RECOMMENDATIONS OF THE SUB-COMMITTEE FOR CREATION OF CADRE BASED (UNIFORM CADRES) POSTS IN ALL CENTRAL & STATE DRUGS TESTING LABORATORIES & SETTING OF MOBILE DRUGS TESTING LABORATORIES

PREPARED BY:

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&
CHAIRMAN OF THE SUB-COMMITTEE

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PREFACE

In this report, as a Chairman of the Sub-Committee, I am delighted to present the recommendations on drafting the draft recruitment rules for the purpose of formation of uniform cadres/ cadre based posts for all the state and central drugs testing laboratories, so as to achieve a harmony in cadres of laboratory personnel for uniform implementation of Drugs & Cosmetics Act, 1940 and Rules there under. During the term of holding the Chairmanship of the sub-committee set-up by the DCG (I), New Delhi a couple of meetings was conducted and extensive brainstorming was done on proposing a harmonised model for uniform cadres. Finally, we arrived at a unanimous model for the assigned duty. Further, the sub-committee members also discussed about the feasibility of mobile drugs testing vans for spot testing of drugs in field level by the drugs law enforcement officers.

In the next few pages a detailed report is furnished for the easy understanding and recommendations made by the sub-committee on the assigned tasks.

ACKNOWLEDGEMENTS

I am thankful to the Drugs Controller General (India), for appointing me as Chairman of this sub-committee and giving me an opportunity to recommend the harmonised cadres for all the state and central drugs testing labs and to make a feasibility study on mobile drugs testing facility for introduction on a large scale in the country. I also thank all the Sub-committee members for their valuable contributions made during the series of meetings. I thank every member of this sub-committee for sparing their valuable time for attending the two meetings conducted on my call in spite of their busy schedule.

I personally thank Dr. G. Praveen Kumar, Junior Scientific Officer, Drugs Control Laboratory, Vijayawada for assisting me in drafting the entire sub-committee report and made it possible.

Dr. A. RAVI SHANKAR, I.P.S
Chairman of the Sub-committee
&
Director General
DCA, Govt. of A.P, Guntur

1.0 APPOINTMENT ORDER COPIES OF THE SUB-COMMITTEE

File No. X.19013/2/2017-DC (Part 3)
Directorate General of Health Services
Central Drugs Standard Control Organisation
O/o Drugs Controller General (I)

Date30 JAN 2018

OFFICE MEMORANDUM

Subject: Constitution of a Sub-committee to make a proposal for cadre based posts for all the drugs testing laboratories and provision of one mobile testing laboratory for offices of CDSCO and each State/UT under the Central Govt. Scheme - reg.

The 52rd meeting of Drugs Consultative Committee (DCC), a statutory body under the Drugs and Cosmetics Act, 1940 was held on 18th September, 2017 and the deliberated the matters arising out of the administration of the Drugs and Cosmetics Act, 1940 and Rules made there under in the country.

DCC recommended to constitute a sub-committee:

1) to make a proposal for cadre based posts for all the drugs testing laboratories keeping in view, the inter laboratories transfer policy, creation of additional posts for all laboratories, transfer of posts of laboratories from one state to the another/ Centre etc. and

2) to make a proposal for providing and setting up of mobile testing laboratories for offices of CDSCO Zonal, Sub-zonal & Ports and also to each State/UT drugs control offices for rapid screening of the medical products under the Central Govt. Scheme.

Composition of sub-committee:

1. Dr. Ravi Shankar IPS, Director General, DCA, Andhra Pradesh as Chairman
2. Dr. H. G. Koshia - Commissioner, FDCA, Gujarat as member
3. Shri. Lalsawma, Joint Director,FDA, Mizoram as member
4. Dr. R.A Singh, Director, CDTL Chandigarh as member
5. Dr. Raman Mohan Singh, Director, CDTL, Mumbai as member
6. Shri. C Hariharan, Director, CDL, Kolkata as member
7. Dr. Bangarurajan, JDC(I), CDSCO(HQ), as Convener

The subcommittee is requested to submit their report within 6 months.

To,
The Members of Committee

File No. X.19013/2/2017-DC (Part 3)
Directorate General of Health Services
Central Drugs Standard Control Organisation
O/o Drugs Controller General (I)

FDA Bhawan, Kotla Road,
New Delhi-110002,
Date 19 FEB 2018

To,
All the Central Drugs Testing Laboratories and State/UT Drugs Controllers

Subject: Cadre based posts for all the drugs testing laboratories and provision of one mobile testing laboratory for offices of CDSCO and each State/UT under the Central Govt. Scheme – reg.

The 52nd meeting of Drugs Consultative Committee (DCC), a statutory body under the Drugs and Cosmetics Act, 1940 was held on 18th September, 2017 and the deliberated the matters arising out of the administration of the Drugs and Cosmetics Act, 1940 and Rules made there under in the country.

DCC recommended constituting a sub-committee under the chairmanship of Dr. Ravi Shankar IPS, Director General, DCA, Andhra Pradesh

1. To make a proposal for cadre based posts for all the drugs testing laboratories keeping in view, the inter laboratories transfer policy, creation of additional posts for all laboratories, transfer of posts of laboratories from one state to the another/ Centre etc. and

2. To make a proposal for providing and setting up of mobile testing laboratories for offices of CDSCO Zonal, Sub-zonal & Ports and also to each State/UT drugs control offices for rapid screening of the medical products under the Central Govt. Scheme.

The first meeting of the sub-committee was held at CDSCO (HQ) on 09.02.2018 and in this meeting sub-committee briefly discussed on the existing and proposed Organogram in the states as well as central drugs testing laboratories. The sub-committee proposed to collate the existing Organogram of States as well as Central Drugs Testing Laboratories for taking holistic considerations before giving its final recommendations.

In view of above, it is requested that all the Directors of Central Drugs Testing Laboratories and State Drugs Controllers shall send the existing Organogram (along with other relevant details as per enclosed Annex-I) of the laboratories under their control to CDSCO-HQ via email **dccdtab@cdsco.nic.in** with a copy to **dci@nic.in** latest by 01.03.2018 for the purpose of review by sub-committee formed in this regard.

Yours faithfully

(Dr. G.N Singh)
Drugs Controller General of India

Copy To:
All Zonal / Sub-zonal offices of CDSCO, for necessary coordination and timely submission of data by SLAs and Directors of Central Drugs Laboratories in their jurisdiction

2.0 MEMBERS OF THE SUB-COMMITTEE

At the 52nd Consultative Sub-committee meeting held on 18.09.2017 it was proposed to constitute a sub-committee with the following members to submit proposals for creation of cadre based posts for all central and state drugs testing laboratories.

1. Dr. Ravi Shankar IPS, Director General, DCA, AP - Chairman
2. Dr. H. G. Koshia, Commissioner, FDCA, Gujarat – Member
3. Shri. Lalsawma, Joint Director, FDA, Mizoram– Member
4. Dr. R. A. Singh, Director, RDTL, Chandigarh– Member
5. Dr. Raman Mohan Singh, Director, CDTL, Mumbai – Member
6. Shri. C. Hari Haran, Director (I/c), CDL, Kolkata - Member
7. Dr. Bangarurajan, JDC (India), CDSCO (HQ) - Convener

Special Invitees: The following members were the special invitees for the meetings conducted by the sub-committee.

