19	LAKSHADWEEP	6	0	0.00	0.00	0.00
20	MADHYA PRADESH	570	60	10.53	8.01	13.05
21	MAHARASHTRA	443	40	9.03	6.36	11.70
22	MANIPUR	138	14	10.14	5.11	15.18
23	MEGHALAYA	69	12	17.39	8.45	26.33
24	MIZORAM	80	11	13.75	6.20	21.30
25	NAGALAND	106	14	13.21	6.76	19.65
26	ORISSA	263	20	7.60	4.40	10.81
27	PUDUCHERRY	42	4	9.52	0.65	18.40
28	PUNJAB	360	41	11.39	8.11	14.67
29	RAJASTHAN	463	46	9.94	7.21	12.66
30	SIKKIM	24	8	33.33	14.47	52.19
31	TAMILNADU	583	45	7.72	5.55	9.89
32	TELANGANA	167	21	12.57	7.55	17.60
33	TRIPURA	95	9	9.47	3.58	15.36
34	UTTAR PRADESH	1084	129	11.90	9.97	13.83
35	UTTARAKHAND	124	15	12.10	6.36	17.84
36	WEST BENGAL	227	18	7.93	4.41	11.44
	All Government sources	**8369**	**839**	**10.02**	**9.38**	**10.68**

National average of NSQ from Government sources is 10.02%. Rows in Pink have NSQ percentage above National average and Rows in green have NSQ percentages below National average.

Note: When proportions are estimated, larger sample sizes yield more precise estimates. The precision is expressed in terms of confidence intervals. When the sample is large, we have narrow confidence interval, and when the sample size is small we have wide confidence interval. For instance, NSQ of 7.72% for Tamil Nadu has a confidence interval of 5.55 - 9.89 based on the sample size of 583 whereas NSQ of 33.33% for Sikkim has confidence interval of 14.47 - 52.19 based on a sample size of 24. Thus the estimate NSQ percentage is more precise for Tamil Nadu compared to that of Sikkim.

Exhibit 10.35
Location wise sample sizes and NSQ percentages from Government sources

S.No.	Location	No. of sources	No. of samples	NSQ%
1	Corporations	232	1366	8.57
2	Metropolitan Cities	52	299	7.36
3	Muncipial Towns	628	3695	10.96
4	Taluk Headquaters	246	1446	10.44
5	Villages	263	1563	9.21

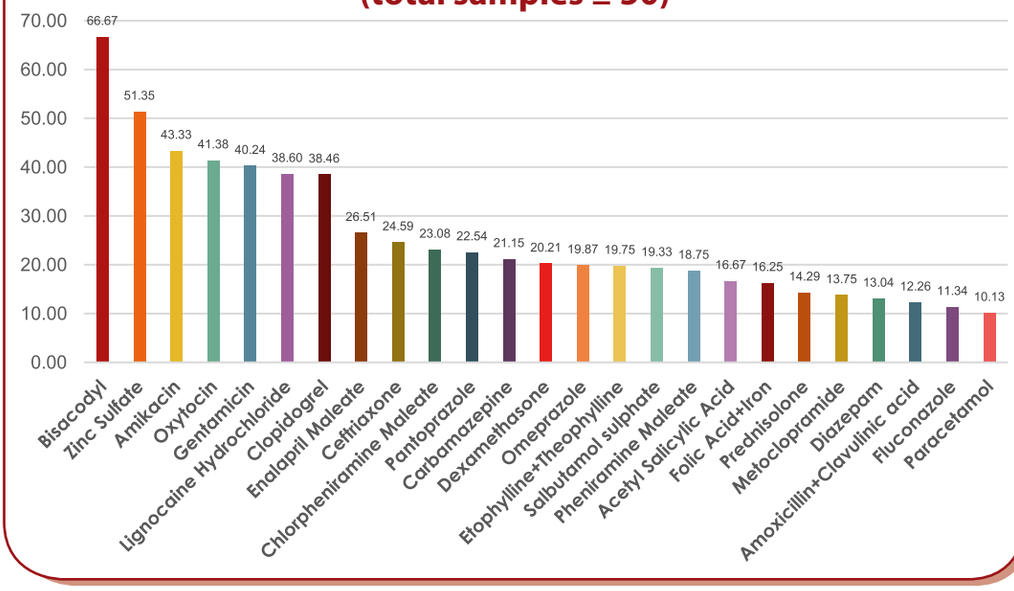
Exhibit 10.36
NSQ percentage estimates for Government sources

