DRAFT

Strengthening of State Drugs Regulatory System
"Memorandum of Understanding (MoU)"

between

Ministry of Health & Family Welfare, Government of India

and

Government of ..... [Name of State/UT]

1. Preamble.

1.1 One of the main interventions of the Central Government to achieve its Public Health objectives is to ensure that drugs available to the public are safe, efficacious and conform to the prescribed quality standards. Regulatory control over the quality, safety and efficacy of drugs in the country is exercised through a central legislation called the Drugs and Cosmetics Act, 1940 and the Drugs and Cosmetics Rules, 1945 made thereunder.

1.2 The Central Drugs Standard Control Organization (CDSCO) is the central drugs regulatory organization responsible for implementation of the provisions of the Drugs and Cosmetics Act, 1940 and the Drugs and Cosmetics Rules, 1945 in respect of matters falling within the purview of the Central Government.

1.3 Under the provisions of this Act and Rules made thereunder, the regulatory control over the drugs and cosmetics imported into the country is exercised by the Central Government through CDSCO.

1.4 Under the provisions of the Drugs & Cosmetics Act, 1940 and the Drugs & Cosmetics Rules, 1945, the manufacture, sale and distribution of drugs and cosmetics are regulated by the State Drugs Control Authorities appointed by the State Governments. Even sale of imported drugs after having been permitted by the CDSCO is monitored and regulated by State Drug Control Departments. Accordingly, the Drugs Control Departments of the States/ UTs play a vital role in implementing the provisions of the Drugs & Cosmetics Act, 1940 and the Drugs & Cosmetics Rules, 1945.

1.5 The Indian Pharmaceutical Industry is one of the most vibrant sectors of Indian economy. It has been growing at the rate of 10-12% per annum. It is the 3rd largest in the world by volume and 10th by value. The total size of the Indian Pharmaceutical Industry is about Rs.2 lakh crore, out of which exports account for nearly 55%. To ensure the quality, safety and efficacy of medicines both for domestic use and for exports, the States regulatory system is required to be strengthened.

1.6 The major concerns relating to States drug regulatory systems are as below:

- Inadequate or weak drug control infrastructure at the State level.
- Inadequate drug testing facilities.
- Non-uniformity of enforcement of law and rules.
- Lack of training to regulatory officials.
- Lack of data base.
- Inadequate IT services.

1.7 The need to ensure the quality, safety and efficacy of drugs both for the domestic consumers as well as for export purpose is paramount and if it is not ensured, it affects public health, national interest, and India's reputation in the world. There is, therefore, the need for systematic collection and testing of sufficient number of samples in laboratories. The laboratories in States are therefore, required to be strengthened. The capacity and the strength of the technical manpower also required to be augmented. It is proposed to achieve an optimum system of regulation ensuring uniform enforcement of the laws across the country through a strengthened drug regulatory mechanism.

1.8 For undertaking the mandated activities, appropriate infrastructure, both at the Centre and in the States is required and new infrastructure developed and manpower recruited.

1.9 A network of efficient drugs testing laboratories will need to be established for ensuring that only safe drugs are available for consumption. The risk assessment component of the drug safety and quality also needs to be strengthened by inter-linking these laboratories. The Centre and the State / UT Governments will, therefore, strengthen the existing set-up of surveillance system and increase consumer awareness about current and new drugs safety and quality related threats.

1.10 Keeping in view the above, the signatories to this Memorandum of Understanding (MoU) have agreed as set out here in below.

2. Duration of the MoU.

2.1 This MoU will be operative with effect from 01.09.2015 and will remain in force till March 31, 2018 or till its renewal by mutual agreement whichever is earlier.

3. State proposal and financing.

3.1 The Central Government will provide a resource envelope to support implementation of an agreed State Drug Regulatory System. To begin with an indicative amount will be intimated to the State/UTs Government for preparation of the Annual Action Plan.