(i) Dr. Gandhi, Director, Truth Labs, Hyderabad.

(ii) Dr. N. Murugesan, Director, CDTL, Chennai.

Attendees: The following were the attendees for the meetings by the sub-committee.

1. Smt. Jyoti J. Sardesai, Director, DCA, Goa
2. Smt. Lotika Khajuria, State Drugs Controller of J & K State
3. Sh. T. Kailasam, Joint Director (FAC), DCA, Telangana
4. Shri. ACS Rao, DDC(I), CDSCO (HQ)
5. Smt. Annam Visala, DDC(I), CDSCO (HYD)
6. Dr. Santosh Indraksha, ADC(I), CDSCO(HQ)
7. G.Raghuvaran, Drugs Inspector, CDSCO (HQ)
8. P. Rajesham, Drugs Inspector, CDSCO (HQ)
9. Dr. G. Praveen Kumar, Jr. Scientific Officer, DCL, Vijayawada

3.0 PREAMBLE

3.1 Indian Pharmaceutical sector is the 3rd largest in the world by volume & 13th in value and it is one of the most vibrant sectors of Indian economy. It is growing at the rate of 14% per annum and is presently about Rs 1Lakh 20 thousand Crore out of which exports account for Rs 60,000 Crore. Drugs from India are exported to more than 200 countries & vaccines are exported to more than 151 countries. There are about 8,000 drug manufacturing units in the country and 7.5 lacs retail/sale outlets. This industry 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.

3.2 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 to be strengthened. The capacity and the strength of the technical manpower also requires 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.

3.3 A secure 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 securely 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.

3.4 Effective implementation of Drugs & Cosmetics Act, 1940 and rules thereunder 1945 is based on the analytical test report issued with testing confidence in Form-13 in Government laboratories for effective prosecutions and convictions. This makes a strong platform for proper vigilance at regulators level to minimize the movement of spurious and misbranded and NSQ drugs and thereby making safe and efficacious drugs available for safe-guarding public health by and large. In the mean time, the genuine drug manufacturers should also be protected. All this can be done by carrying out analysis of drugs and cosmetics with confidence and proper documentation etc in compliance with Schedule-L of D&C Act, 1940 and NABL/ ISO-17025 standards.

3.5 Some of the central and state drugs testing laboratories are already recognized by NABL for their competence in drugs testing. However, some need to march towards pursuit of NABL accreditation.

3.6 With this foreword, it is pertinent to mention that, different states and central drugs testing laboratories have different staffing pattern and recruitment rules etc. and thereby, creating a mess. Further, except Government Analyst appointed u/s 20 of the Drugs & Cosmetics Act, 1940, no other cadre/ post is similar in two laboratories.

3.7 To overcome such kind of confusion, a uniform cadre re-structuring and framing of draft recruitment rules was proposed at the 52nd Drugs Consultative Sub-committee meeting held on 08.09.2017 under the chairmanship of the Drugs Controller General (India), CDSCO, New Delhi to meet functionality, legality and the professional requirement and progress in the career.

4.0 BACKGROUND

4.1 Central Government aims to ensure that the drugs available to the public are safe, efficacious and conforms to prescribed quality standards. Regulatory control over the quality, safety and efficacy of drugs in the country is exercised through a central legislation called Drugs & Cosmetics Act, 1940 and rules made there under.

4.2 Each state's drugs control department conducts its own recruitment based on the qualification criteria laid down in D&C Rules, 1945. Since the recruitment process is different for each state, the training process is also likely to be different. Similarly, different states and central drugs testing laboratories have different staffing pattern and recruitment rules.

4.3 Main purpose of any cadre review is to restructure a cadre in such a way as to remove the deficiencies which might be existing at

the time of service or have crept in subsequently and ensure that the cadre structure satisfies the functional, structural and personnel consideration. Cadre restructuring exercise should provide an opportunity to overcome various bottlenecks, remove existing distortions and bring about the rationalisation of cadre structure so as to improve the efficiency and morale of the laboratory cadre officers and thereby enhance the effectiveness of the Service in fulfilment of the objectives for which it has been established.

4.4 Movement of officials from one laboratory to another is good for gaining experience. However, it has to be viewed against the fact that many officials and staff may not be interested to move away from their present station. This will enhance the sharing of experimental learning and definitive sharing of best practices. It will also give opportunity to the Central officers to serve in their states as well as work in the Central institutes with more pride.

4.5 India, is becoming the largest exporter and consumer of medicines with ever increasing population. In this regard, as the number of retail supply chain increases there must a vigil on the activities carried out during the supply of drugs and their stability during storage. Hence, there would be number of drugs testing personnel increase year by year.

5.0 OBJECTIVES

5.1 Major part of the cadre review/ restructuring exercise concerns advance projection of manpower requirement over the review period and the planning for the recruitment for this period. Rationalisation of the cadre from the functional, structural and personnel angles is the other major objective of any cadre review. By and large following are cited as the major objectives of a cadre restructuring/ review.

- Estimate future manpower requirement on a scientific basis for a period of 5 years at a time.
- Plan recruitment in such a way as to avoid future promotional blocks and at the same time prevent gaps building up.
- Restructure the cadre to harmonise the functional needs with the legitimate career expectations of its members and to
- Enhance the effectiveness of services.
- To fix the quota of deputation from central to central labs and state to state labs and in turn state to central labs etc.
- To suggest a model on recruitment cycle to be followed.

5.2 The prime objective of the sub-committee that has been set up is to recommend to CDSCO/ DCC on draft recruitment rules and creation of cadre based (uniform cadres) posts in all Central and State Drugs Testing Laboratories.

6.0 SCOPE

6.1 The recommendations that are made by the Sub-committee for setting up of recruitment rules and cadre based posts in all Central and State Drugs Testing Laboratories will be applicable for all the Central/ Regional/ State Drugs Testing Laboratories in the country. Further, the scope of the sub-committee is to make recommendations only on the creation of similar cadre posts to avoid confusion amongst different drugs testing laboratories and their reports in the country and to make a free passage for inter-state and state-centre deputations in a hassle free manner.

6.2 Further, the sub-committee will also recommend the feasibility for introducing the mobile drugs testing facility in all the CDSCO zonal and sub-zonal offices and technical and manpower requirements for its launch.

7.0 GENERAL PRINCIPLES

7.1 Under the provisions of the Drugs & Cosmetics Act (D&C 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.

7.2 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 D&C Act, 1940 and Rules, 1945.

8.0 EXCELLENCE IN DRUGS TESTING :: INDIAN SCENARIO

8.1 Total drugs testing in the country by Government laboratories amounts to 1,11,000 samples per year. Out of this the central drugs testing labs under CDSCO analyses about 23,000 samples only (i.e. about 25%) and remaining 75% samples are analysed by 31 state drugs testing labs.

8.2 In India till date, the Drugs Testing Laboratories both at central and provincial level are under-equipped in terms of testing infrastructure and human resources.

9.0 MEETINGS OF THE SUB-COMMITTEE

The Sub-committee has conducted a couple of meetings to discuss, examine and deliberate the issue of creation of cadre based posts and to prepare draft recruitment rules.