S.No.	Government Sources	No. of sources	Samples Collected	NSQ Samples	NSQ%
1	State Government Medical Store Depot	432	2557	267	10.44
2	CGHS Dispensary	74	438	18	4.11
3	Civil Hospital Store	587	3464	382	11.03
4	ESI Dispensary	328	1910	172	9.01
	Total	**1421**	**8369**	**839**	**10.02**

The NSQ percentages were also estimated for molecules with reasonable sample sizes from Government sources. These are shown in Exhibit 10.37. The figure shows that NSQ percentages were very high in Government sources. Few examples are hereunder:

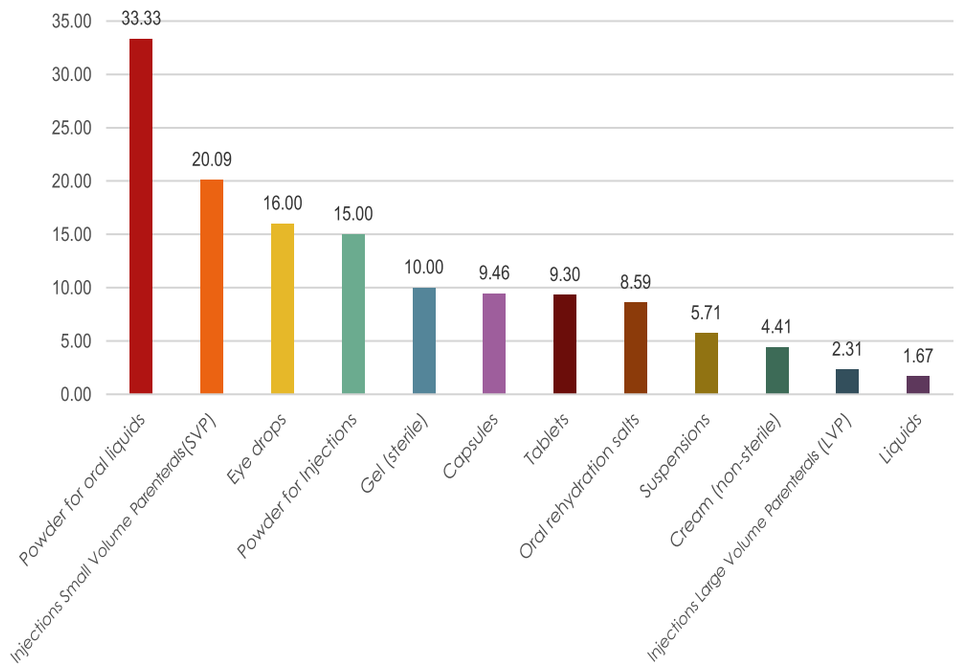
- **Bisacodyl:** 44 (66.67%) out of 66 samples drawn from Government sources under the survey were declared NSQ upon laboratory testing.
- **Zinc Sulphate:** 38 (51.35%) out of 74 samples drawn from Government sources under the survey were declared NSQ upon laboratory testing.
- **Amikacin:** 26 (43.33%) out of 60 samples drawn from Government sources under the survey were declared NSQ upon laboratory testing.
- **Oxytocin:** 24 (41.38%) out of 58 samples drawn from Government sources under the survey were declared NSQ upon laboratory testing.

Exhibit 10.37
Molecules with more than 10.02% NSQ samples (total samples ≥ 50)



The NSQ percentages with respect to dosage forms (with at least 10 Government sources) are shown in Exhibit 10.38. Again it can be inferred that NSQ percentage for various dosage forms were generally very high as shown hereunder:

Exhibit 10.38
NSQ percentages of dosage forms with at least 1 NSQ sample



- Small Volume Parenterals: 171 (20.09%) out of 851 samples drawn from Government sources under the survey were declared NSQ upon laboratory testing.
- Powder for Injection: 24 (15%) out of 160 samples drawn from Government sources under the survey were declared NSQ upon laboratory testing.
- Tablets: 528 (9.30%) out of 5676 samples drawn from Government sources under the survey were declared NSQ upon laboratory testing.