3.2 Subject to the availability of funds and overall prioritization, the amount of grants-in-aid to be released to the State during 2015-16, 2016-17 and 2017-18 including States share, will be as may be agreed to between the Department of Health & Family Welfare and the State Government. The State/ UT will provide their share of the total expenditure on this count from their own resources. The Centre and States shares will be in the ratio of 75:25 for all States except Jammu and Kashmir, Himachal Pradesh, Uttarakhand, Sikkim and Seven North-Eastern States for which the ratio will be 90:10.

3.3 The States/UTs will prepare an Annual Action Plan for 2015-16, 2016-17 and 2017-18 in the proforma prescribed for the purpose [Appendix I to IV] based on the quantum of funds provided to it. The proposal shall be consistent with the general principles laid down in the National and State policies relevant to the Sector and other agreed action plans.

3.4 Based upon the proposal, the States/UTs will set its own annual level of achievement for the programme's core indicators in consultation with the Central Government.

3.5 The Central Government may issue mandatory deliverables, which would need to be adhered to by the States.

3.6 The implementation of the action plan as set out in the proposal shall be reviewed at the State level once every month.

3.7 A review would be carried out every three months by the Central Government.

3.8 In order to facilitate the States/UTs in expeditious finalization of the Action Plans, the Ministry of Health and Family Welfare has prepared a indicative list of equipment, manpower and space, etc. required for different levels of laboratories which is Appendix IV to this MoU.

3.9 Further, since the Central Government will also be procuring a number of equipment, etc. for its existing and new labs through M/s HLL Infra Tech Engineering Services Ltd., the States/UTs could also exercise an option to avail of the facilities of M/s HLL Infra Tech Engineering Services Ltd. on such terms and conditions as are generally applicable to such procurements by the Central Government.

3.10 Such States/UTs, as are not able to undertake construction activities on their own, could also avail the services of M/s HLL Infra Tech Engineering Services Ltd. on terms and conditions applicable to MoHFW projects.

4. Funds flow arrangements.

4.1 The first instalment of grant-in-aid of the total earmarked grant to be released to the State/UTs after signing of the MoU and receiving the specific proposals from the State/UT concerned a long with the confirmation that the State/ UT will make available its share within a month of the transfer of Central share.

4.2 Subsequent releases shall be regulated on the basis of a written report to be submitted by the States/UTs indicating the progress of agreed deliverables including the following:

- Documentary evidence indicating achievement of targets/ milestones for the agreed performance indicators.
- Statement of Expenditure confirming utilization and the share of the State/UT Government having been deposited/ credited.
- The funds for 2017-18 will be released only after utilization certificate (s) (in prescribed form as in Appendix-V) are made available to the Central Government.

5. Ceilings for expenditures.

5.1 Based on the examination of Annual Plan of the States/UTs there would be ceilings for different items of expenditure as mentioned in Appendix VI.

6. Year-wise phasing of expenditure.

6.1 The approved amount of grants-in-aid will be released to the States during 2015-16 to 2017-18 and year-wise phasing of expenditure will be as may be agreed to between the States/UTs and the Central Government and will be subject to such further changes as the Central Government may make for 2016-17 and beyond.

7. Performance Indicators.

7.1 Release of funds will be subject to satisfactory progress of agreed Performance Indicators relating to implementation of agreed deliverables.

7.2 The agreed Performance Indicators are as given at Appendix-VII.

8. Institutional Arrangements: National Level.

8.1 At the National level, the Drugs Controller General (India) will be responsible for implementation of the scheme.

8.2 The proposal of the State shall be appraised for approval and sanctioned by the Ministry of Health and Family Welfare.

8.3 The Ministry of Health & Family Welfare will monitor the progress of implementation of the Scheme.

9. Institutional Arrangement: State Level.

9.1 At the State level, the Drugs Controller / Officer in-charge of Department of Drugs Control will be responsible for implementation of the Scheme.