The Sub-committee members have conducted **1st meeting** at Conference Hall, CDSCO Head Officer, New Delhi **on 09.02.2018**. The following are the outcomes of the 1st meeting.

The **2nd meeting** of the Sub-committee members was held at Conference Hall, CDSCO Zonal Office, Hyderabad on **13.03.2018**. The following are the outcomes of the 2nd meeting.

- Organogram of laboratory officials consisting of **7** levels are finalized after detailed discussion and considering existing structure of nationwide laboratories.

Minutes copies of the both the meetings are annexed to this proposal at the end of the document.

10.0 EXISTING CENTRAL & STATE DRUGS TESTING LABS ORGANOGRAMS

The Sub-committee had studied some of the Central and states drugs testing laboratories and here under projected the existing models to have an understanding of the human resources pattern.

10.1 Organogram of Regional Drugs Testing Laboratory, Chandigarh

S.No	Post Name	Qualifications	Method of Appointment	Scale of Pay
1	Junior Scientific Assistant	M.Pharm, or M.Sc. in Microbiology or Chemistry or Biochemistry	By Direct Recruitment	Rs. 9300-34800 (G.P. Rs.4200/-)
2	Senior Scientific Assistant	-do-	By Promotion of J.S.A and By Direct Recruitment and By Deputation	Rs. 9300-34800 (G.P. Rs.4600/-)
3	Senior Scientific Officer-II	-do-	By Promotion of S.S.A and By Direct Recruitment and By Deputation	Rs. 15600-39100 (G.P. Rs.5400/-)
4	Director	M.Pharm, or M.Sc. in Chemistry or Biochemistry	By Promotion of S.S.O and By Direct Recruitment and By Deputation	Rs. 37400-67000 (G.P. Rs.8700/-)

Similar pattern observed in other central drugs testing laboratories.

10.2 Organogram of State Drugs Control Laboratory, Andhra Pradesh

S.No	Post Name	Qualifications	Method of Appointment	Scale of Pay
1	Junior Analyst	B.Pharm/ M.Sc in Chemistry/ Microbiology/ Biochemistry or B.Sc with AIC	By Direct Recruitment	Rs. 28940-78910
2	Junior Scientific Officer	M.Pharm/ M.Sc in Chemistry/ Microbiology/ Biochemistry or B.Sc with AIC (for Direct Rectt.)	By Promotion of Jr. Analyst and by Direct Rect. in the Ratio of 67% and 33%	Rs. 35120-87130
3	Senior Scientific Officer	-do-	By Promotion of J.S.O	Rs. 42490-96110
4	Joint Director (Lab)	-do-	By Promotion of S.S.O	Rs. 52590-103290

10.3 Organogram of State Drugs Control Laboratory, Telangana State

S.No	Post Name	Qualifications	Method of Appointment	Scale of Pay
1	Junior Analyst	B.Pharm/ M.Sc in Chemistry/ Microbiology/ Biochemistry or B.Sc with AIC	By Direct Recruitment	Rs. 28940-78910
2	Junior Scientific Officer	M.Pharm/ M.Sc in Chemistry/ Microbiology/ Biochemistry or B.Sc with AIC (for Direct Rectt.)	By Promotion of Jr. Analyst and by Direct Rect. in the Ratio of 67% and 33%	Rs. 35120-87130
3	Senior Scientific Officer	-do-	By Promotion of J.S.O	Rs. 42490-96110

10.4 Organogram of State Drugs Testing Laboratory, Karnataka State

S.No	Post Name	Qualifications	Method of Appointment	Scale of Pay
1	Laboratory (Drugs) Technician	Diploma in Pharmacy	By Direct Recruitment	Rs. 30350-58250
2	Lab Supervisor	-do-	By Promotion of Drug Technician	Rs. 33450-62600
3	Junior Scientific Officer	B. Pharmacy and experience in Analysis if Drugs & Cosmetics	By Promotion of Drug Technician having B. Pharmacy in Ratio of 33% and by Direct Rect. in the Ratio of 66%	Rs. 43100-83900
4	Scientific Officer	-do-	By Promotion of J.S.O	Rs. 52650-97100
5	Chief Scientific Officer	-do-	By Promotion of Scientific Officer	Rs. 67550-104600
6	Principal Scientific Officer	-do-	By Promotion of C.S.O	Rs. 74400-109600

10.5 Organogram of State Drugs Testing Laboratory, Kerala State

S.No	Post Name	Qualifications	Method of Appointment	Scale of Pay
1	Analyst (Grade-III)	B. Pharma	By Direct Recruitment	Rs. 39500-83000
2	Analyst (Grade-II)	-do-	By Promotion of Drug Technician	Rs. 42500-87000
3	Analyst (Grade-I) & Govt. Analyst	-do-	By Promotion of Drug Technician having B. Pharmacy in Ratio of 33% and by Direct Rect. in the Ratio of 66%	Rs. 45800-89000
4	Chief Government Analyst	-do-	By Promotion of J.S.O	Rs. 68700-110400

10.6 Organogram of State Drugs Testing Laboratory, Tamilnadu State

S.No	Post Name	Qualifications	Method of Appointment	Scale of Pay
1	Junior Analyst	B. Pharm or M.Sc	By Direct Recruitment	Not available
2	Senior Analyst	-do-	By Promotion of Junior Analyst	Not available
3	Deputy Government Analyst	-do-	By Promotion of Senior Analyst	Not available
4	Government Analyst	-do-	By Promotion of Dy. Govt. Analyst	Not available

10.7 Organogram of State Drugs Testing Laboratory, Odisha State

S.No	Post Name	Qualifications	Method of Appointment	Scale of Pay
1	Senior Laboratory Assistant	B. Pharma	By Direct Recruitment	Rs. 9300-34800 (G.P. 4200)
2	Junior Scientific Officer	-do-	By Promotion of S.L.A	Rs. 9300-34800 (G.P. 4600)
3	Senior Scientific Officer	-do-	By Promotion of J.S.O	Rs. 9300-34800 (G.P. 5400)
4	Principal Scientific Officer	-do-	By Promotion of S.S.O	Rs. 15600-39100 (G.P. 6600)

10.8 Organogram of State Drugs Testing Laboratory, Jammu & Kashmir State

S.No	Post Name	Qualifications	Method of Appointment	Scale of Pay
1	Senior Laboratory Technician	B. Pharma or B.Sc with Chemisry	50% by Direct Rectt. & 50% by Promotion of Lab Technicia	Rs. 9300-34800 (G.P. 4260)
2	Instrument Technician	-do-	By Promotion of S.L.T	Rs. 9300-34800 (G.P. 4280)
3	Senior Scientific Officer	M.Pharma	By Promotion of Instr. Technician	Rs. 9300-34800 (G.P. 4300)
4	Assistant Drug Analyst	M.Pharma for Direct Rectt.	20% by Direct Rct. And 80% by promotion of B.Pharma candidates	Rs. 9300-34800 (G.P. 4800)
5	Drug Analyst	-do-	By promotion of A.D.A	Rs. 15600-39100 (G.P. 6600)

10.9 Comparative Statement of Designations of some Drugs Testing Laboratories in Southern States & RDTL, Chandigarh

State Name	Andhra Pradesh	Telangana	Karnataka	Kerala	Tamilnadu	Odisha	J&K	RDTL Chandigarh
Designation	Joint Director (Lab)	-	Principal Scientific Officer	Chief Government Analyst	Government Analyst	Principal Scientific Officer	Drug Analyst	Director
	Sr. Scientific Officer	Sr. Scientific Officer	Chief Scientific Officer	Analyst Gr-I	Deputy Government Analyst	Sr. Scientific Officer	Assistant Drug Analyst	Senior Scientific Officer-II
	Jr. Scientific Officer	Jr. Scientific Officer	Scientific Officer	Analyst Gr-II	Senior Analyst	Jr. Scientific Officer	Senior Scientific Officer	Senior Scientific Assistant
							Instrument Technician	
Feeder Post	Junior Analyst	Junior Analyst	Junior Scientific Officer	Analyst Gr-III	Junior Analyst	Sr. Laboratory Assistant	Senior Laboratory Technician	Junior Scientific Assistant

Feeder Category Posts appointment is done through Public Service Commissions in respective States.

