



**GOVERNMENT OF INDIA**  
**MINISTRY OF HEALTH & FAMILY WELFARE**  
**DIRECTORATE GENERAL OF HEALTH SERVICES**  
**CENTRAL DRUGS STANDARD CONTROL ORGANISATION**  
**CENTRAL DRUGS TESTING LABORATORY – MUMBAI**

Accredited By : NABL (ISO/IEC 17025:2017 in Chemical & Biological Testing)

Certified For : IMS (ISO - 9001:2015; ISO - 14001:2015; ISO - 45001:2018)

# **ANNUAL REPORT 2021-22**

## **CENTRAL DRUGS TESTING LABORATORY – MUMBAI**

**Zonal FDA Bhavan, GMSD Compound, Bellasis Road,  
Mumbai Central, Mumbai - 400 008.**

**Phone No.: 022-2300 2309, 022-2300 2138**

**Fax : 022 – 2309 9240**

**Email: [cdtlmumbai@cdsco.nic.in](mailto:cdtlmumbai@cdsco.nic.in)**

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# **FROM THE DIRECTOR'S DESK**

## **Annual Report (2021-22)**



The year 2021-22 started with challenges & opportunities & CDTL-Mumbai strived to meet the needs of the hour, reasserting the message of “Health First” by testing essential medicines. The laboratory is rewarding a strong signal of quality policy on consistent basis.

CDTL-Mumbai has steadily built itself through sustained pursuit of excellence. It is reflected in the quality output & demonstrated through our focus on Research & Development & regulatory testing of drugs, cosmetics & medical devices & consistently. Our inhouse scientific talent pool strengthens our intellectual capital thereby contributing in the passion to deliver & this passion in turn shapes our culture of excellence. In these critical & uncertain time CDTL-Mumbai has responded timely & efficiently to tackle the challenges.

CDTL-Mumbai has an ISO – 17025:2017 Accreditation by NABL for Chemical & Biological discipline and is committed to promote, coordinate & implement the system for testing in accordance with the relevant National & International Standards & Guides. Quality is of utmost importance & CDTL-Mumbai ensures that it achieves the quality & compliance motive.

In CDTL-Mumbai, we believe that employees are the most valuable assets & key players of our success & sustained growth. Therefore we continue to conduct various employee benefit activities, trainings, recreational & team building programmes to enhance employees skills & motivate as also to foster the team spirit. Key focus is employee protection & keeping workplace COVIDI-19 free. CDTL also conducts in-house training programmes to develop technical / functional capabilities in order to meet future talent requirements.

With Best Regards,

**Dr. Raman Mohan Singh**

**Director**

**CDTL-Mumbai**



## **INTRODUCTION**

Central Drugs Testing Laboratory (CDTL) - Mumbai is one of the regulatory laboratories of the Ministry of Health & Family Welfare, Government of India working under the administrative control of the Drugs Controller General (India), CDSCO, DGHS.

It is the laboratory's quest to meet and excel the highest standards for maintaining the quality of drugs in India.

### **Some features of our facility :-**

- Modern Quality Control, Quality Assurance, Microbiological and R & D laboratories supported with high-tech equipments.
- NABL Accredited (ISO/IEC-17025:2017) for Chemical and Biological Testing.
- Implemented the E-governance and online Reporting through SUGAM PORTAL.
- Conforms to International Environmental, Health and Safety regulations (ISO 9001:2015, ISO 14001:2015 & ISO 45001:2018).
- The laboratory is divided into two major divisions – Chemical & Biological. The various sections functional under these divisions are Wet Chemistry, Instrumentation, Analytical Research and Development, Reference Standards, Sample Warden, Microbiology, Medical Devices, Cosmetics and Quality Assurance.





## **VISION**

- ❖ To be recognized globally for providing world class testing facilities for Safeguarding human and animal health by establishing and reviewing quality objective at various levels of the organization.
- ❖ To safeguard and enhance public health by quality and excellence in testing of drugs, cosmetics and medical devices.
- ❖ To be a part of modern regulatory system in India to protect public health by Ensuring provision of safe, effective and quality drugs and pharmaceuticals based on scientific excellence accountable to both, the Government and the public.

## **MISSION**

- ❖ To provide quality and effective analytical services achieved through advanced testing in the area of drugs and pharmaceuticals by dedicated and committed work force by adhering core values of transparency, accountability, efficiency, commitment, credibility and innovation.
- ❖ To be a smart drugs testing laboratory equipped with latest sophisticated equipments and having clean and green eco-friendly environment.

## **QUALITY POLICY**

Central Drugs Testing Laboratory–Mumbai is committed to :

- ❖ Perform quality testing as per ISO/IEC 17025:2017 and NABL guidelines to attain the highest proficiency and unbiased testing of Drugs & Cosmetics & Medical Devices in transparent, well documented and controlled environmental condition to attain proper justified quality results.
- ❖ Ensure that all laboratory personnel familiarize themselves with quality documentation while implementing policies and procedures in their work.
- ❖ Strive for continual improvement related to laboratory functions through personnel involvement at all levels.

## **QUALITY OBJECTIVES**

- ❖ To make all the laboratory staff aware to the requirements of ISO/IEC 17025:2017 by conducting regular training and interactions.
- ❖ To implement effective quality system in the laboratory.
- ❖ To ensure dependable and accurate testing facility.
- ❖ To operate in such an environment so that the test result obtained is very close to the true result.
- ❖ To provide test results at the earliest and to the best satisfaction.
- ❖ To update technical knowledge / skill of scientific / technical staff by in-house and outside training.
- ❖ Regular participation in Proficiency Testing and Inter laboratory Comparison Programs.
- ❖ To provide proper & safe working environment to adopt Good Laboratory Practices.

## **STATUTORY & OTHER MAJOR FUNCTIONS**

- ❖ Analysis of Drugs and Pharmaceuticals, Cosmetics and Medical Devices in terms of schedule to the Drugs & Cosmetics act, 1940 & rules there under so as to specify the standards of identity, purity & strength for the drugs imported, manufactured for sale, stocked or exhibited for sale or distribution in India.
- ❖ The Director, CDTL - Mumbai acts as “Appellate Authority” as per Drugs & Cosmetics Act, 1940 for the testing of Copper T and Tubal Rings (Intrauterine Contraceptive Device).
- ❖ Analysis of Import drugs & Cosmetics samples entering through the port offices.
- ❖ Analysis of Registration samples for approval of site registration as per GMP.
- ❖ Analysis of New Drugs to get license for manufacturing the same.
- ❖ To undertake Analytical Research on standardization and methodology of Drugs.
- ❖ Analysis of Drugs & Pharmaceutical formulations received as Survey Samples from Central Drugs Standard Control Organization and its Zonal Offices.
- ❖ Analysis of Drugs & Pharmaceutical formulations received as National Survey sample from CDSCO or other offices under Ministry of Health & Family Welfare.
- ❖ Imparting training to Drugs Analysts deputed by the Government laboratories from time to time.



## OVERVIEW

India enjoys an important position in the global pharmaceutical sector. The country has a large pool of scientists with potential to steer the industry to greater heights by evolving in terms of newer drugs, cosmetic & medical devices, regulating the quality of the same. The drug regulation India is based on the centrally enacted Drugs & Cosmetics Act, 1940 & rules thereunder.

The pandemic included the growing need of medicines & the laboratory reinforced focus on global compliance, people potential & moving towards our goal of new beginnings & sustained analysis output of medicines. CDTL-Mumbai strives to give quality testing report & in turn shape a better future for the society.