9.2 The Chief Secretary/ Addl. Chief Secretary / Principal Secretary (Health) will monitor the progress of implementation of the Scheme.

10. Performance Review.

10.1 The Ministry of Health & Family Welfare in the Central Government will convene meetings periodically to review the progress of achievement of the agreed State performance indicators.

10.2 The State shall also organize such reviews at State level and the offices of the Central Government will also participate in some of the review meetings.

10.3 The review meetings may sometimes lead to adding to or modifying the proposals. Such modifications will have to be recorded in writing and will form supplements to this MoU.

11. The Central Government Commitments.

11.1 Release of funds as per the agreed performance indicators and agreed timelines.

11.2 Assisting the States in mobilizing technical assistance inputs to State Government including in the matter of recruitment of staff or procurement of equipment.

11.3 Consultation with States on a regular basis for review of progress.

11.4 Consideration of requests from the State for policy, procedural and programmatic changes.

11.5 Dissemination of and discussion on any evaluation, report etc., that has a bearing on policy and/or have the potential to cause a change of policy.

12. State Government Commitments.

12.1 The State Government will ensure that the funds made available to support the agreed performance indicators under this MoU are used for financing the agreed performance indicators with agreed financing schedule and not used to substitute routine expenditures that are the responsibility of the State Government.

12.2 The State/ UT Government shall contribute its share as the case may be, against the funds released by the Central Government. Non-contribution of the same shall lead to suspension of release of funds.

12.3 Statements of Expenditure are to be submitted after release of each instalment of funds and before release of the next instalment.

12.4 Duly audited Utilization Certificates are sent to the Central Government immediately after close of the financial year, within the period stipulated in the General Financial Rules of the Government of India.

12.5 Representatives of the Ministry of Health & Family Welfare, Government of India may undertake field visits in any part of the State in connection with the issues under the purview of this MoU and will have access to such information as may be necessary to make an assessment of the progress of activities included under this MoU.

13. Maintenance of Accounts and Audit.

13.1 Funds allocated in terms of this MoU will be kept separately along with share of State.

13.2 The State will organize the audit of the funds immediately on the close of every financial year. The State Government will prepare and provide to the Central Government, a consolidated statement of expenditure, including the interest that may have accrued.

13.3 The funds routed though the MoU mechanism will be liable to statutory audit by the Comptroller and Auditor General of India.

14. Suspension.

14.1 Non-compliance of the commitments and obligations set hereunder and/or upon failure to make satisfactory progress may require Ministry of Health & Family Welfare to review the assistance committed through this MoU leading to suspension, reduction or cancellation thereof. The Ministry of Health & Family Welfare commits to issue appropriate alert to the State/ UT Government before contemplating any such action.

Signed this on day of 2015.

For and on behalf of

Government of……. (Designation) Addl. Chief Secretary/ Principal Secretary/ Secretary in-charge of Drug Control Department	Government of India (Joint Secretary in-charge of Drugs Control, Ministry of Health & Family Welfare)

APPENDIX I

PROFORMA FOR STATE ANNUAL ACTION PLAN

State Drugs Control Department [Separate sheets for 2015-16, 2016-17 & 2017-18]

Name of State			
Number of manufacturing units		Number of Sales units (Retail)	
Number of samples drawn	2014-15	2013-14	2012-13

A) **Manpower Requirement**					
S. No	Designation	Existing Strength	Proposed addition in manpower	Total Emoluments per official	Total Addl. Expenditure
1	Drug Inspector				
2	Assistant Drug Inspector				
3	Data Entry Operator				
4	Technical Data Associate				
5	Other (specify)				
Total Cost					
B) **Civil Works**					
- Availability of space for expansion of existing offices					
- New Offices (if any)					
- Availability of land free from encumbrances and suitable for construction					
- Details of proposed construction					
Total Cost @Rs. 3000/sft					
C) **Information Tech. / Furniture**					
- Furniture					
- Computers / IT support [Details to be given]					