A study on existing staff patterns of one Regional Drugs Testing Laboratory, Chandigarh and some state drugs testing laboratories in southern part of India has given a glimpse of different designations and recruitment rules/ procedures etc.

In view of the above and keeping in view the implementation of D&C Act, 1940 in India across states it is proposed to frame uniform designations and recruitment rules for technical personnel of Drugs Testing Laboratories across states and centre. Henceforth, the following 7 tier designations system is proposed.

S. No:	**Post Name**
1	Scientific Assistant
2	Senior Scientific Assistant
3	Junior Scientific Officer
4	Scientific Officer
5	Senior Scientific Officer
6	Deputy Director
7	Director

The following are the draft recruitment rules for the above said posts:

11.0 PROPOSED UNIFORM TECHNICAL & SUPERVISORY STAFFING PATTERN FOR CENTRAL AND STATE DRUGS TESTING LABORATORIES

S.No	Name of the Post	Classification	Recruitment Mode	Pay Band & Grade Pay (Pre-revised as per 6th CPC)	Educational and Other Qualifications	Period of Probation	Training	Special Increments if any
1	Scientific Assistant	Group 'B' Non-gazetted Non-ministerial	By Direct Recruitment (selection through state/ central Public Service Commission)	15600-39100 GP-4200/-	**Essential**: Masters degree in Chemistry or Biochemistry or Microbiology or M. Pharmacy or Pharmaceutical Chem **Desirable**: Ph. Din the subject concerned	2 years in continuous service of 3 years	Two months Training in Analysis of Drugs and Cosmetics at CDL, Kolkata and to attend other training programs as per need	For Candidates possessing Ph.D four (4) additional increments
2	Senior Scientific Assistant	-do-	By Promotion of Scientific Asst. with minimum3 years of service	15600-39100 GP-4600/-	-do-	On promotion 1 year in a continuous service of 2 years	Interactive trainings with NIPER or IPC or other States or CDL from time to time	-do-
3	Junior Scientific Officer	Group 'B' Gazetted Non-ministerial	As per DoPT norms	15600-39100 GP-4800/-	-do-	-do-	Trainings at IPC/ CDL or any other institute	-do-
4	Scientific Officer	Group 'A' Gazetted	-do-	15600-39100 GP-5400/-	-do-	-do-	-do-	-do-
5	Senior Scientific Officer (to be notified as Govt. Analyst)	-do-	-do-	15600-39100 GP-6600/-	-do-	-do-	-do-	-do-

6	Deputy Director	-do-	-do-	15600-39100 GP-7600/-	-do-	-do-	-do-	-do-
7	Director	-do-	By Promotion of Deputy Director only	15600-39100 GP-8700/-	-do-	-do-	-do-	-do-

12.0 PROPOSED SUPPORTING STAFF:-

S.No.	Name of the Post	Classification	Recruitment Mode	Pay Band & Grade Pay	Educational and Other Qualifications	Period of Probation
1	Lab Attendant	-	By Direct Recruitment	5200-20200 GP-2400/-	10+2 certificate	2 years in a continuous service of 3 years
2	Junior Laboratory Assistant	Group 'C' Non-gazetted	By Promotion of LA with minimum of 3 years service	5200-20200 GP-2600/-	**Essential**: B.Sc with Chemistry as one of the subject	On promotion 1 year
3	Senior Laboratory Assistant	-do-	By Promotion of JLA with minimum of 5 years service	5200-20200 GP-2800/-	-do-	-do-

Supporting Staff to be recruited on Outsourcing basis

13.0 PROPOSED ADMINISTRATIVE STAFF:-

S.No.	Name of the Post	Recruitment Mode	Pay Band & Emoluments	Educational and Other Qualifications
1	Sample Custodian	On Outsourcing basis	Consolidated Pay	B.Sc with Chemistry as one of the subjects
2	Data Base Administrator	-do-	-do-	M.C.A with knowledge of networking
3	Despatch Clerk	-do-	-do-	Any graduate

14.0 PAY SCALES HARMONISATION RECOMMENDED BY THE SUB-COMMITTEE

S. No:	Post Name	Pay Scale Recommended (as per 6th CPC) pre-revised
1	Scientific Assistant	15600-39100 (GP-4200/-)
2	Senior Scientific Assistant	15600-39100 (GP-4600/-)
3	Junior Scientific Officer	15600-39100 (GP-4800/-)
4	Scientific Officer	15600-39100 (GP-5400/-)
5	Senior Scientific Officer	15600-39100 (GP-6600/-)
6	Deputy Director	15600-39100 (GP-7600/-)
7	Director	15600-39100 (GP-8700/-)

15.0 IMPORTANT RECOMMENDATIONS BY THE COMMITTEE

15.1 It was opined by the Sub-committee members that the said 7 cadres above, may be accepted to a given level/ cadre based on administrative ease and convenience by a given state department.

15.2 It is further opined that, the Promotion/ Advisory panel to the post of Director shall comprise of Director from the prestigious research institutes like Indian Institute of Science, Bengaluru or Indian Institute of Chemical Technology, Hyderabad.

15.3 Further, the sub-committee members were of uniform opinion that, there must be mandatory Pre-Promotion tests and Post-Promotion training at all designations.

15.4 In general, the promotion to direct recruitment quota to be earmarked at all levels may be as per the norms fixed by the Department of Personnel & Training (DoPT).

15.5 All other conditions of service shall be as laid down by DoPT from time to time.

15.6 *Promotions shall be linked with proficiency and educational qualifications & eligibility requirement should be*

different at all levels. For this, Proficiency Testing is to be conducted by a committee constituted by the Head of the Department.

15.7 *The Committee is of the unanimous opinion that, to maintain morale and motivation of entry level cadres, time bound promotions are essential up to the cadre of Senior Scientific Officer who is to be notified as Government Analyst. These promotions are to be affected after three (3) years of service upto Junior Scientific Officer (JSO) cadre and five (5) years of service from JSO to Scientific Officer and there to Senior Scientific Officer.* The committee opined that, a regular and promising career advancement scheme has to be implemented to attract skilled and talented youth.