The 8369 samples drawn from Government sources were from 663 manufacturing units. Of these 14 manufacturing units contributed to 42.55% of the NSQ formulations from Government sources. NSQ percentages for manufacturing units are shown in Exhibit 10.39 and 10.40. It can also be inferred from data that drugs supplied by some of the manufacturing units had very high NSQ percentages as shown hereunder:

- **MERCURY LABORATORIES LTD.:** 27 (38.03%) out of 71 samples of the manufacturer drawn from Government sources under the survey were declared NSQ upon laboratory testing.

- **JACKSON LABORATORIE LTD.:** 35 (37.23%) out of 94 samples of the manufacturer drawn from Government sources under the survey were declared NSQ upon laboratory testing.
- **OM BIOMEDIC PVT. LTD.:** 25 (35.21%) out of 71 samples of the manufacturer drawn from Government sources under the survey were declared NSQ upon laboratory testing.

Exhibit 10.39

NSQ percentages of 13 manufacturing units with sample size more than 50 from Government sources and NSQ percentage above national average of 10.02%

S. No.	Manufacturing Unit	State	Number of Samples	Number NSQ	NSQ Percent
1	MERCURY LABORATORIES LTD	GUJARAT	71	27	38.03
2	JACKSON LABORATORIES LTD	PUNJAB	94	35	37.23
3	OM BIOMEDIC PVT LTD	UTTARAKHAND	71	25	35.21
4	SUPER FORMULATION PVT LTD	MADHYA PRADESH	56	14	25.00
5	SCOTT EDIL PHAMACIA LTD	HIMACHAL PRADESH	115	25	21.74
6	THERAMAX LABORATORIES	HARYANA	54	11	20.37
7	LABORATE PHARMACEUTICALS INDIA LTD	HIMACHAL PRADESH	126	23	18.25
8	ZEE LABORATORIES LTD	HIMACHAL PRADESH	222	40	18.02
9	IND SWIFT LTD	HIMACHAL PRADESH	53	9	16.98
10	EUROKEM LABORATORIES PVT LTD	TAMIL NADU	58	9	15.52
11	SKYMAP PHARMACEUTICALS LTD	UTTARAKHAND	57	8	14.04
12	KERALA STATE DRUGS AND PHARMACEUTICALS LTD	KERALA	113	14	12.39
13	BHARAT PARENTERAL LTD	GUAJARAT	58	6	10.34

Exhibit 10.40
Manufacturing units with sample size between 25-49 from Government sources and NSQ percentage above national average of 10.02%

S. No.	Manufactuting Unit	State	No. of Samples	NSQ Samples	%NSQ
1	NORRIS MEDICINE LTD	GUJARAT	31	14	45.16
2	NANDANI MEDICAL LABORATORIES PVT LTD	MADHYA PRADESH	42	12	28.57
3	MODERN LABORATORIES	MADHYA PRADESH	47	13	27.66
4	C I LABORATORIES	WEST BENGAL	43	8	18.60
5	RKG PHARMA PVT LTD	HARYANA	48	8	16.67
6	ARVIND REMEDIES LTD	TAMIL NADU	50	7	14.58
7	RHYDBURG PHARAMACUTICALS LTD	UTTARAKHAND	37	5	13.51
8	VITAL HEALTH CARE PVT LTD	MAHARASHTRA	43	5	11.63
9	DAFFODILLS PHARMACEUTICALS LTD	UTTAR PRADESH	38	4	10.53

Ports

For ports, it was decided to draw 3 samples from each consignment. In all, 4,987 samples were tested from 1,708 consignments. These samples were drawn from 57 molecules. The break-up of samples drawn from different ports is shown in Exhibit 10.41.

Exhibit 10.41
Number of samples from 8 Air/Sea Ports

S. No.	Port	Air Port	Sea Port	Total
1	Delhi	93	-	93
2	Ahmedabad	18	-	18
3	Mumbai	687	2682	3369
4	Chennai	68	1423	1491
5	Hyderabad	15	-	15
6	Kolkata	1	-	1
	Total	**882**	**4105**	**4987**

Summary of the molecules sampled from Ports are given in Exhibit 10.42 and Exhibit 10.43.