Total Cost	
D) **Recurring Cost**	
- Stationary	
- Misc. [To be specified]	
Total Cost	
Grand Total (A+B+C+D)	

[Annex support documents (if any)]

APPENDIX II

PROFORMA FOR STATE ANNUAL ACTION PLAN

For State Drugs Testing Laboratory [Separate sheets for 2015-16, 2016-17 & 2017-18]

Name of State					
Address of Laboratory(ies)	(I) (II) (III)				
	Testing Capacity per Annum	Samples Tested			
		2014-15	2013-14	2012-13	
Laboratory I					
Laboratory II					
Laboratory III					
A) **Manpower Requirement**					
S. No	Designation	Existing Strength	Proposed addition in manpower	Total Emoluments per official	Total Addl. Expenditure
1	Drugs Analyst(s)				
2	Bench Chemist(s)				
3	Microbiologist(s)				
4	Support Staff				
5	Other (specify)				
Total Cost					
B) **Equipment Requirement**					
Name and quantity of Equipment required	[Details to be annexed along with details of existing equipment available within the laboratory. Equipment will be taken from the annexed list]				

AMC/CMC cost/annum	
Total Cost	

C) **Civil Works** [cost to be calculated @3000/sft]		
	Existing area	Area required for expansion/ up-gradation
Lab I		
Lab II		
Lab III		

Details of land available for new labs (if required)	
New construction with Area	
Total Cost	
D) **Recurring Cost**	
Chemicals	
Glass wares	
Stationary	
Misc./ other expenses (to be specified)	
Total Cost	
Grand Total (A+B+C+D)	

[Annex support documents (if any)]

APPENDIX III

Summary of Funds Required
[For Financial Years 2015-16 to 2017-18]

S.No	Items	Financial Year	Drugs Control Department	Drugs Testing Laboratory(ies)	Total (Rs in Lakhs)
1	Manpower requirement	2015-16			
		2016-17			
		2017-18			
2	Civil works	2015-16			
		2016-17			
		2017-18			
3	IT / Furniture	2015-16			
		2016-17			
		2017-18			
4	Equipment	2015-16			
		2016-17			
		2017-18			
5	Recurring cost	2015-16			
		2016-17			
		2017-18			
Grand Total					

APPENDIX IV

List of Equipments for New Laboratory having different testing capacity											
S. N.	Name of instruments	Make	Cost aprox. /Inst	Capacity				Cost			
			(in Crore)	1000 samples	3000 Samples	5000 Samples	10000 samples	1000 samples	3000 Samples	5000 Samples	10000 samples
1	UV/VIS Spectrophotometer	Perkin Elmer, Schimadzu, Lab India, Agilant or Equivalent	0.1	1	2	3	4	0.1	0.2	0.3	0.4
2	FT-IR Spectrophotometer with accesories	Perkin Elmer, Schimadzu, Brooker, Agilant or Equivalent	0.15	1	1	1	2	0.15	0.15	0.15	0.3
3	HPLC (**Gradient**) with PDA, fluorescent & RI detector, Auto sampler & essential Columns	Waters, Agilant, Schimadzu, Thermofischers or equivalents	0.4	1	1	0	0	0.4	0.4	0	0
4	HPLC (**Gradient**) with PDA, fluorescent & RI detector, ELSD, Auto sampler & essential Columns	Waters, Agilant, Schimadzu, Thermofischers or equivalents	0.7	0	0	1	1	0	0	0.7	0.7
5	HPLC (**Gradient**) with UV detector, auto sampler & essential Columns	Waters, Agilant, Schimadzu, Thermofischers or equivalents	0.25	2	6	10	16	0.5	1.5	2.5	4
6	GLC with FID detector with head space	Perkin, Agilant, Schimadzu, Thermofischers or equivalents	0.3	1	1	1	1	0.3	0.3	0.3	0.3
7	Atomic absorption spectrometer(AAS) with hydride & graphite furnace	Perkin, Agilant, Schimadzu, Thermofischers or equivalents	0.4	0	1	1	1	0	0.4	0.4	0.4
8	HPTLC	Camage, Desaga or equivalent	0.8	0	0	0	1	0	0	0	0.8
9	Poteniometric Titrator with necessary electrodes	Metrom, Metler or equivalent	0.1	1	2	2	3	0.1	0.2	0.2	0.3
10	KF titrator	Metrom, Metler or equivalent	0.1	1	1	1	2	0.1	0.1	0.1	0.2