15.8 *Accordingly, as and when the entry level cadres get vacated due to promotions/ or any other reason or higher cadres get vacated due to retirements, a* ***recruitment cycle is recommended*** *here under for compliance. It is of opinion that, entry level cadres are to be filled through direct recruitment once when number of vacancies reaches* ***to five (5) posts.***

15.9 The Committee is of the opinion that, 4th and 5th cadres i.e. *Scientific Officer and Senior Scientific Officer* are to be categorized as **Selection Grade** for the purpose of avoiding stagnation.

16.0 TESTING DIVISIONS

The above personnel are to be allocated into the following mandatory Testing Divisions in all Laboratories:-

1) Chemical & Instrumental Division
2) Microbiological Testing Division
3) Pharmacology/ Toxicology Division
4) Pharmacognosy/ Phytochemistry Division
5) Biochemistry Division
6) Medical Devices Testing Division
7) Cosmetics Testing Division

17.0 TRAINING

17.1 Training at the time of Induction

At least two months room training is required for the newly inducted laboratory officials involved in drugs testing, so that they should have sufficient exposure and acquaintance with usage, maintenance and calibration of various instruments/ equipments

used in laboratory for testing of drugs. Training also is useful to understand the functioning of the department as well as about the Rules and Regulations and minimum procedures to be adopted while discharging their duties.

17.2 In-service periodical training

There shall be a periodical training for the in-service laboratory technical staff at least once in three years to update their knowledge about the various testing procedures and new methodologies as well as with respect to good laboratory practices. Such training can be either out sourced to the high profile institutes like Central Drugs Standard Control Organization, National Institute of Biologicals, National Institute of Pharmaceutical Education and Research or Indian Pharmacopoeia Commission, Ghaziabad or such training can be arranged in -house also.

18.0 CADRE WISE JOB CHARTS

18.1 SAMPLE CUSTODIAN

- To receive the samples of drugs and cosmetics through post in laboratory.

- To open the samples in presence of the Government Analyst and to validate the Form-18s.
- To maintain the receiving and reporting registers of samples in Coding Cell.
- To maintain the confidentiality of samples in the Coding Cell.
- To assist the Government Analyst in distribution of samples to sections for analysis.
- To ensure that the reports of Form-13s are typed and to see that an end-to-end confidentiality is maintained.

18.2 DATA BASE ADMINISTRATOR

- To maintain LIMS in an effective manner and to ensure proper networking of all computers and instruments.
- To maintain digital records of laboratory.
- To maintain archival of e-records for their timely retrieval.

18.3 LAB ATTENDANT

The Lab Attendants shall have the functions and responsibilities as under:

- Monitoring cleaning and sanitation in the lab.
- Collection and transfer of material required for the lab use.
- Cleaning and drying of the Apparatus.
- Monitoring cleaning and maintenance of lab instruments and equipments.
- Operation of autoclave etc.
- To assist the Senior Scientific, Scientific and Junior Scientific Officers in their day to day work.
- Dispatch of test reports.
- Disposal of left- over quantity of the used sample portions.

18.4 SCIENTIFIC & SENIOR SCIENTIFIC ASSISTANT:

- To receive the samples of drugs and cosmetics from the unit officer i.e. Scientific Officer.
- To complete the analysis as per the method prescribed/ suggested by the Scientific Officer or as per the methods published in national and international pharmacopoeias or any other journals etc.
- To analyze not less than 10-12 samples per month.
- To report the quality of the sample subjected to analysis in Form-13 as per D&C Act and onward submission of the same to Scientific Officer.

- To get trained in CDL, Kolkata and/ or IPC, Ghaziabad from time to time on different trends in analysis of pharmaceutical products.

- To get trained in such institutes atleast once in 5 years.

- To regularly calibrate all the analytical instruments/ machinery used in drugs analysis and records pertaining to such calibrations and also prepare all the analytical reagents and their standardization in line with pharmacopoeial specifications.

- To maintain Good Laboratory Practices as per Schedule-L1 of D&C Act, 1940 and to regularly interact with the Scientific Officer and other higher officials of the laboratory for practicing better analysis methods in laboratory.

18.5 JUNIOR SCIENTIFIC OFFICER

- To receive the samples of drugs and cosmetics from the Coding Cell of the laboratory in prescribed form.

- To allot the samples to the Drugs Analyst under him/ her control for analysis along with the method of analysis and tests to be carried out.

- To interact with the Drugs Analyst regularly on trouble shooting if any during analysis of samples.

- To compile the data generated from the Scientific Assistants and keep under his/ her control.

- To receive the test reports generated by Scientific & Sr. Scientific Assistants for endorsing and onward forwarding to Scientific Officer for opinion.

- Preparation of indents of chemicals and glassware and other consumables for use in his/ her section.

- To initiate the Annual Confidential Reports in respect of Scientific Assistant and Senior Scientific Assistant.

18.6 SCIENTIFIC OFFICER

- To co-ordinate with the Coding Cell and the unit assigned to him/ her for effective analytical work.

- To consolidate the scientific data on drugs analysis received from different units under control.

- To interact with Scientific Officers in preparation of annual indents for procurement.

- To participate in various professional trainings conducted by USP/ EP/ BP time to time at least twice in such cadre.

- To monitor the analysis of any not of standard quality sample if reported.

- To coordinate with the lower cadres officials for strict implementation of GLP in laboratory.

- To initiate the Annual Confidential Reports in respect of Junior Scientific Officer.

18.7 SENIOR SCIENTIFIC OFFICER

- To interact with the Deputy Director and Director of the lab for maintaining the analysis standards.

- As a notified Government Analyst to declare the opinion on quality of drugs and cosmetics received.

- Participation in different workshops/ conferences/ Training programs conducted by different MNCs or other Government agencies.

- To participate in the Audits regularly conducted by NABL or other accreditation agencies.

- To assist in the activities related to technical and administrative to Director.

- Conduct of Training Programs in consultation with other States and Overall supervision of Analytical work in Lab

- To initiate the Annual Confidential Reports in respect of Chief Scientific Officer.

18.8 DEPUTY DIRECTOR

- To assist the Senior Scientific Officer in all technical issues related to analysis.
- To maintain data of the sections and statistics of laboratory.
- To coordinate with other subordinate staff and Director for implementing Good Laboratory Practices and other best practices followed in other labs and so on.
- To keep a track of training programs for regular updation of human resources for effective analysis.

18.9 DIRECTOR

- To coordinate with the Head of the Department in all issues related to the Laboratory.
- To furnish the annual indents for different consumables and instruments to the Department Head.
- To interact with the lower officials of the laboratory regularly in all issues pertaining to analysis and other key decisions.
- To develop an annual action plan of analysis in consultation with subordinates for effective implementation of GLP.
- To involve in day-to-day administrative activities related to Lab and do correspondence related to it.

- To interact with other state officers and CDSCO on various good practices to be implemented from time to time.

- Shall be responsible for validation and revalidation of the methods/ techniques.

- Shall be responsible for arranging the periodical audit of the lab and for corrective action & preventive action (CAPA).

- To also prepare the annual budget requirement etc. or any other schemes for development of lab.

- To initiate the Annual Confidential Reports in respect of Deputy Director.

- Shall be responsible for accreditation of laboratory from NABL.