The laboratory's strong fundamentals and its resilient policies have enabled us to record another remarkable year of growth. We at CDTL, are better prepared today to achieve our quest of doing quality work, effective execution of compliance to International Standards and also imparting knowledge through our training cell.

CDTL-Mumbai is one of the National Laboratory in India engaged in the Research & analysis of Drugs, Cosmetics & Medical Devices. The laboratory keeps a macro perspective & sample testing output is grown significantly. The laboratory has continued to evolve over the decades with the shifting trends of the pharmaceutical industry.

The laboratory's presence in the regulatory sector is supported by advanced testing facilities. Committed employees & guidance of senior officials act as key drivers in achieving our goals.

CDTL-Mumbai is emerging as an exciting growth story in the regulatory sector. Our commitment in what we do today, will drive recognition tomorrow. As we grow our capacity, capability and analytical research development expertise, the objective is to deliver results.

By giving emphasis on a high level of compliance & quality standards.

***“Wherever the art of Medicine is loved, there is also a love of Humanity”***

***- Hippocrates***

## **ACTIVITIES PERFORMED IN 2021-22:**

### **A) Sample Warden Section :**

- This section deals with the processes right from sample receipt, checking the physical integrity of received material, checking for Method of Analysis/Standard/Impurities required for testing and acknowledgement, issue of samples to respective divisions and report generation.
- Requirements for sample testing is also communicated to the sender and receipt of Reference Standards and additional material is facilitated.
- Monthly / Quarterly Key Performance Indicators, Monthly Drug Alerts, Monthly Sample data reports and other pertinent is generated here. Control of samples after testing is done as per storage conditions.
- The testing fees of Registration, New Drugs, Miscellaneous Samples is calculated and communicated to sender.
- All the samples received in this section are given Registration number. All these samples are kept in the required storage conditions and distributed to the different sections as per the directions given by SSO-II.
- All these samples are registered and routed through OASIS LIMS system.
- Disposal of samples and reports with raw data as per approved CDTL SOP is carried out on regular basis.
- API tested are sent to Standard Section along with copy of report for use as Secondary Working Standard in future.



## Highlights :

### 1. Analysis of COVID-19 related Medicines :

During this COVID-19 pandemic period the laboratory has received the samples of life saving Antiviral drug Remdesivir Bulk, Favipiravir Bulk, Umifenovir Bulk, Amphotericin B Bulk and formulations such as Remdesivir Injection, Remdesivir Sublingual tablets, Remdesivir oral solution, Favipiravir tablets, Amphotericin lyophilized injection which were analysed on urgent basis including the weekly off days by the team of analysts for the welfare of COVID 19 patients.

### 2. Revenue Generation :

The revenue generated in the form of testing fee for Registration / New Drugs Samples received for analysis is **Rs. 25,38,435/-** in the this year 2021-22. Charges for the tests of these samples are collected as per Drugs & Cosmetics Act & rules and deposited in Government of India account through “Bharat Kosh”.

### 3. Total samples received and analysed from April 2021 to March 2022.

Month / Year	Received	Reported *	Pass	Fail NSQ	Under analysis at end of the month
Apr – 2021	111	176	172	4	153
May – 2021	165	129	122	7	186
Jun - 2021	288	171	165	6	299
Jul - 2021	269	230	223	7	337
Aug – 2021	224	255	250	5	297
Sep - 2021	278	256	247	9	319
Oct – 2021	270	240	236	4	349
Nov – 2021	262	271	264	7	340
Dec – 2021	268	274	263	11	331
Jan – 2022	151	216	213	3	253
Feb – 2022	256	195	191	4	305
Mar - 2022	416	285	272	13	436
Total	2,958	2,698	2,618	80	-

\*Note : Samples reported includes the samples received in previous months/years

### 4. Category wise status of samples tested during the period April 2021 to March 2022:

Sample Type	Received during the year (2021-22)	Pass	Fail	Total Reported
Import	586	527	22	549
Registration	650	609	11	620
Zonal Survey Samples	642	531	2	533
New Drugs	112	108	4	112
Miscellaneous	54	40	1	41
Legal Samples	815	715	40	755
Inter Laboratory Comparison	93	86	-	86
Proficiency	2	1	-	1
Medical Device	4	1	-	1
Total	2,958	2,618	80	2,698



5. Sample Output with No. of Tests Performed for the year 2021-22 :

**Chemical Division**

Months	Backlog Sample	Samples Received	Total Samples	Reported Samples	No. of Tests Performed	HPLC Tests
April-2021	46	87	133	96	650	176
May-2021	38	99	133	68	751	136
June-2021	65	126	182	107	1,068	272
July-2021	68	144	212	124	1,088	339
Aug-2021	121	187	308	186	1,427	410
Sept-2021	122	185	307	179	1,287	390
Oct-2021	128	157	287	171	1,119	285
Nov-2021	121	184	305	199	1,162	306
Dec-2021	106	174	280	168	1,093	486
Jan-2022	112	155	267	155	962	276
Feb-2022	112	167	279	152	1,129	326
March-2022	124	266	390	213	1,509	366
<b>Total</b>	<b>1,163</b>	<b>1,931</b>	<b>3,083</b>	<b>1,818</b>	<b>13,245</b>	<b>3,768</b>

**Biological Division**

Months	Backlog Sample	Samples Received	Total Samples	Reported Samples	No. of Tests Performed	HPLC Tests
April-2021	59	76	135	87	505	143
May-2021	48	72	120	77	662	125
June-2021	43	96	136	76	839	160
July-2021	43	136	179	93	799	180
Aug-2021	53	67	120	81	609	133
Sept-2021	39	71	115	87	647	140
Oct-2021	28	65	99	64	416	98
Nov-2021	35	83	118	71	446	92
Dec-2021	47	83	130	86	513	115
Jan-2022	44	49	93	68	368	76
Feb-2022	25	68	93	57	314	61
March-2022	38	97	135	66	573	92
<b>Total</b>	<b>502</b>	<b>963</b>	<b>1,473</b>	<b>913</b>	<b>6,691</b>	<b>1,415</b>

<b>Total Chemical + Biological Division</b>	<b>1,665</b>	<b>2,894</b>	<b>4,556</b>	<b>2,731</b>	<b>19,936</b>	<b>5,183</b>
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## B) Reference Standard Section :

- The main function of this section is to distribute and maintain the reference material required for testing of drug samples. The reference material is received in the section from sample warden section which is labeled as per the SOP and maintained between 2-8°C. The material is distributed to analysts as per their requirement which is returned back to the section after analysis. The information regarding purity/potency, LOD/Water is maintained in the computer for easy reference. This information is regularly updated in Sample Warden, Chemical and Biological divisions for easy reference.
- The validity of Primary Reference substances is also checked at regular intervals from the respective website.
- The section also maintains the API, which are reported as of standard quality, as 'in-house working standard' for future use after validation. These materials are retested as per the schedule, to determine moisture and assay and decision is taken accordingly about its future use.
- To minimize the use of Certified Reference Standards, correspondence with API manufacturers is also done by this section to obtain candidate API material for which Primary Reference Standards are available in the laboratory. These APIs are tested against the Primary Reference Standard and are used as Secondary Standards.
- The regular work like receipt of standard, labeling, issuing them for analysis is carried out.
- Month wise schedule for retesting / testing of reference material is also followed to overcome the need of reference material required for day to day analysis of the samples.
- Total number of reference material received during the period is : 1603 Nos.