Exhibit 10.42
Molecules sampled from Ports

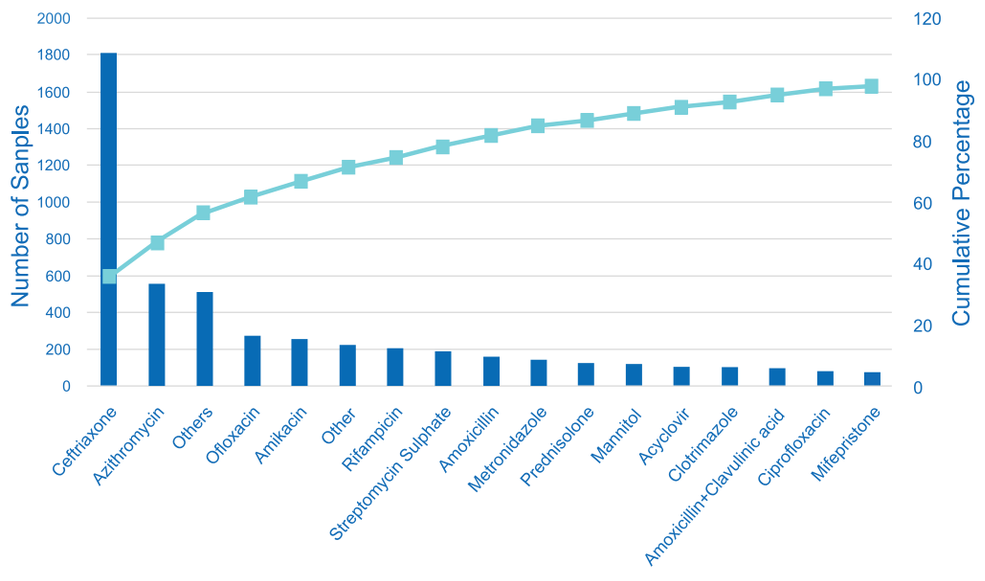


Exhibit 10.43
Complete list of molecules sampled from Ports

S. No.	Molecule ID	Generic Name	Frequency
1	M040	Ceftriaxone	1807
2	M028	Azithromycin	553
3	M170	Ofloxacin	274
4	M013	Amikacin	253
5	M197	Rifampicin	204
6	M209	Streptomycin Sulphate	186
7	M018	Amoxicillin	156
8	M160	Metronidazole	141
9	M185	Prednisolone	119
10	M147	Mannitol	116
11	M007	Acyclovir	102
12	M055	Clotrimazole	102
13	M019	Amoxicillin+Clavulinic acid	97
14	M048	Ciprofloxacin Hydrochlorid	75
15	M161	Mifepristone	70
16	M207	Spironolactone	64
17	M041	Cephalexin	55
18	M067	Dexamethasone	54
19	M086	Doxycycline	49
20	M155	Methyl Prednisolone	43
21	M148	Medroxy Progesterone Acetate	42
22	M132	Isosorbide Mononitrate/Dinitrate	36
23	M039	Ceftazidime	34
24	M051	Clindamycin	31
25	M162	Misoprostol	26
26	M030	Benzathine Benzylpenicillin	24
27	M177	Paracetamol	24
28	M123	Ibuprofen	21
29	M156	Methyldopa	21
30	M159	Metoprolol	21

S. No.	Molecule ID	Generic Name	Frequency
31	M212	Sulphadiazine	18
32	M169	Nystatin	16
33	M085	Dopamine Hydrochloride	15
34	M108	Furosemide	15
35	M112	Griseofulvin	12
36	M139	Levothyroxine	12
37	M206	Sodium Valproate	12
38	M101	Etoposide	11
39	M091	Enalapril Maleate	10
40	M025	Atracurium Besylate	9
41	M003	5-Fluorouracil	8
42	M152	Mesna	8
43	M120	Hydrocortisone Sodium Succinate	6
44	M133	Lamivudine	6
45	M014	Amiodarone	3
46	M031	Bisacodyl	3
47	M083	Dobutamine	3
48	M097	Ethinylestradiol	3
49	M124	Imatinib	3
50	M167	Nitrofurantoin	3
51	M066	Daunorubicin	2
52	M149	Mefloquine	2
53	M181	Phenytoin Sodium	2
54	M218	Vecuronium Bromide	2
55	M118	Hydrochlorthiazide	1
56	M122	Hyoscine Butyl Bromide	1
57	M143	Lopinavir+Ritonavir	1

Among the drugs consignments sampled at ports 92% were from China and 2% each from Italy and France. This information is shown in Exhibit 10.44.