19.0 RULES GOVERNING INTER-STATE TO CENTRE DEPUTATION

19.1 The transfer or inter-state deputation of Drugs Analyst or any other higher cadres in Drugs Testing Laboratory of any state is regulated by the O.M.No.6/8/2009-Estt. (Pay II) order of DoPT dated: 17.06.2010 and other orders issued by Government of India from time to time in this regard.

19.2 Inter-state deputation or transfer of Laboratory staff initially should be for a period of 2 years and can likely be extended for for a period of 5 years but it should not be more than a period of 5 years.

19.3 During the period of deputation the employee will be under the administrative control of concerned state.

20.0 INTER-LABORATORY TRANSFER POLICY

The Sub-committee is of opinion that following should be the inter-laboratory transfer/ deputation policy:

20.1 Deputation of personnel in any cadre from State to Central lab or Central to Central laboratories should be reserved at the rate of 30% of total sanctioned posts in any cadre.

20.2 For example, the sanctioned strength in a given cadre is 10 then the number of personnel who can work on deputation/ transfer shall be 03. Further, deputation/ transfer can be effected when the cadre strength minimum cadre strength in any cadre is four (4) and above. In case, the

cadre strength is four (4) the number of persons to be allowed to work on deputation can be restricted to one (1)

20.3 In case of higher cadres when there is sanctioned strength of 1 or 2 then the deputation/ transfer in that cadre cannot be affected, while the recruitment is to be done with the local employees of a given state.

20.4 Deputation of personnel in any cadre from State to State laboratories should be reserved at the rate of 20% of total sanctioned posts in any cadre. Further, the explained rules will be governing the transfer/ deputation of individuals from state to state labs.

21.0 TRANSFER OF POSTS BETWEEN LABORATORIES

The sub-committee is of the opinion that, the transfer of posts of laboratories from one state to another/ Centre **may not be feasible** since, the creation or accepting to the proposed harmonisation to the uniform cadres by a given state will be the sole responsibility of a state and or centre and transferring the posts in between states or state to centre may create administrative difficulty and accepting the same by opposite state may lead to financial burden on the *ex-chequer*.

22.0 CREATION OF ADDITIONAL POSTS IN ALL LABORATORIES

22.1 For effective implementation of D&C Act in the country the report generated from Government Analyst plays a pivotal role. The statutory report generated in Form-13 dictates the action to be taken by state licensing authorities for keeping a strict vigil on the movement of spurious and not of standard quality drugs in the country. For laboratories to function effectively, human resources and infrastructure are the key factors in turn.

22.2 As per the Mashelkar Sub-committee Report, 2003 less than 1% of drugs manufactured in the country are tested in Government drugs testing laboratories and this would not serve the purpose. The basic reason for this being low man power and under-equipped infrastructure in state laboratories. The situation in the country over the past decade has changed due to increase in funding to state and central laboratories from various ways and means. The testing excellence needs to be enhanced at all levels of management. This could be achieved through regular recruitments of manpower by respective states public service commission's and UPSC at central level and

their training for skill development at regular intervals and up-gradation of testing infrastructure and their maintenance for smooth and effective analysis of drug samples in a time bound manner.

22.3 The following is the proposed ratio of different cadres of posts at each level in order to meet the expectations of the CDSCO fixed target of 10,000 samples analysis per annum by some states in the country.

Description of Work		**Number per month**	**Number of personnel to be present to reach the task**	**Number of samples lifted per year**
No. of samples to be lifted by each Drugs Inspector	:	10	80	9600
No. of samples to be analysed by Scientific & Sr. Scientific Assistant	:	10	40 each cadre	9600
No. of Jr. Scientific Officer to be present (@ 2 Scientific & 2 Sr. Scientific Assistants per each JSO)	:	-	20	-
No. of Scientific Officers to be present	:	-	10	-
No. of Senior Scientific Officers to be present	:	-	06	to sign 800 plus reports per month
No. of Deputy Directors to be present	:	-	03	-

22.4 Further, the sub-committee is of the unanimous opinion that the creation of additional manpower as per the harmonisation principle will be left to the states based on whether the state is a consumer or producer state and

based on budget availability and administrative ease and convenience. For example, smaller state like Sikkim may or may not have a Director to the laboratory.

23.0 CENTRAL PORTAL FOR LABORATORY INFORMATION MANAGEMENT SYSTEM

23.1 The sub-committee is of the opinion that, there must be a central portal for the receipt of samples at laboratory level, state wise and for drugs samples allotment and generation of test report in Form-13 by a notified (u/s 20 of the D&C Act, 1940) Government Analyst. Accordingly, at all levels digital signatures must be issued at all user levels to ensure digitally authenticated secured reports.

23.2 The launching of this central portal is highly useful as this will generate reports in a time bound manner and delivery of services by laboratory in fast mode and transparency would also increase. Further, this would also enable the CDSCO to have a national repository of NSQs, spurious drugs and manufacture's

profile and will help in technical evaluation of various manufacturers in drugs procurement (tenders).

24.0 MINUTES OF THE SUB-COMMITTEE MEETINGS

The following are the minutes of the two meetings conducted by the sub-committee to discuss/ brainstorm on the objectives for which the sub-committee was set up.

MINUTES OF THE 1ST MEETING OF THE SUB-SUB-COMMITTEE DATED: 09.02.2018

Following are the details of the meeting of Sub-Sub-committee for creation of cadre based posts for all the drugs testing laboratories and provision of one mobile testing laboratory for offices of CDSCO and each State/ UT under Central Govt. Scheme on recommendation of 52nd DCC.

The meeting was held on 09-02-2018 with reference to the 52nd DCC meeting held on 18th September, 2017 by inviting all related stake holders to participate in this subsub-committee for creation of cadre based posts for all the drugs testing laboratories and provision of one mobile testing laboratory for offices of CDSCO and each State/ UT under Central Govt. Scheme.

Minutes of the meeting of Sub-Sub-committee for creation of cadre based posts for all the drugs testing laboratories and provision of one mobile testing laboratory for offices of CDSCO and each State/ UT.		
Date: 09-02-2018	Time 02.00 a.m. to 5.30 pm	FDA Bhawan, CDSCO, 1st Floor Conference Room, Kotla Road, New Delhi