- **Following IPRS were procured from Indian Pharmacopoeia Commission received in 2021-22 : (30 Nos.)**

Sr. No.	IPRS	Sr. No.	IPRS
1	Albendazole	16	Indapamide
2	Atomoxetine Hydrochloride	17	Linezolid
3	Cefpodoxime Proxetil	18	Metformin Hydrochloride
4	Cetirizine Hydrochloride	19	Miconazole Nitrate
5	Clomipramine Hydrochloride	20	Naproxen
6	Cyanocobalamine	21	Prednisone
7	Diclofenac Sodium	22	Proguanil Hydrochloride
8	Dicyandiamide	23	Propranolol Hydrochloride
9	Diphenhydramine Hydrochloride	24	Remdesivir
10	Domperidone	25	Sertraline Hydrochloride
11	Etophylline	26	Sertraline Impurity E
12	Fexofenadine Hydrochloride	27	Simvastatin
13	Flavoxate Hydrochloride	28	Tenofovir Disoproxil fumarate
14	Gentamicin sulphate	29	Theophylline
15	Gliclazide Impurity F	30	Thyroxine sodium

- **Following EPCRS were received in 2021-22 : (47 Nos.)**

Sr. No.	EPCRS	Sr. No.	EPCRS
1	Albendazole CRS	25	Isosorbide - 2 - nitrate
2	Albendazole Impurity mixture	26	Lithocholic acid
3	Albendazole SST mixture	27	Lovastatin
4	Amphotericin B	28	Lysine Hydrochloride
5	Amphotericin B for peak Identification	29	Metamizole Sodium
6	Arginine	30	Mexiletin Impurity D
7	Chenodeoxycholic acid	31	Mupirocin Lithium
8	Chloramphenicol	32	Nystatin
9	Dermaton sulphate and oversulphated chondroitin sulphate	33	Propofol for peak Identification
10	Disodium edetate	34	Propofol Impurity J
11	Disodium EDTA	35	Quetiapine for SST
12	Docosahexanoic acid	36	Rocuronium bromide for peak Identification
13	Eicosapentanoic acid Ester CRS	37	Rosuvastatin calcium
14	Ethambutol for SST	38	Salbutamol sulphate Impurity B
15	Ethambutol Hydrochloride	39	Sodium Alendronate for SST
16	Folic acid	40	Sodium Alendronate Trihydrate
17	Folic acid Impurity A	41	Theobromine
18	Folic acid Impurity D	42	Trometamol
19	Folic acid Impurity I	43	Ursodeoxycholic acid
20	Framycetin	44	Ursodeoxycholic acid for SST
21	Fusidic acid Impurity Mixture	45	Vitamin C
22	Gliclazide Impurity F	46	Vitamin D
23	Heparin low molecular mass for calibration CRS	47	Voriconazole Impurity E
24	Heparin sodium		



➤ **Following USPRS were received in 2021-22 : (29 Nos.)**

Sr. No.	USPRS	Sr. No.	USPRS
1	Amphotericin B	16	Oversulphated Chondroitin sulphate
2	Brinzolamide Related Compound A	17	Polymyxin B Sulphate
3	Brinzolamide Related Compound B	18	Propylene Glycol
4	Carboplatin	19	Rocuronium Bromide
5	Doxycycline Hyclate	20	Rocuronium peak Identification
6	Heparin sodium for Assay	21	S-Adenosyl Homocysteine
7	Heparin sodium for Identification	22	Tazobactam
8	Isotretinoin	23	Tazobactam Related compound A
9	Metoprolol Related Compound C	24	Tretinoin
10	Metoprolol Succinate	25	Ubidecarenone
11	Mupirocin Lithium	26	Ubidecarenone For SST
12	Mupirocin	27	Ubidecarenone Related Compound A
13	Neomycin Sulfate	28	Vardenafil Hydrochloride
14	Nystatin	29	Vardenafil for SST
15	Ofloxacin		

➤ **Following Candidate Materials were received in 2021-22 from Manufacturers : (50 Nos.)**

Sr. No.	Candidate Materials	Sr. No.	Candidate Materials
1	Aceclofenac	26	L-methionine
2	Acyclovir	27	L-phenylamine
3	Allopurinol	28	Lumefantrine
4	Amlodipine Besylate	29	Memantine Hydrochloride
5	Atorvastatin Calcium	30	Metoclopramide Hydrochloride
6	Azithromycin Dihydrate	31	Metoprolol tartrate
7	Caffeine	32	Metronidazole
8	Carbamazepine	33	Montelukast sodium
9	Carvedilol	34	Moxifloxacin Hydrochloride
10	Cefaclor	35	Nimesulide
11	Cefixime Trihydrate	36	Norgesterol
12	Cefpodoxime Proxetil	37	Olanzapine
13	Cefuroxime Axetil	38	Phenylephrine Hydrochloride
14	Cetirizine Hydrochloride	39	Pioglitazone Hydrochloride
15	Ciprofloxacin Hydrochloride	40	Polymyxin B Sulphate
16	Clarithromycin	41	Remdesivir
17	Coenzyme Q10	42	Rosuvastatin calcium
18	Diclofenac Sodium	43	Secnidazole
19	Fluconazole	44	Simvastatin
20	Glimepiride	45	Tadalafil
21	Hyoscyamin sulphate	46	Ticlopidine Hydrochloride
22	Indapamide	47	Tinidazole
23	Ketoconazole	48	Tolnafate
24	L-arginine	49	Topiramate
25	Lidocaine	50	Ubidecarenone

➤ **Following Candidate Materials were received in 2021-22 from Remnant Samples : (186 Nos.)**

<b>Sr. No.</b>	<b>Remnant Samples</b>	<b>Sr. No.</b>	<b>Remnant Samples</b>
1	Ademetionine 1, 4-butanedisulfonate	49	Ivermectin
2	Albendazole	50	Lacosamide
3	Albuterol sulphate	51	Leflunomide
4	Alogliptin benzoate	52	Leuprolide Acetate
5	Alpha lipoic Acid	53	Levamisole Hydrochloride
6	Amantadine Hydrochloride	54	Levetiracetam
7	Amfenac Sodium	55	Levocarnitine
8	Amlodipine Besilate	56	Levocetirizine Dihydrochloride
9	Amoxicillin sodium	57	Levofloxacin hemihydrate
10	Amphotericin B	58	Levomepromazine maleate
11	Ampicillin trihydrate	59	Levonorgestrol
12	Antipyrine	60	Limecycline
13	Antipyrine	61	Lisinopril Dihydrate
14	Ascorbic acid	62	L-isoleucine
15	Ascorbyl palmitate	63	L-Methyl folate
16	Atenolol	64	L-ornithine L-aspartate
17	Atomoxetine Hydrochloride	65	Losartan potassium
18	Atorvastatin Calcium	66	Magnesium Oxide
19	Atracurium Besylate	67	Mecobalamin
20	Azithromycin	68	Medroxy progesterone Acetate
21	Azosemide	69	Methylprednisolone sodium succinate
22	Bacitracin Zinc	70	Melglumine
23	Baclofen	71	Meloxicam
24	Benazepril Hydrochloride	72	Memantine Hydrochloride
25	Benfotiamine	73	Meropenem
26	Betahistine dihydrochloride	74	Meropenem with Sodium Carbonate
27	Betamethasone	75	Mesalazine
28	Bethamethasone Valerate	76	Metamizole Sodium
29	Bivalirudin	77	Methotrexate disodium
30	Bromfenac Sodium	78	Methyl testosterone
31	Bromo-Palboypirimidinone	79	Metoprolol Succinate
32	Buprenorphine Hydrochloride	80	Metronidazole
33	Butaphosphan	81	Mexiletine Hydrochloride
34	Caffeine	82	Minocycline Hydrochloride
35	Carbetocin	83	Montelukast Sodium
36	Carisoprodol	84	Moxidectin
37	Cefoperazone sodium	85	Moxifloxacin Hydrochloride
38	Cefpirome Sulphate	86	Neomycin Sulphate
39	Ceftiofur Sodium	87	Nepafenac
40	Ceftriaxone Sodium	88	Nicotinamide
41	Cefuroxime Axetil	89	Nitrofurantoin monohydrate
42	Cefuroxime sodium	90	Nitroxoline
43	Chloramphenicol	91	Norfloxacin
44	Cholic Acid	92	Nystatin
45	Chondroitin Sulphate Sodium	93	Ofloxacin
46	Citicoline sodium	94	Oxcarbazepine
47	Clarithromycin	95	Pancreatin
48	Clindamycin Hydrochloride	96	Paracetamol