The consignments came from about 108 manufacturing companies overseas. It was observed that eight companies from China accounted for 57.7% of the

samples of which two companies alone accounted for 35.19% of samples. The list of these eight companies is given in Exhibit 10.45 along with their respective number of samples drawn under the survey. No sample drawn from ports was found to be NSQ.

Exhibit 10.44
Countries contributing to the majority of the samples from imports

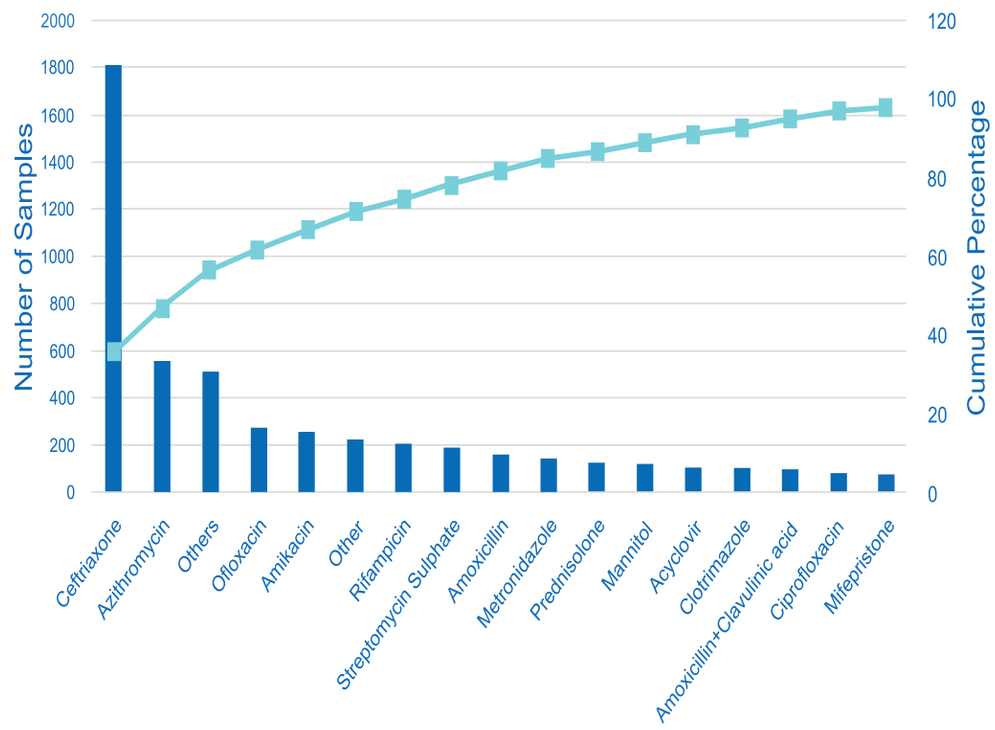


Exhibit 10.45
Eight companies contributing to the majority of sampled consignments at Ports

S. No.	Manufacturer Name	Country	No. of Samples
1	Sinopharm Weiqida Pharmaceutical Co. Ltd.	China	1318
2	Livzon Syntpharm Co. Ltd.	China	437
3	Zhejiang Guobang Pharma Co. Ltd.	China	260
4	Qilu Tianhe Pharma Co. Ltd.	China	194
5	Zhejiang Apeloa Kangyu Pharma Co.Ltd.	China	184
6	Shenyang Antibiotic Manufacturer	China	177
7	Hebei Shengxue Dacheng Pharma Co.Ltd.	China	168
8	Tianjin Tianyao Pharmaceuticals Co., Ltd.	China	140

Analysis of Spurious Drugs

Of all samples from retail outlets and Government sources, 13 were found to be Spurious as per section 17B(d) of Drugs & Cosmetics Act, 1940 (Exhibit 10.46). Of these 8 were from retail outlets and 5 were from Government sources.