Meeting called by	Dr. K. Bangarurajan, Joint Drugs Controller (Convener of Subsub-committee)
Type of meeting	Official Meeting of Subsub-committee for creation of cadre based posts for all the drugs testing laboratories and provision of one mobile testing laboratory for offices of CDSCO and each State/ UT, constituted by Drugs Consultative Sub-committee
Meeting Chair	Dr. Ravi Shankar, IPS, Drugs Controller, Andhra Pradesh (Chairman).
Note taker	Dr. Santosh Indraksha, Assistant Drugs Controller (India), CDSCO (HQ)
Attendees	8. Dr. Bangarurajan, Joint Drugs Controller (India), CDSCO (HQ). (convener) 9. Dr. Ravi Shankar IPS, Drugs Controller, Andhra Pradesh. (Chairman) 10. Sh. C Hariharan, Director, CDL, Kolkata 11. Sh. Lalsawma, Joint Director, FDA, Mizoram 12. Dr. Raman Mohan Singh, Director, CDTL, Mumbai.
Meet and Greet	
Dr. K. Bangarurajan	Welcome note and agenda.
Discussion	Dr. K. Bangarurajan, Convener of the meeting, welcomed and greeted all respectable dignitaries and members of the subsub-committee on behalf of Chairman and briefed about the following agenda to panel a. To make a proposal for cadre based posts for all the drugs testing laboratories keeping in view, the inter laboratories transfer policy, creation of additional posts for all laboratories, transfer of posts of laboratories from one state to the another/ Centre etc. and b. To make a proposal for providing and setting up of mobile testing laboratories for offices of CDSCO Zonal, Sub-zonal & Ports and also to each State/UT drugs control offices for rapid screening of the medical products under the Central Govt. Scheme. Dr. Bangarurajan handed over to Dr. Ravi Shankar (Chairman) for proceedings of the meeting formally.
Introduction and Background	
Dr. Ravi Shankar,	
Discussion	The chair greeted all members and emphasized the importance of drugs testing laboratories in the pharmaceutical regulatory system and for the effective implementation of Drugs and Cosmetics Act. He felt that there could be effective policies to enrich and empower the drugs testing laboratories which will leads to increased functioning of drug law enforcement. He requested the panel members to express their views/concerns on the said matter.
Conclusions	Harmonized Lab cadre structure is to create for effective implementation of Drugs and Cosmetics Act.
Existing Organogram/Structure of Central Drug Laboratories	
Dr. Hariharan	

Discussion	• Dr. C Hariharan, Director, CDL, Kolkata gave power point presentation and explained about existing organogram in the lab like Director (G.P.-8700), Deputy director, Senior scientific officer (Grade-1) Scientific Officer, junior scientific officer, Senior scientific assistant and Junior scientific assistant. • He proposed the laboratory structure in a way that there should be chemistry wing, Bio chemistry wing, Microbiology wing, Pharmacology/toxicology wing, Pharmacognosy wing, Cosmetics wing and Medical devices wing in all the labs on the basis of their need. • He emphasized the necessity of specialization in educational qualification for senior scientific officer level post which will increase value of respective report. • He briefed about the promotion process existed in the CDL, like some posts laid under the category of 50 % promotion basis and 50% by direct recruitment and some posts are only through direct recruitment. • The sub-committee felt that there should be supporting staff (Junior Lab Assistant and Senior Lab Assistant) to the JSA to support the entry level work like solutions preparation etc. and their qualification could be minimum of degree in science. • Chair proposed nomenclature for Director and Deputy Director as Chief Scientific Officer and Principle Scientific officer respectively. • Dr. Raman Mohan Singh emphasized the necessity of mobile testing laboratories and necessary instruments to carry out the qualitative and quantitative tests.
Final Conclusion:	
• Before conducting next meeting, information shall be sought on existing organogram/structure from all central and state drugs testing laboratories. • Next meeting shall be held at Zonal Office, Hyderabad, CDSCO along with above mentioned experts on 09-March-2018.	

Meeting ended with the vote of thanks by Convener Dr. K. Bangarurajan, Joint Drugs Controller (India).

MINUTES OF THE 2ND MEETING OF THE SUB-COMMITTEE DATED: 13.03.2018

Following are the details of the 2ndmeeting of Sub-Sub-committee for creation of cadre based posts for all the drugs testing laboratories and provision of

one mobile testing laboratory for offices of CDSCO and each State/ UT under Central Govt. Scheme on recommendation of 52nd DCC.

The meeting was held on 13th March, 2018 with reference to the 52nd DCC meeting held on 18th September, 2017 by inviting all related stake holders to participate in this subsub-committee for creation of cadre based posts for all the drugs testing laboratories and provision of one mobile testing laboratory for offices of CDSCO and each State/ UT under Central Govt. Scheme.

Minutes of the meeting of Sub-Sub-committee for creation ofcadre based posts for all the drugs testing laboratories and provision of one mobile testing laboratory for offices of CDSCO and each State/ UT.		
Date:13-03-2018	Time 10.30 a.m. to 5.00 pm	Conference Hall, CDSCO, Hyderabad
Meeting called by	Dr. K. Bangarurajan, Joint Drugs Controller (Convener of Subsub-committee)	
Type of meeting	Official Meeting of Subsub-committee forcreation of cadre based posts for all the drugs testing laboratories and provision of one mobile testing laboratory for offices of CDSCO and each State/ UT, constituted by Drugs Consultative Sub-committee	
Meeting Chair	Dr. Ravi Shankar, IPS, Drugs Controller, Andhra Pradesh (Chairman)	
Note taker	G.Raghuvaran, Drugs Inspector, CDSCO (HQ)	

Attendees	10. Dr. Ravi Shankar IPS, Drugs Controller, Andhra Pradesh. (Chairman) 11. Sh. Lalsawma, Joint Director, FDA, Mizoram 12. Dr. R.A. Singh, Director, RDTL, Chandigarh 13. Dr. Raman Mohan Singh, Director, CDTL, Mumbai. 14. Sh. C Hariharan, Director, CDL, Kolkata 15. Dr. K. Bangarurajan, Joint Drugs Controller (India), CDSCO (HQ) (Convener) 16. Smt. Jyoti J. Sardesai, Director, Drugs Control Administration, Goa 17. Sh. T. Kailasam, Joint Director (FAC), Telangana 18. Smt. LotikaKhajuria, State Drugs Controller of Jammu & Kashmir 19. Dr. N. Murugesan, Director I/C, CDTL, Hyderabad 20. Shri. ACS Rao, DDC(I), CDSCO (HQ) 21. Smt. Annam Visala, DDC(I), CDSCO (HYD) 22. Dr. Santosh Indraksha, ADC(I), CDSCO(HQ) 23. Dr. Gandhi P C Kaza, Advisor, Government of Andhra Pradesh and West Bengal. 24. G.Raghuvaran, Drugs Inspector, CDSCO (HQ) 25. P.Rajesham, Drugs Inspector, CDSCO (HQ) 26. Dr. G. Praveen Kumar, Jr. Scientific Officer, Drugs Control Lab, Vijayawada.
Meet and Greet	
Dr. K. Bangarurajan	Welcome and Introduction by Members
Discussion	Dr. K. Bangarurajan, Convener of the meeting, welcomed and greeted all respectable dignitaries and members of the subsub-committee on behalf of Chairman. Then Dr. K. Bangarurajan, requested Hon. Chair Dr. Ravi Shankar to take over the proceedings.
Opening of Session for discussion	
Dr. Ravi Shankar,	Overview of earlier meeting of sub-sub-committee and further expectations
Discussion	Dr. Ravi Shankar opened up the session by giving brief overview of the earlier meeting. The members deliberated various matters in details to arrive at final consensus. ➢ Creation of cadre based posts and re-structuring of all the drugs testing laboratories. ➢ Pre-promotional test and post-promotional training at each level. ➢ Mobile testing laboratory requirements like equipments and personnel etc. Requirements related mobile testing laboratory was discussed on phone with the Dr. H.G. Koshia, Commissioner, FDCA, Gujarat. ➢ Creation of master reference library consisting of spectral chromatograms of Infra-red and Raman spectroscopy. ➢ Chain of custody of samples and its report generation.