11	Dissolution apparatus (manual)	Electro, Lab India, Veego Agilant or equivalent	0.05	2	3	3	5	0.1	0.15	0.15	0.25
12	Dissolution apparatus with auto sampler	Electro, Lab India, Veego Agilant or equivalent	0.15	1	1	1	2	0.15	0.15	0.15	0.3
13	DT apparatus with facility for Bolus, vaginal tablets & suppository.	Electro, Lab India, Veego Agilant or equivalent	0.02	2	2	4	4	0.04	0.04	0.08	0.08
14	Polari meter Digital Single Wavelength	Roudalf, Anaten par or equivalent	0.06	1	1	0	0	0.06	0.06	0	0
15	Polari meter digital with multi wavelength	Roudalf, Anaten par or equivalent	0.15	0	0	1	1	0	0	0.15	0.15
16	Refractrometer digital	Roudalf, Anaten par or equivalent	0.04	1	1	1	1	0.04	0.04	0.04	0.04
17	Melting point apparatus digital	Lab Inida, or equivakent	0.02	1	1	1	1	0.02	0.02	0.02	0.02
18	Analytical balance (4 digit) with printer along with Anti Vibration table	Metler, Satorius, Citizen, or Equivalent	0.025	1	2	3	5	0.025	0.05	0.075	0.125
19	Visco meter		0.005	0	0	1	1	0	0	0.005	0.005
20	PH meter Digital		0.005	1	1	2	2	0.005	0.005	0.01	0.01
21	Hot Air Oven		0.01	2	2	4	4	0.02	0.02	0.04	0.04
22	Vacuum Oven		0.01	1	1	1	1	0.01	0.01	0.01	0.01
23	Sonicator		0.005	1	1	3	4	0.005	0.005	0.015	0.02
24	Fume Hood		0.002	1	1	1	1	0.002	0.002	0.002	0.002
25	Centrifuge		0.005	1	1	2	2	0.005	0.005	0.01	0.01
26	UV Cabinet		0.001	1	1	1	0	0.001	0.001	0.001	0
27	Magnetic Stirrer		0.001	1	1	3	3	0.001	0.001	0.003	0.003
28	Refrigerator		0.0015	1	1	3	3	0.0015	0.0015	0.0045	0.0045
29	Photo Fluorimeter		0.005	1	1	1	1	0.005	0.005	0.005	0.005
30	Colorimeter		0.002	1	1	1	1	0.002	0.002	0.002	0.002

31	Thermostatic water bath		0.005	1	1	1	2	0.005	0.005	0.005	0.01
32	Flame Photometer		0.02	1	0	0	0	0.02	0	0	0
33	Platinum Crucible		0.02	0	1	1	1	0	0.02	0.02	0.02
34	Computer with Printer		0.007	5	10	15	20	0.035	0.07	0.105	0.14
35	Eye Wash and Shower		0.006	1	2	3	4	0.006	0.012	0.018	0.024
36	Muffle Furnace Digital		0.005	1	1	2	2	0.005	0.005	0.01	0.01
37	Water purification system		0.08	1	1	2	4	0.08	0.08	0.16	0.32
38	Other small instrument ,chemicals and glass wares							0.1	0.2	0.35	0.6
	Total Rs in Cr.							**2.39**	**4.21**	**6.09**	**9.60**