Exhibit 10.46
List of samples declared Spurious under section 17B(d) of Drugs & Cosmetics Act (Contd.)

S. No.	Generic Name	Brand Name	Dosage Form	Name Manufacturer	Source	Reason
1	Amoxicillin	V-MOX 500	Capsules	AIMS INTERNATIONAL	State Govt. Medical Store Depot	Identification Negative
2	Prednisolone	Pred-10 Tab	Tablets	CRYSTAL PHARMACEUTICALS	Civil Hospital Store	Identification Negative
3	Cefixime	NA	Tablets	ZEST PHARMA	Civil Hospital Store	Identification Negative
4	Amoxicillin	PANTAMOX DRY SYRUP	Suspensions	KOPRAN LABORATORIES LIMITED	State Govt. Medical Store Depot	Identification Negative
5	Amoxicillin		Suspensions	ZEE LABORATORIES.	State Govt. Medical Store Depot	Identification Negative
6	Prednisolone	PRED-10	Tablets	CRYSTAL PHARMACEUTICALS	Retail Outlet	Identification Negative
7	Methyl Prednisolone	NELCORTIL - 8	Tablets	Francies Remedies India Pvt. Ltd.	Retail Outlet	Identification Negative

Exhibit 10.46
List of samples declared Spurious under section 17B(d) of Drugs & Cosmetics Act

S. No.	Generic Name	Brand Name	Dosage Form	Name Manufacturer	Source	Reason
8	Amoxicillin	KLOKMAX 250DT	Tablets	ZEE LABORATORIES LIMITED	Retail Outlet	Identification Negative
9	Sulphamethoxazole + Trimethoprim	STARPRIM DS	Tablets	CRYSTAL PHARMACEUTICALS	Retail Outlet	Identification Negative
10	Sulphamethoxazole + Trimethoprim	COTRIMOXAZOLE	Tablets	CRYSTAL, PHARMACEUTICALS	Retail Outlet	Identification Negative
11	Amoxicillin + Clavulinic acid	MOCLATE 625	Tablets	UNISON PHARMACEUTICALS	Retail Outlet	Identification Negative
12	Amoxicillin + Clavulinic acid	MOXWAY-CV	Powder for oral liquids	M SEA PHARMACEUTICALS	Retail Outlet	Identification Negative
13	Amoxicillin + Clavulinic acid	Max Cv 625	Tablets	Universal health Care	Retail Outlet	Identification Negative

The break-up details of these 13 samples is given in Exhibit 10.47. Therefore, the estimates of Spurious drug percentages were: 0.0237% for retail outlets, and 0.0597% for Government sources.

Exhibit 10.47
Dosage form and Source wise break-up of Spurious samples

S. No.	Dosage Form	State Government Medical Store Deport	Civil Hospital Store	Retail Outlet	Grand Total
1	Capsules	1			1
2	Powder for oral liquids			1	1
3	Suspensions	2			2
4	Tablets		2	7	9
	Grand Total	**3**	**2**	**8**	**13**

Summary

In this chapter, the survey results have been analysed from two different angles. One is about the conduct of the survey and the other is about results of Lab tests and Quality of drugs in terms of NSQ and Spurious drugs. Summary of survey aspects presents the analysis and results with regard to the first aspect, that is, about the conduct of the survey and sampling, and summary of lab test results and quality of drugs are presented in other section.

Summary of Survey Aspects

The survey was conducted to assess the quality of drugs pertaining to the formulations under 224 molecules selected from the National List of Essential Medicines-2011. As per the objectives, the survey was conducted for three sources, namely, Retail Outlets, Government sources and Ports. The results of the survey are summarized below:

a) 33,656 drug samples drawn from 5,717 Retail Outlets and 8,369 samples drawn from 1,421 Government sources were subjected to laboratory test/analysis. In the case of Ports, 4,987 samples drawn from 1708 consignments from 8 ports were subjected to laboratory test/analysis.

b) The total number of samples drawn from 3 sources together was 47,012 from 183 different molecules of which 46 molecules accounted for nearly 80% of the samples. About 33% of the samples were drawn from Municipal Towns, 26% from Villages, 23% from Corporation Areas, 13% from Taluk headquarters and 5% from Metropolitan Cities.