Conclusions	➢ Organogramof laboratory officials consisting of 5 levelsare finalized after detailed discussion and considering existing structure of nationwide laboratories. (Annexure-I) ➢ Promotions shall be linked with proficiency and educational qualifications &eligibility requirement should be different at all levels ➢ Equipments like Near IR Spectrometer, Raman Spectrometer, X-Ray metal analyzer and HPTLC analyzer to be mounted on mobile testing laboratory. Required analysts shall be deputed on rotational basis from concerned laboratories. Also one full time driver for mobile van has to be appointed. ➢ Master reference spectra library (Infra-red and Raman spectrums of drugs) shall be prepared with the help of industry and all Deputy Drugs Controllers in respective zone. Initially reference library shall contain the fast moving drugs, life saving drugs, National List of Essential Medicines and drugs prone to be spurious. ➢ Online report generation and digitally approved by the head of the laboratory.

Meeting ended with the vote of thanks by Convener Dr.K. Bangarurajan, Joint Drugs Controller(India).

25.0 CONCEPT OF MOBILE DRUGS TESTING LABORATORY

25.1 In a country like India with 1.2 billion population and daily increase in consumption of medicines there could be a chance that wrongdoers can manufacture spurious drugs or NSQ drugs may appear on and off due to various lapses in manufacturing process. Further the non-medical use of antibiotics is increasing day-by-day which is leading to antibiotic resistance and generation of superbugs. To curb this problem, random checks are to be done by drug law enforcement officer's at various levels. Random checks for drug quality at field level can be done by implementing the concept of Mobile Drugs Testing Laboratory (MDTL) where the mobile van will be taken along with enforcement officer's which house a couple of drugs testing personnel to carry out random check of samples.

25.2 Further, in other agriculture related sectors like pisciculture, aquaculture and poultry the use of antibiotics in aqua feed supplements is increasing day to day and their use in aqua products cultivation is banned and there are stringent regulations for export of best quality aqua products to European Union. Hence, as the antibiotics and their application is under the control of Drugs Control

departments and the unwarranted use of antibiotics in other allied sectors of agriculture can be curbed by the scheme of mobile drugs testing laboratory so that the feed/ feed supplements quality can be monitored at field level and so on for stringent legislation.

25.3 Advantages of MDTL

- Random quality checks are essential to build confidence in public about the regulatory system.
- Occasional testing would be useful to control wrongdoers in drug manufacturing
- On spot or immediate testing of spurious or NSQ drugs samples would be useful for complete analysis in shorter time so that misbranded or NSQ or adulterated drugs can be easily identified and their movement can be curbed before the entire stock is consumed by the public.
- To have an active checkpoint to manage the supply chain so that no mimicking samples/ batches enter into supply chain.

25.4 Disadvantages of MDTL

- Cost incurred to set up MDTL is high.
- Recruiting trained additional manpower may incur additional cost to the Governments.
- Recurring cost for maintenance of equipments and vehicle may be shooting up every year.
- Creation of reference library for all the active pharmaceutical ingredients would be a difficult task.
- The results given by the spot testing instruments though validated *in vitro* level; their performance with different type of formulations in field level without damage of the sample would give different results. Hence, reliability may vary.

25.5 The concept of mobile drugs testing laboratory is already in use in the state FDA, Gujarat state. The cost incurred to the Government of Gujarat was Rs. 1 crore to set up this MDTL.

25.6 During the 2nd meeting of the sub-committee held on 13.03.2018 at Hyderabad, a teleconference session was held with Dr. H.G. Koshia, Commissioner, FDCA, Gujarat to enquire about the success story of the MDTL. He informed

that the concept of MDTL has been a success in the state of Gujarat.

25.7 With a view to provide best healthcare services to the patient throughout the state, the Gujarat Food and Drug Control Administration (FDCA) recently procured an advanced on the spot mobile drug testing lab equipped with high-tech devices at a total investment of Rs. 1 crore. Dr. Koshia pointed out that, the state of the art mobile drug testing lab has been equipped with near infrared spectrophotometer which has been acquired at a cost of Rs. 35 lakh; x ray fluorescence spectrometer and ion mobility spectrometer acquired at the cost of Rs. 21 lakh each, and the Raman spectrophotometer acquired at the cost of Rs. 18 lakh along with the additional cost associated with the mobile van which comes to around Rs. 20 lakh.

25.8 Based on the above observations, it could be concluded that the introduction of mobile drugs testing laboratory may be done with the following equipments and manpower on the van for it to become operational.

S.No.	Equipment Name	No. to be present

1	Near IR spectrometer	01
2	Raman Spectrometer	01
3	X-ray metal analyzer	01
4	HPTLC	01

Manpower requirements:

(i) Senior Scientific Assistant – 1 No.

(ii) Junior Scientific Officer – 1 No.

(iii) Van Driver – 1 No.

25.9 The sub-committee opined that, required analysts shall be deputed on rotational basis from concerned laboratories.

25.10 Master reference spectra library (Infra-red and Raman spectrums of drugs) shall be prepared with the help of industry and all Deputy Drugs Controllers in respective zone. Initially reference library shall contain the fast moving drugs, life saving drugs, National List of Essential Medicines and drugs prone to be spurious.

25.11 Online report generation and digitally approved by the head of the laboratory

25.12 The sub-committee is of the opinion that, the **Mobile Drugs Testing Laboratory to be sanctioned one to each**

district in the country with required manpower and infrastructure and one each to CDSCO zonal and sub-zonal offices for spot testing of drug samples.

(A)

(B)

(C)

Photographs: (A) A model picture of a van used in mobile drugs testing
(B) A model picture of interiors of mobile drugs testing van
(C) A model picture of a mobile foods testing inaugurate in Goa state by the Chief Minister

26.0 CONCLUSIONS

With the above background following conclusions are offered:

25.1 The sub-committee is of the opinion that the following seven (7) cadres may be proposed across all the drugs testing labs in the country for uniform designations *viz*, Scientific Assistant, Senior Scientific Assistant, Junior Scientific Officer, Scientific Officer, Senior Scientific Officer, Deputy Director and Director. Further, the Departmental Promotion Sub-committee for the promotion to higher level posts at central level may be constituted by DoPT and at State level state sub-committee may be constituted by respective states.

25.2 Further, the sub-committee has opined that Mobile Drugs Testing Laboratory to be sanctioned one to each district in the country with required manpower and infrastructure and one each to CDSCO zonal and sub-zonal offices for spot testing of drug samples.

25.3 The sub-committee recommends the set-up of a Central Portal for the generation of digitally signed analytical reports which would also make the national repository of all the NSQs and Standard Quality samples feasible.

27.0 SIGNATURES OF SUB-COMMITTEE MEMBERS

In view of the above the undersigned Sub-committee members examined all the issues in a comprehensive manner after deliberate discussions and prepared this Recommendations report in detail which is submitted herewith for further necessary action

(Dr. Ravi Shankar IPS)
Director General, DCA
Govt. of AP – Chairman

(Dr. H. G. Koshia)
Commissioner, FDCA
Gujarat – Member

(Lalsawma)
Joint Director, FDA,
Mizoram– Member

(Dr. R. A. Singh)
Director, RDTL
Chandigarh– Member

(Dr. Raman Mohan Singh)
Director, CDTL
Mumbai – Member

(C. Hari Haran)
Director (I/c), CDL
Kolkata - Member

(Dr. Bangarurajan)
JDC (India), CDSCO (HQ)
Convener