97	Clomiphene citrate	142	Pemetrexed Disodium Heptahydrate
98	Cloxacillin sodium	143	Pepsin
99	Coenzyme Q10 (Ubidecarenone)	144	Phenylramidol Hydrochloride
100	Colchicine	145	Piperacillin sodium and Tazobactam Sodium
101	Cyanocobalamin	146	Pitavastatin calcium
102	Cyproterone Acetate	147	Potassium clavulanate diluted with microcrystalline cellulose
103	Daptomycin	148	Pramipexole dihydrochloride monohydrate
104	Daunorubicin Hydrochloride	149	Praziquantel
105	Dehydroepiandrosterone	150	Prednisolone
106	Dicloxacillin Sodium	151	Pregabalin
107	Dicloxacillin Sodium Monohydrate	152	Progesterone
108	Digoxin	153	Progesterone
109	Docetaxel Anhydrous	154	Prothionamide
110	Domperidone	155	Quinine Hydrochloride
111	Dopamine Hydrochloride	156	Ranitidine Hydrochloride
112	Doxycycline Hyclate	157	Remdesivir
113	Dutasteride	158	Resperidone
114	Dydrogesterone Granules	159	Rifamycin S
115	Enoxaparin Sodium	160	Rifaximin
116	Eplerenone micronised	161	Riluzole
117	Erdosteine	162	Rivaroxaban
118	Erythromycin	163	Rosuvastatin calcium
119	Esomeprazole sodium	164	Sertraline Hydrochloride
120	Ethambutol Hydrochloride	165	Sevelamer Hydrochloride
121	Ethinylestradiol	166	Sildenafil Citrate
122	Ethionamide	167	Simvastatin
123	Ethosuximide	168	Sorbitol
124	Ezetimibe	169	Ceftizoxime Sodium
125	Felodipine	170	Sulbactam Sodium
126	Fingolimod Hydrochloride	171	Sulphamethaxazole
127	Flupenthixol Dihydrochloride	172	Tacrolimus
128	Fluticasone propionate	173	Tacrolimus premix
129	Fluvoxamine Maleate	174	Tacrolimus premix 20%
130	Furosemide	175	Teicoplanin
131	Fusidic acid	176	Theophylline
132	Gentamicin sulphate	177	Thiamine Hydrochloride
133	Gliclazide	178	Thioacetic acid
134	Glutathione	179	Topiramate
135	Guaifenesin	180	Tramadol Hydrochloride
136	Heparin Sodium	181	Tranexamic acid
137	Hydrochlorothiazide	182	Trimetazidine Hydrochloride
138	Hydrocortisone sodium succinate	183	Trimethoprim
139	Ibuprofen	184	Tylvalosin Tartrate
140	Isoniazid	185	Undecyenoic acid
141	Itopride Hydrochloride	186	Ursodeoxycholic acid



➤ **Following Secondary Reference Standards were prepared in 2021-22: (46 Nos.)**

Sr. No.	Secondary working standard	Sr. No.	Secondary working standard
1	Aceclofenac (1 Batch)	24	Fluconazole (2 Batches)
2	Allopurinol (2 Batches)	25	Gentamicin Sulphate (2 Batches)
3	Ascorbic acid (3 Batches)	26	Gliclazide (1 Batch)
4	Automoxetine Hydrochloride (1 Batch)	27	Ibuprofen (1 Batch)
5	Azithromycin (1 Batch)	28	Levocetirizine Dihydrochloride (3 Batches)
6	Carbamazepine (2 Batches)	29	Lisinopril Dihydrate (1 Batch)
7	Carbidopa (1 Batch)	30	Lorazepam (1 Batch)
8	Cetirizine Hydrochloride (1 Batch)	31	Metoclopramide HCL (2 Batches)
9	Chloroquine sulphate (1 Batch)	32	Metronidazole (1 Batch)
10	Chlorpheniramine maleate (2 Batches)	33	Montelukast Sodium (1 Batch)
11	Cinacalcet Hydrochloride (1 Batch)	34	Mycophenolate Mofetil (1 Batch)
12	Clindamycin Bisulphate (3 Batches)	35	Nitrofurantoin (3 Batches)
13	Clindamycin Hydrochloride (4 Batches)	36	Ofloxacin (2 Batches)
14	Clobetasol Propionate (4 Batch)	37	Ondansetron Hydrochloride (2 Batches)
15	Cloxacillin Sodium (1 Batch)	38	Pantoprazole Sodium (2 Batches)
16	Cyanocobalamine (1 Batch)	39	Phenylephrine Hydrochloride (3 Batches)
17	Diclofenac sodium (1 Batch)	40	Pyridoxine Hydrochloride (3 Batches)
18	Dicyclomine Hydrochloride (1 Batch)	41	Roxithromycin Hydrochloride (3 Batches)
19	Domperidone maleate (2 Batch)	42	Theophylline (6 Batches)
20	Dopamine Hydrochloride (1 Batch)	43	Timolol Maleate (2 Batches)
21	Doxycycline Hyclate (2 Batches)	44	Tolnaftate (1 Batch)
22	Ethionamide (1 Batch)	45	Tranexamic acid (3 Batches)
23	Ferrous fumarate (1 Batch)	46	Ursodeoxycholic acid (3 Batches)



## C) Quality Assurance Section :

Quality Assurance is the sum total of organized arrangement made with objective of ensuring that medicines are of the quality required for their intended use. Quality Assurance is a team work for achieving common goal.

The Quality Assurance Section focuses on quality management & provides confidence that quality requirements are fulfilled. This section comprises of procedural activities implemented in the laboratory's quality system & ensures the operations are in accordance with the ISO/IEC 17025 : 2017 Standard.