c) For Retail Outlets and Government sources, the samples were selected based on the 3-stage survey design. One of the main hurdles in the selection of samples was in the first stage sampling where the sources were to be selected from the list of retail outlets and government sources. The major difficulty faced here was that the lists of sources with addresses were not readily available, and some States could only provide the number of sources. This was an important area where the State Drug Authorities need to improve their databases for future needs. Despite the problem of getting complete list of sources with their addresses, the selection of sources was tackled with reasonable satisfaction due to untiring efforts of NIB in obtaining the lists to the maximum extent possible.

d) In terms of obtaining samples from the randomly selected sources, the execution has been reasonably satisfactory. In about sixty percent of the cases, the samples were actually drawn from the specified locations. However, in case of five states (Manipur, Andhra Pradesh, West Bengal, Sikkim and Telangana), it was observed that there were problems in obtaining samples from assigned sources. The reasons for this may be investigated. The inclusion of representatives of Civil Society /Pharmacy Council of India in the sample collection teams was specifically designed to neutralize any biases that might arise due to aberrations of this kind.

e). The implementation of second stage sampling, the molecule selection at the sources, was taken care by the very design itself by providing the random lists of molecules for each Source independently. In the third stage one formulation was selected from each selected molecule using the prescribed method of random sampling.

Summary of Lab Test Results and Quality of Drugs

The total number of samples tested was 47,012 of which 33,656 were from Retail Outlets, 8,369 were from Government sources and 4,987 were from Ports. About 80% of the samples drawn From Retail Outlets and Government sources were Tablets. The total number of tests performed such as identification, dissolution, assay, etc., were 69. Of these, all tests were not applicable to all formulations. The main results of the analysis of lab tests are summarized below:

National Survey NSQ and Spurious Drugs Database

a) Out of the 47,012 samples tested, 13 samples were found to be Spurious and 1,850 samples were found to be NSQ. Therefore, The estimated percentage of NSQ Drugs in India is 3.16% and of Spurious drugs is 0.0245%.

Retail Outlets

a) Total 1,011 samples out of the 33,656 samples tested from Retail Outlets were found to be NSQ and 8 samples were found to be Spurious

b) The estimated percentage of NSQ formulations from Retail Outlets in India is 3% and is not expected to be more than 3.19% (the upper 95% confidence limit), and the estimated percentage of Spurious drugs from retail outlets is 0.0237%.

c) State wise, NSQ percentage estimates for Retail outlets varied from 0 to 8.82% percent (with the exception of Lakshadweep); Three States/UTs i.e. Andaman and Nicobar Islands, Dadra and Nagar Haveli, Goa had 0%NSQ. Fourteen States/UTs had NSQ percentage below the national average of 3% for Retail Outlets. Eighteen States had NSQ percentage above the national average of 3% for Retail Outlets.

d) The total number of non-compliance out of all tests of all samples from Retail Outlets was 1,251. Out of 69 tests performed on these samples, they failed in 28 tests, of which, Dissolution and Assay accounted for 56.4% of the non-compliance.

Government sources

a) Total 839 samples out of the 8,369 samples tested from Government sources were found to be NSQ and 5 samples were found to be Spurious.

b) The estimated percentage of NSQ formulations from Government sources in India is 10.02% and the 95% confidence interval for the same is 9.38% to 10.68% and the the estimated percentage of Spurious drugs from Government sources is 0.0597%. State wise, NSQ percentage estimates varied from 0 to 17.39% with the exception of Sikkim. Four UTs i.e. Chandigarh, Dadra and Nagar Haveli, Daman and Diu and Lakshadweep had 0%NSQ. Eighteen States/UTs had NSQ Percentage below national average of 10.02% for Government sources. Thirteen States had NSQ percentage above national average of 10.02% for Government sources.

c) The total number of non-compliance out of all tests of all samples from Government sources was 1,177. Out of 69 tests performed on these samples, they failed in 27 tests, of which, Assay and Dissolution accounted for 46.1% of the non-compliance.

Ports

a) Samples were drawn from 8 Ports from 1708 consignments. 97% of the samples came from Mumbai and Chennai Ports.

b) None of the samples were found to be NSQ or Spurious.