List of Equipments for Microbiology Lab										
S.N 0.	Name of instruments	Cost aprox./ Inst	Capacity				Cost			
		(in Crore)	1000 samples	3000 Samples	5000 Samples	10000 samples	1000 samples	3000 Samples	5000 Samples	10000 samples
1	Biosafety cabinet	0.04	-	1	1	1	-	0.04	0.04	0.04
2	Laminar Air flow Bench	0.02	-	2	2	2	-	0.04	0.04	0.04
3	Autoclave wall fitted double door	0.05	-	1	1	1	-	0.05	0.05	0.05
4	Autoclave vertical	0.02	-	1	1	1	-	0.02	0.02	0.02
5	BOD incubator	0.02	-	3	3	3	-	0.06	0.06	0.06
6	Incubator	0.02	-	2	2	2	-	0.04	0.04	0.04
7	Zone reader (Projection type)	0.02	-	1	1	1	-	0.02	0.02	0.02
8	Colony counter	0.01	-	1	1	1	-	0.01	0.01	0.01
9	Refrigerator	0.0025	-	2	2	2	-	0.005	0.005	0.005
10	Deep Freezer (-20 C)	0.04	-	1	1	1	-	0.04	0.04	0.04
11	Drying oven	0.01	-	1	1	1	-	0.01	0.01	0.01
12	Cooling cabinet	0.02	-	1	1	1	-	0.02	0.02	0.02
13	Analytical balance	0.02	-	1	1	1	-	0.02	0.02	0.02
14	Precision balance	0.005	-	1	1	1	-	0.005	0.005	0.005
15	UV Cabinet	0.01	-	1	1	1	-	0.01	0.01	0.01
16	Microscope	0.01	-	1	1	1	-	0.01	0.01	0.01
17	Filtration unit	0.002	-	1	1	1	-	0.002	0.002	0.002
18	UV-Vis Spectrophotometer	0.08	-	1	1	1	-	0.08	0.08	0.08
19	Centrifuge	0.002	-	1	1	1	-	0.002	0.002	0.002
20	Vortex	0.001	-	1	1	1	-	0.001	0.001	0.001
21	Anaerobic Jar	0.002	-	1	1	2	-	0.002	0.002	0.004

22	Water bath	0.002	-	1	1	2	-	0.002	0.002	0.004
23	Hot plate	0.001	-	1	1	1	-	0.001	0.001	0.001
24	Washing machine	0.002	-	1	1	1	-	0.002	0.002	0.002
25	pH meter	0.005	-	1	1	1	-	0.005	0.005	0.005
26	Miscellaneous - Chemicals, Culture, Media, Glass wares							0.1	0.1	0.1
	Total							**0.597**	**0.597**	**0.601**

Cost for Instruments				
Details	**1000 samples**	**3000 Samples**	**5000 Samples**	**10000 samples**
Chemical Lab	2.39	4.21	6.09	9.60
Microbiology Lab	-	0.60	0.60	0.60
Grand Total (Rs in Cr.)	**2.39**	**4.81**	**6.69**	**10.20**

Area requirement for chemical, Instrumentation and Microbiology					
S.N0.	**Particulars**	**Sample Testing Capacity in each lab per Annum**			
		1000 samples	**3000 Samples**	**5000 Samples**	**10000 samples**
1	Area required (chemical and instrument testing)	5000 Sq. Ft	10000 Sq. Ft	15000 Sq. Ft	25000 Sq. Ft
2	Area required for Microbiological testing	-	2000 Sq. Ft	3000 Sq. Ft	5000 Sq. Ft
3	Building construction cost @ Rs. 6000/Sq. Ft	3 Cr	7.2 Cr	10.8 Cr	18 Cr