The maintenance of Quality Management System (QMS) is crucial to a laboratory for providing the correct test results. The QA Section covers important elements of Management System such as documentation, SOPs, Quality Control of Samples & Participation and conducting External Quality Assessment Schemes. Quality Assurance team takes to view the quality requirements, audits the results of control measurements and analyses quality performance in order to ensure that appropriate quality standards and procedures are implemented. This year the laboratory participated in Inter Laboratory Comparison programmes conducted by CDTL-Chennai, RDTL-Guwahati, CDL-Kolkata, and RDTL-Chandigarh. This helps to review the quality levels and defines necessary improvements in the existing quality management system framework. Another activity initiated this year was revision of Quality System Procedures and Standard Operating Procedures. Also SOPs for new instruments and processes are framed for communication in the laboratory cycle. The Quality Assurance Section shall continually improve the effectiveness of its management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

### **Following activities were performed in the year 2021-22:**

1. The registration process of CDTL-Mumbai in NABL Portal with respect to details such as information of the Laboratory Details, Discipline Details, Scope of Accreditation, Organization, Calibration status of each instrument, Reference Materials, Quality Control Activity etc, uploading of the revised Quality Manual was completed and the details submitted.
2. Uncertainties calculated for the drugs to be added in the scope. The drugs for which Measurement Uncertainty was calculated were Azithromycin, Omeprazole Gastro resistant Capsules IP 20mg, Amoxicillin Capsules IP, Metformin Hydrochloride Tablets IP, Cetirizine Hydrochloride Tablets IP and Albendazole Tablets IP 400mg.

3. Measurement of Uncertainty was calculated for Acid value & Peroxide value of Hair Oils, tested as per IS 7123:2019 & fineness (75µm & 150 µm) for skin powders as per & IS 6356:2004.
4.
  - a. Z-Score calculated for Azithromycin, Omeprazole Gastro resistant Capsules IP 20mg, Amoxicillin Capsules IP, Metformin Hydrochloride Tablets IP, Cetirizine Hydrochloride Tablets IP and Albendazole Tablets IP 400mg and communicated to the participants.
  - b. Z-score received from CDL-Kolkata for ILC programme conducted by them. The Z-score for Aspirin gastro resistant tablets IP 75mg & Bromhexine hydrochloride tablets IP 8mg found satisfactory.
  - c. Satisfactory Z-Score received from IPC-Ghaziabad for PT - round w.r.t. Assay by UV.
5. Out of specification & Repeat Analysis related documents were reviewed.
6. Log books /Raw data books issued as per requirements.
7. Compiling of Monthly Progress Report of CDTL-Mumbai.
8. Preparation of MRM Minutes & review meetings.
9. CDTL-Mumbai had the IMS (ISO 9001: 2015, ISO 14001: 2015; and ISO 4500:2018) Recertification on 2<sup>nd</sup> to 4<sup>th</sup> June 2021. It was ensured that all the procedures and policies of IMS are being effectively followed. All related documents were reviewed.
10. Consultant for IMS-Nutan Consultancy Services guided the CDTL team for preparation of the audit. All documents requested for audit purpose were forwarded to them as and when required.
11. CDTL-Mumbai successfully faced the NABL Reaccreditation Audit on 21<sup>st</sup> and 22<sup>nd</sup> June 2021. All the parameters that may be evaluated were reviewed by the auditor so that the laboratory achieves the overall goal of continual improvement. Three minor NCs were observed for which corrective actions were taken.
12.
  - Calibration of all Digital Hygrometer and Analytical Balance done
  - Calibration of K-type thermometer done through NABL accredited calibration agency.
  - Calibration of scale done through NABL accredited calibration agency.
  - Order placed to NABL accredited agency for calibration of Thermometer
  - Enquiry floated for calibration of instrument like Temperature & Pressure Indicators, Vernier calliper, Stop Watch, Balances, Micropipette, Hygrometer, Weight Box, K-type Thermometer etc. through NABL accredited agency.
  - Order placed for calibration of Vernier Calliper, Test Sieves and Weight box.
  - Calibration of BOD Incubator, Vacuum Oven, Oven, Water Bath, Balances, Autoclave, Heating Block, Ultra deep freezer done by NABL accredited agency.

- Order placed through NABL accredited agency for calibration of Temperature and – Pressure Indicators, Analytical Balance and Micropipette.

13. **Feedback received & sent to stakeholders / vendors:**

- Feedback sent to Sacardande Engineers Pvt. Ltd. as requested by them.
- Feedback sent to IPC-Ghaziabad as requested by them.
- Feedback sent to CDTL-Hyderabad as requested by them.
- Satisfactory feedback received from Emcure Pharmaceuticals Ltd.
- Satisfactory feedback received from Centrient Pharmaceutical India Pvt. Ltd.
- Satisfactory feedback received from Esschem Pvt. Ltd.
- Satisfactory feedback received from Centrient Pharmaceuticals India Pvt. Ltd. and Alivira Animal Health Ltd.
- Satisfactory Feedback received from following customers for the services rendered by CDTL-Mumbai :
  - a) RDTL-Guwahati
  - b) ADC-Air Cargo Sahar-Mumbai
  - c) ADC-Nhava Sheva - JNPT
  - d) Arbro Pharmaceuticals Pvt. Ltd. - New Delhi.
  - e) Boehringer Ingelheim India Pvt. Ltd.

14. **Proficiency Testing and ILC :**

- IP Prednisone tablet samples received for ILC testing from IPC-Ghaziabad.
- Proficiency Testing plan as per Form-163 updated & subsequently uploaded on NABL portal as advised.
- Participated in Proficiency testing for the year 2021-22.
- Sample received from Proficiency Testing Provider IPC-Ghaziabad for Proficiency Testing (Assay by UV). The results were communicated to IPC.
- Participated in proficiency testing for cosmetics & essential oil for S.aureus, Pseudomonas aeruginosa & Candida albicans was received from Fare Labs Pvt. Ltd., Gurgaon.
- Participated in proficiency testing for Skin Cream for Thermal Stability, pH, Total Fatty Substance, Total Residue, Heavy Metals and Arsenic conducted by Aashvi Proficiency Testing & Analytical Services PT round A-PT-13/2022.

15. Health check up of entire CDTL-Mumbai & NTTL-Mumbai staff done.

16. Participated in S. K. Joshi excellence award conducted by QCI. Laboratory details, location, discipline details, scope of accreditation organization and equipment etc. details uploaded in the portal.



17. NABL accreditation in accordance with the standard ISO/IEC 17025:2017 was granted by Quality Council of India for Chemical & Biological discipline with validity from 23/06/2021 to 22/06/2023. The scope for which laboratory had applied was approved by the NABL authorities.
18. External training was restarted by inviting eminent speakers.
19. Invitation was sent to eminent speakers to deliver lectures in the training schedules.
20. Prepared 4 year Internal Audit Plan and Yearly schedule of Internal Audit for 2021-22.
21. Calibration calendar prepared for Analytical Balance, pH Meter, Environment Monitoring, Monitoring of Refrigerator and Laboratory Freezer Temperatures, Environment Monitoring, Validation and Calibration in Microbiology schedules for the year 2021-22.
22. Expansion of scope was proposed by Quality Manager & Technical Manager. Various tests such as Specific Optical Rotation, Loss on drying, Sulphated ash, Assay (by UV), related substances (by HPLC), Heavy metal, Identification tests were added in the existing drugs under scope. Also it was proposed to add Remdesivir Injection for Sterility and BET and Skin Cream for pH and Fatty Matter in the scope. Accordingly preparations for the same initiated.
23. Internal Audit was conducted on 22<sup>nd</sup> and 23<sup>rd</sup> February 2022. All sections in the laboratory were covered in the audit as per the notification issued.
24. History Log of Instruments under scope were reviewed.
25. Job description issued to newly recruited analysts.
26. MU calculation initiated for Dissolution by UV for Paracetamol tablets IP in view of expansion of scope.
27. Monthly Review meetings are done every month to discuss technical & administrative matters. All section incharges & Division head discuss laboratory activities with the Director.