Man Power requirement for each lab									
		1000 Samples		**3000 Samples**		5000 samples		**10000 samples**	
	Designation	**No. of posts**	Financial implication per month	**No. of posts**	Financial implication per month	**No. of posts**	Financial implication per month	**No. of posts**	Financial implication per month
1	Director (Rs. 37400-67000 + GP 8700)	0	0	1	154803	1	154803	1	154803
2	Deputy Director (Rs. 15600-39100 + GP Rs.7600)	1	91745	1	91745	1	91745	1	91745
3	Senior Scientific Officer (Rs. 15600-39100 + GP Rs. 6600)	2	178630	4	357260	4	714520	4	1429040
4	Scientific Officers (Rs. 15600-39100 + GP Rs. 5400)	4	345596	8	691192	8	691192	10	863990
5	Senior Scientific Assistant (Rs. 9300-34800 + GP Rs. 4600)	12	818016	24	1636032	40	2726720	60	4090080
Total Manpower		19		38		54		76	
Financial implication/month (Rs in Cr.)			1433987		2931032		4378980		6629658
Financial implication/Annum			17207844		35172384		52547760		79555896

(Rs in Cr.)		1.72		3.52		5.25		7.96

Contractual Man Power requirement for each lab					
	Designation	**1000 samples**	**3000 Samples**	**5000 Samples**	**10000 samples**
1	Laboratory Attendants	4	8	10	10
2	Data Entry Operator	2	4	5	8
3	Office Assistant	2	4	5	8
	Total Manpower	8	16	20	26

List of Equipments for Mini Labs					
Sl No	**Name of the Instrument**	**Quantity Required**	**Approximate Cost**	**total cost**	**Proposed to IFD**
1	UV Spectrophotometer	1	800000	800000	500000
2	FTIR	1	1500000	1500000	
3	Digital Melting Point Apparatus	1	200000	200000	
4	HPLC Gradient System with UV-Vis detectors	2	2500000	5000000	
5	Drying Oven	2	120000	240000	
6	Muffle furnace	1	175000	175000	
7	Water Bath	2	10000	20000	
8	Magnetic Stirrer	2	10000	20000	
9	pH Conductivity Meter	2	20000	40000	
10	Digital Polari meter	1	1500000	1500000	
11	Digital Refractrometer	1	50000	50000	
12	Water Purifier	1	700000	700000	
13	Gas Chromatography with Head Space	1	3,000,000	3000000	3,600,000
14	Tablet Disintegration Apparatus	2	150000	300000	
15	Tablet Dissolution Apparatus with Auto sampler	2	500000	1000000	
16	Analytical Balance (Sensitivity 1 mg & 0.1 mg each)	2	200000	400000	
17	Fume hood	1	1000000	1000000	
18	Centrifuge	1	100000	100000	
19	Orbital Shaker with optional Access	1	50000	50000	
20	Vortex Centrifuge	1	20000	20000	
21	Vacuum Oven	1	300000	300000	

22	Emergency Safety Shower	1	10000	10000	
23	Chemical Storage Cabinet	1	100000	100000	
24	Hot Air Oven	1	200000	200000	
25	Eye Wash	1	10000	10000	
26	Spot extractor	1	10000	10000	
27	Karl Fischer	1	1000000	1000000	400,000
28	Auto Titrator	1	1000000	1000000	500,000
29	UV Cabinet	1	10000	10000	
30	Magnetic Stirrer	1	10000	10000	
31	Soxhlet Apparatus	1	10000	10000	
32	Vacuum Pump	2	10000	20000	
33	Calibrated Weight Box	2	10000	20000	
34	Atomic Absorption Spectrophotometer	1	3000000	3000000	400000
35	Sonicator	1	10000	10000	
36	Viscometer	1	300000	300000	
37	Pharma Refrigerator	2	400000	800000	80000
38	Domestic Refrigerator	2	50000	100000	
			19045000	**23025000**	
Total			**1.90 Cr**	**2.30 Crore**	