## D) Central Chemical Store :

- Chemicals and glassware required for routine laboratory testing are received, labelled, stored as per environmental conditions and distributed to chemical and microbiological division as per their requirement.
- The entry of incoming and outgoing material is done in the available software which also indicates if quantity of certain material is below the required minimum stock or if it is exhausted. This also helps in the early procurement of chemicals and to avoid delay in testing of samples.
- Chemicals are labelled and stored as per the compatibility data available.
- Critical tests are performed for Solvents, Reagent, which are used for samples under NABL Scope.
- MSDS for organic solvents, certificate for Class A glassware & documentation for critical test are also maintained.

Months	Number of Chemicals received	Number of Glassware's received	Number of Critical tests performed	Number of Supply order sent
April-2021	13	4	-	28
May-2021	35	0	-	26
June-2021	17	0	-	13
July-2021	33	0	-	19
Aug-2021	24	2	-	43
Sept-2021	37	12	2	13
Oct-2021	33	15	-	22
Nov-2021	33	0	2	29
Dec-2021	20	-	-	20
Jan-2022	40	10	2	14
Feb-2022	22	4	6	24
March-2022	31	1	3	23
Total	338	48	15	274



## E) Instrument Section :

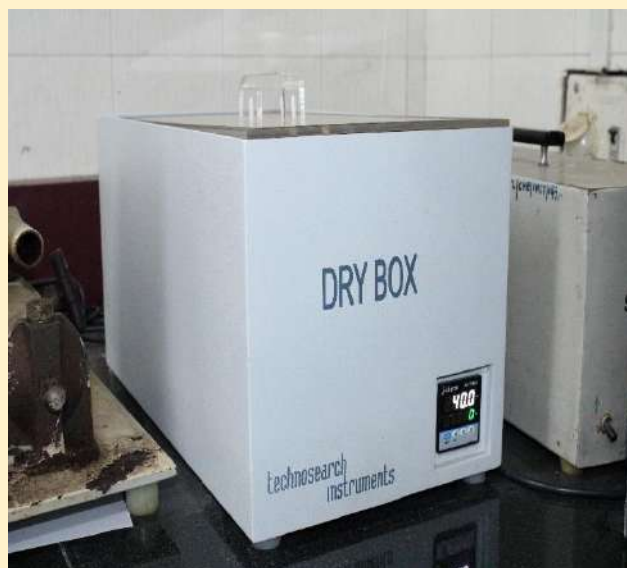
Purchase activities for 2021-22 for instruments purchase and maintenance is summarized as below :

Months	No. of AMC/CMCs	No. of Enquires	No. of Purchase Orders	No. of Tenders
April-2021	3	-	4	-
May-2021	1	7	3	-
June-2021	4	11	4	-
July-2021	21	10	5	-
Aug-2021	9	8	13	-
Sept-2021	4	6	6	-
Oct-2021	5	8	6	-
Nov-2021	3	4	7	-
Dec-2021	5	9	1	-
Jan-2022	8	5	14	-
Feb-2022	2	3	12	-
March-2022	3	3	6	1
<b>Total</b>	<b>68</b>	<b>74</b>	<b>81</b>	<b>1</b>

### New Instruments procured in the Year 2021-2022

Sr. No.	Instrument Name	Qty.	Name of the supplier	Make	Purchase Date
1	Vaccum Oven	1	Scientific Sales Syndicates	JIO - Tech	24-06-2021
2	GC Gas Generator - (Nitrogen/Air)	1	PCI Analytics	PCI	17-05-2021
3	Circulating Water Bath	1	Scientific Sales Syndicates	CENTROFIX	21-05-2021
4	Dry box for FTIR	1	Kimaya Enginners	Technosearch eng	28-07-2021
5	Liquid density meter	1	Anton-Par	Anton- Par	10-11-2021
6	Viscometer with Helipath	1	Triton	Anton- Par	04-01-2022
7	Sonicator - 10 LITRE	3	Scientific Sales Syndicates	S clean	20-12-2021
8	Rotary evaporator	1	Science Enterprises	Science enterprises	17-01-2021
9	Sonicator with chilling facility	2	Scientific Sales Syndicates	S Clean	09-03-2022
10	pH-Conductometer	1	Scientific Sales Syndicates	Horiba	08-03-2022
11	Oil free Vaccum Pump	2	C Abhaykumar	Riviera Glass Pvt Ltd	22-03-2022
12	Polystyrene film for FTIR (For calibration purpose)	1	Raj Analytical	Raj Analytical	10-03-2022





## **F) Standards Development Cell :**

### **1. Activities related to Indian Pharmacopoeia Cell :**

Various queries from IPC and other stake holders were addressed and communicated. Following are details :

<b>Months</b>	<b>Received No. of queries from IPC and other Stakeholders</b>
<b>April-2021</b>	10
<b>May-2021</b>	13
<b>June-2021</b>	28
<b>July-2021</b>	21
<b>Aug-2021</b>	14
<b>Sept-2021</b>	22
<b>Oct-2021</b>	25
<b>Nov-2021</b>	27
<b>Dec-2021</b>	12
<b>Jan-2022</b>	26
<b>Feb-2022</b>	11
<b>March-2022</b>	7
<b>Total</b>	<b>216</b>

### **2. Activities related to BIS Standards Development :**

#### **A) Activities related to Medical Devices Sectional Committee BIS-MHD 03 :**

**The following documents were received for comments & suggestions or voting & were addressed**

- 1) ISO Ballot on CIB - Resolution C2/2021-Skipping CD Stage for ISO/AWI 7439.
- 2) ISO Ballot on ISO 4074:2015 (Ed 3).
- 3) ISO/CD 24484, Female condoms: Guidance on the use of ISO 25841 in quality management female condoms received for suggestions and comments.
- 4) C3/2021 : Reappointment of convenors for additional term 2022-24.
- 5) ISO (17653) : Additional lubricants for male natural rubber latex condoms effects on condom strength.
- 6) ISO/CD 24484, Female condoms : Guidance on the use of ISO 25841 in quality management female condoms.
- 7) Draft Standard on Intra Uterine Conceptive Device - Copper T (380 A).
- 8) Draft Standard on Revision of IS 7080 (Part 3) : 1992 "MTP Suction Apparatus Specification Part 3 : Electrically Operated.
- 9) Draft Documents on Menstrual Cups.
- 10) Draft Documents on Intrauterine Contraceptive Devices - Specification for Copper-T (380A).
- 11) ISO Ballot on ISO/DTR 23148, Compatibility of lubricants with synthetic male condoms.
- 12) ISO Ballot on ISO/TC157 1018, Non-systemic contraceptives and STI barrier prophylactics.
- 13) Constitution of a new ISO technical constitution of on "Menstrual products" and last date of input/ voting is 03/12/2021 in form of selection of answers along with inputs / comments.
- 14) ISO Ballot on Committee Internal Ballot for Resolution C1/2022, C18 - Cancellation of ISO/TR 23148-Compatibility of lubricants with synthetic male condoms.
- 15) ISO Ballot on ISO 29942:2011 (vers 2), Prophylactic dams - Requirement and test method.

- 16) ISO Ballot on Resolution C2/2022, Cancellation of ISO/AWI TR 23660 - Handling used condoms returned to manufacturer or research Centre.
- 17) Preliminary Draft of MHD 03 (19202): Menstrual Cups specification.

## **B) Activities related to Cosmetics Sectional Committee BIS-PCD:19 :**

**The following documents were received for review, comments, voting, suggestions & were addressed**

- 1) Wide Circulation of PCD 19 (17248) : Henna MEHENDI powder (Revision of Indian Standard) specification for Cosmetics.
- 2) Wide Circulation of PCD 19 (17248) : Henna MEHENDI powder (Revision of Indian Standard) specification for Cosmetics.
- 3) Classification of Cosmetic Raw Materials and Adjuncts –
  - i) 17644: Part 2 : 2017 - List of Raw Material generally not recognised as Safe GNRAS and Restricted ingredients.
  - ii) 17647: Part 2 : 2017 - List of Preservatives allowed in Cosmetics with restriction.
  - iii) 17650: Part 2 : 2017 - List of UV filters Cosmetics and Restrictions (Revision of Indian Standard), specifications for cosmetics.
- 4) PCD 19 - Shampoo BIS standard specifications for cosmetics.
- 5) PCD 19 - IS 4704 Fourth revision received for clarification regarding: Toluene 2, 5 Diamine used in hair dyes and products intended for coloring eyelashes.
- 6) Revised draft document for revision of IS 7884-Shampoo Specification.
- 7) Revised drafts on Shampoo and Oral Rinses – Specification.
- 8) Draft document for inclusion of Test methods for determination of milder surfactants, in IS 17117-Hair Shampoo for babies – Specification.
- 9) Draft document for inclusion of Type 3 cool variant in IS 3959 - Skin power.
- 10) ISO Ballots for voting (ISO/TC 2017 Cosmetics).
- 11) Draft for revision - PCD 19 (14704) C Oral Rinses and IS 3959 - Skin Powder specification.
- 12) Inputs on the Queries regarding IS 4707 (Part 2).
- 13) ISO Ballots for voting (ISO/TC 2017 Cosmetics)- (i) ISO 12787:2011 (vers 2), (ii) ISO 22716:2007 (vers 3) (iii) ISO 29621:2017 (Ed 2).
- 14) Draft for reviews - Isopropyl Alcohol : IS 10301 : 1982 specification for Isopropyl Alcohol for Cosmetics industry and IS 2631:2020 specification.
- 15) ISO Ballots for voting (ISO/TC 2017 Cosmetics) - IS17492:2021/ ISO 24442:2011 - Sun protection Test Methods - In vivo determination of Sunscreen UVA Protection.
- 16) Request for comments on Wide Circulation of PCD 19 (19209) : Amendment No. 1 March to IS 6356:2021 toothpaste specification.
- 17) Review of Indian Standard : IS 9832 : 2002 - Cosmetic Pencil specification (First revision).
- 18) Review of Indian Standard : IS 11377 : 2001 (Guidelines for hygienic manufacture of cosmetics (First revision).
- 19) Review of Indian Standard: IS 1767: 1980 (Specification for dicalcium phosphate for dentifrice (Second revision).



## G) Analytical Research and Development :

- The laboratory has seen tremendous value in investing time in research and development and strives to work closely to generate innovative concepts, methods of analysis and monitors research activities. Analytical Research & Development Section is actively involved in method development & validation.
- Post Graduate students of the Pharmacy colleges were provided 09 months training for their Research Project dissertation for M.Pharma final year who have completed the project successfully.
- This section serves as a learning center for all our technical staff. In the year 2021-22, **13** trainees joined CDTL-Mumbai and were involved in their project work. The laboratory staff was involved in research activities and published **15** articles in different reputed journals and communications. Also **23** more research articles are in process.

### ➤ RESEARCH ARTICLES PUBLISHED DURING THE YEAR 2021-22 :

Sr. No.	Name of the articles	Name of Journal	Volume / Page No.
01	Development and Validation of Reverse Phase High Performance Liquid Chromatography method for quantitative estimation of <b>Capmatinib</b> in Tablet dosage form <b>Shubhada Dalvi*</b> , Pankaj Thakur, Kirti Kumari, Munipalli Vijaya Kumar, Raman Mohan Singh, Sayali Warde	International Journal of Pharmacy & Pharmaceutical Research	IJPPR Journal June 2021, Vol.:21. Issue : 3
02	Estimation of <b>Fluralaner</b> from Bulk and Dosage form by Novel RP-HPLC Technique <b>Shubhada Dalvi*</b> , Pankaj Thakur, Kirti Kumari, Munipalli Vijaya Kumar, Raman Mohan Singh, Sayali Warde, Smita Nayak & B Vaidhun	International Research Journal of Pharmacy & Medical Science	IRJPM Journal 2021, Vol.:4. Issue : 5
03	Analytical method Development and Validation for Estimation of <b>Vortioxetine</b> from Dosage Form. <b>Jayashree Mali*</b> , Raman Mohan Singh, Sayali Warde, Munipalli Vijaya Kumar, A. Kumar, Smita Nayak & B Vaidhun	International Journal of Pharmaceutical Science & Innovation	IJPSA Journal 2021, Vol.:1. Issue : 2
04	Development and Validation of Reverse Phase High Performance Liquid Chromatography method for quantitative estimation of <b>Abemaciclib</b> in Tablet dosage form <b>Ayesha Shaikh*</b> , Raman Mohan Singh, Sujata S Kesare, Munipalli Vijaya Kumar, Harshada Talapadatur	International Journal of Pharmacy & Pharmaceutical Research	IJPPR Journal August 2021, Vol.:22. Issue : 1
05	Estimation of <b>Trametinib</b> from Bulk and Dosage form by using HPLC Technique <b>Diksha Ramteke*</b> , Smita Nayak, B. Vaidhun, P.Thakur, S.K. Singh, V. Munipalli, Raman Mohan Singh, Sayali Warde	International Journal of Pharmaceutical Science & Innovation	IJPSA Journal 2021, Vol.:1. Issue : 2
06	Development and Validation of Novel HPLC method for Analytical Evaluation of <b>Ribociclib</b> <b>Siddesh Kamble*</b> , Vijay Munipalli, Harshada Talapadatur, Raman Mohan Singh, Sayali Warde, Smita Nayak, Bhaskar Vaidhun	International Journal of Pharmacy & Pharmaceutical Research	IJPPR Journal August 2021, Vol.:22. Issue : 1
07	Method Development and Validation for	World Journal of	WJPR Journal