Financial Implication (Rs in Cr.)		
S.N0.	**Particulars**	**Sample Testing Capacity in each lab per Annum**

		1000 samples	3000 Samples	5000 Samples	10000 samples
1	Equipments and Instruments	2.39	4.81	6.69	10.20
2	Man power	1.72	3.52	5.25	7.96
3	Building construction	3	7.2	10.8	18
4	Recurring cost per annum	0.03	0.05	0.1	0.15
Total Cost		**7.14**	**15.58**	**22.84**	**36.31**

APPENDIX-V

Form GFR 19-A

[See Rules 212 (1)]

Form of Utilization Certification

Sl. No.	Letter No. & Date	Amount
	Total	

Certified that out of grants-in-aid of Rs. ……..(Rupees……), sanctioned during the year…….. in favour of ……(name of the State Government) under sanction letter File No…….. dated…….. under the Scheme of Strengthening of States Drugs Regulatory Authorities and Rs. …… (Rupees……) on account of unspent balance of the previous year, a sum of Rs……(Rupees……) has been utilized for the purpose for which it was sanctioned and that the balance of Rs…… (Rupees……..……) remaining unutilized at the end of the year has been surrendered to the Government of India

(vide letter No..... dated.....) / will be adjusted towards the grants-in-aid payable during the next year.

2. Certified that I have satisfied myself that the conditions on which the grants-in-aid was sanctioned have been duly fulfilled/are being fulfilled and that I have exercised the following checks to see that the money was actually utilized for the purpose for which it was sanctioned. The details of Checks exercised are as below:

1.

2.

3.

4.

5.

Signature of the Authorized Officer.....

Designation.....

State Govt./UT Administration

Date _____

Seal _____

APPENDIX VI

CEILINGS OF EXPENDITURE

There would be ceilings for different items of expenditure as follows:

Item	Rate ceiling	Total Cost ceiling
Construction of building (per lab), in case there is no lab	Rs. 3,000/- per Sq. Feet	Rs…….crore
Equipment (per lab)	-	Rs. 10 crore
Manpower (Lab) [Regular or Contractual]	50 personnel	Rs. 40,000/- per person (average for different level posts)
Manpower (Drug Inspector) [Regular or Contractual]	……Drugs Inspectors	Rs. 50,000/- per month
Maintenance and running cost (per lab)/ per annum	-	Rs. 2.5 crore
Furniture & office machinery, including computers (for existing labs & drug control offices)	-	Rs. 5 crore
Establishment of new labs as per prescribed criteria	Category 'A': Category 'B': Category 'C': Category 'D':	(1000 samples/ annum) Rs. 5 crore
NABL accreditation	On actual basis within overall limit of agreed funds	

Appendix VII

Quantifiable Outcomes

Activities	2015-16	2016-17	2017-18
Issue of State Licenses			
Setting up of enforcement structure in States / UTs (Manpower)			
Up-graduation of infrastructure/operational equipment's /facilities for strengthening State Drugs Regulatory Structures			
Number of Drugs Samples Tested			
Upgradation of Laboratories			
Setting up of Laboratories			
NABL Accreditation of Laboratories			
E-Governance (I.T. Applications)			

Monitoring Format for Different Components of Enforcement Structure under the Centrally Sponsored Scheme

A. Monitoring format for setting up of Enforcement Structure in States/UT:

1. Name of State/UT:
2. Sanction Letter No. / Date:
3. No. of staff recruited:
4. Facilities created for enforcement (with capacity):
5. Expenditure made according to guidelines or not. In case of deviation, please specify with reasons:
    a) Details with Name and address, Details of technical staff appointed (attach separate report), and expenditure statement, etc. with analyzing capacity created or proposed.
    b) Is the Monitoring team satisfied with the implementation. If not then specify grounds and suggestions for improvement.

❐❐❐