	quantitative estimation of <b>Olaparib</b> in tablet dosage form by RP-HPLC method <b>Priyanka waje*</b> , Preeti Kikarni, Smita George, Vijay Munipalli, Raman Mohan Singh, Bhaskar Vaidhun	Pharmaceutical Research	Sept 2021, Vol.:10. Issue : 12
08	Development and Validation of Reverse Phase High Performance Liquid Chromatography method for quantitative estimation of <b>Midostaturin</b> in Capsule Dosage form <b>Sayali Thakekar*</b> , Bharati Fegade, Madhuri Jadav, Vijay Munipalli, Raman Mohan Singh, Bhaskar Vaidhun	World Journal of Pharmaceutical Research	WJPR Journal Sept 2021, Vol.:10. Issue : 12
9	HPLC Method Development and Validation for quantitative estimation of <b>Midostaturin</b> Pharmaceutical Dosage form <b>Kirti Kumari*</b> , Pankaj Thakur, Sayali Warde, Vijay Munipalli, Raman Mohan Singh	International journal of Pharmaceutical Research	IJPPR Journal Oct 2021, Vol.:22. Issue : 3
10	Method Development and Validation for quantitative estimation of <b>Acalabutinib</b> in Capsules dosage form by RP-HPLC method <b>Sayali Thakekar*</b> , Bharati Fegade, Madhuri jadav, Vijay Munipalli, Raman Mohan Singh, Bhaskar Vaidhun	International journal of Pharmaceutical Research	IJPPR Journal 30st Jan 2022, Vol.:23. Issue : 2
11	Stability indicating RP-HPLC method for determination of <b>Remdesivir</b> in Sublingual tablets dosage form <b>Hemangi Padhye*</b> , Bhushan Sunawane, Vijay Munipalli, Raman Mohan Singh, Smita Nayak, Bhaskar Vaidhun	International Research Journal of Pharmacy & Medical Science	IRJPMS Journal 2022, Vol.:5. Issue : 3
12	Estimation of <b>Siponimod</b> from Bulk and Dosage form by using HPLC Technique <b>Diksha Ramteke*</b> , Smita Nayak, B. Vaidhun, P.Thakur, S.K. Singh, V. Munipalli, Raman Mohan Singh, Sayali Warde	Journal of Advancement in Pharmacy	JAP Journal, 2022, Vol.:1. Issue : 2
13	Development and Validation of RP-HPLC method for estimation of Mirabegron in Novel Drug Delivery system <b>Abhijeet Chaudhri*</b> , Jagdish chaudhri, Vijay Munipalli, Raman Mohan Singh, Smita Nayak, Bhaskar Vaidhun	World Journal of Pharmaceutical Research	WJPR Journal, Mar 2022, Vol.:11. Issue : 4
14	Simultaneous Estimation of Folic acid and <b>Methotrexate</b> in Tablet Dosage form By high performance liquid chromatography <b>Kamlesh Saindane*</b> , Harshada Talapadtur, Ujwala Parab, Vijay Munipalli, Raman Mohan Singh, Bhaskar Vaidhun	World Journal of Pharmaceutical Research	WJPR Journal, Mar 2022, Vol.:11. Issue : 4
15	Stability indicating RP-HPLC method for determination of <b>Remdesivir</b> oral solution dosage form <b>Priya Patil*</b> , Pratibha Daroi, Vijay Munipalli, Sayali warde, Raman Mohan Singh, Smita George, Bhaskar Vaidhun	World Journal of Pharmaceutical Research	WJPR Journal, Mar 2022, Vol.:11. Issue : 5

➤ **The following M. Pharm Students joined for their Project Work in 2021-2022:**

Sr. No.	Name of student	Name of College	Name of Project	Period	Status
1	Ms. Hemangi Udayraj Padhye	Gahlot Institute of Pharmacy	1. Stability indicating RP-HPLC method for determination of 'Remdesivir' in sublingual tablet dosage form. 2. HPTLC method for determination of 'Nepafenac' in tablet dosage form.	09-Aug-21 to 07-Apr-22	Under Process
2	Mr. Kamlesh Saindane Kashinath	Gahlot Institute of Pharmacy	1. Stability indicating RP-HPLC method for determination of 'Selumetinib' in capsule dosage Form 2. Simultaneous estimation of Methotrexate and Folic acid in Tablet Dodage form By RP-HPLC.	09-Aug-21 to 07-Apr-22	Under Process
3	Ms. Pratiksha Kharat Arun	Gahlot Institute of Pharmacy	1. RP-HPLC method for determination of 'Gilteritinib' in tablet dosage form. 2. HPTLC method for determination of 'Gilteritinib' in tablet dosage form.	09-Aug-21 to 07-Apr-22	Under Process
4	Ms. Shweta Shankar Yadav	Oriental college of pharmacy	1. Simultaneous estimation of "Fluticasone Furoate, umeclidinium Bromide And Vilanterol trifenate" in Nasal formulation by RP HPLC. 2. Simultaneous estimation of "Perindopril Erbumine, Indapamide And Amlodipine " in Tablet dosage form by RP HPLC.	09-Aug-21 to 07-Apr-22	Under Process
5	Mr. Marin Thomas	Oriental college of pharmacy	1. Stability indicating RP-HPLC method for of 'Tafamidis' in Capsule dosage form. 2. HPTLC method for determination of 'Bromfenac' in Ophthalmic solution	09-Aug-21 to 07-Apr-22	Under Process
6	Mr. Adnankhan Jariwala	Oriental college of pharmacy	1. Simultaneous determination of 'Dydrogesteron and Estradiol' in Tablet dosage form by UPLC 2. Simultaneous determination of 'Dydrogesteron and Estradiol' in Tablet dosage form by HPTLC	09-Aug-21 to 07-Apr-22	Under Process
7	Ms. Yogita Hari Nawle	Gahlot Institute of Pharmacy	1. Stability indicating RP-HPLC method for determination of 'Darolutamide' in tablet dosage Form 2. HPTLC method for determination of 'Darolutamide' in tablet dosage Form	17-Aug-21 to 16-Apr-22	Under Process
8	Ms. Twinkle Gajanan Tarole	Gahlot Institute of Pharmacy	1. RP-HPLC method for determination of 'Cefquinome' in IM/IV dosage form. 2. Stabily indicating RP-HPLC method for determination of 'Molnupiravir' in Capsule dosage form.	17-Aug-21 to 16-Apr-22	Under Process
9	Ms. Priya Bhaskar Patil	Gahlot Institute of	1. Stability indicating RP-HPLC method for determination of	17-Aug-21 to 16-Apr-22	Under Process

		Pharmacy	'Remdesivir' in Oral solution dosage form 2. HPLC method for determination of 'Rasagline' in tablet dosage form.		
10	Ms. Pushpani Parve	Gahlot Institute of Pharmacy	1. Stability indicating RP-HPLC method for the determination of 'Ivabradine' in tablet dosage form. 2. HPTLC method for the determination of 'Dacomitinib' in tablet dosage form.	17-Aug-21 to 16-Apr-22	Under Process
11	Ms. Sayali Patil	Gahlot Institute of Pharmacy	1. Stability indicating RP-HPLC method for the determination of 'Imidocacb Dipropionate' in injection dosage form 2. HPTLC method for the determination of 'Tafamidis' in Capsule dosage form	17-Aug-21 to 16-Apr-22	Under Process
12	Mr. Rushikesh Ghuge	Bombay College	1. Stability indicating RP-HPLC method for the determination of 'Venetoclax' in Capsule dosage Form	27-Oct-21 to 26-July-22	Under Process
13	Ms. Komal Sawate	Bombay College	1. Stability indicating RP-HPLC method for the determination of 'Crisobarole ' in ointment dosage form 2. Stability indicating HPTLC method for the determination of 'Venetoclax' in Capsule dosage Form	27-Oct-21 to 26-July-22	Under Process

➤ **The following Research Articles are under communication:**

Sr. No.	Name of Student	Project Name	Name of Journals	Remark
1	Mr. Hemangi Udayraj Padhye	HPTLC method for determination of 'Nepafenac' in tablet dosage form.	Journal of Planar Chromatography	Manuscript of the Article is under communication
2	Mr. Kamlesh Kashinath Saindane	Stability indicating RP-HPLC method for determination of 'Selumetinib' in capsule dosage Form	Research journal of Pharmacy and Technology	Manuscript of the Article is under communication
3	Ms. Pratiksha Kharat Arun	RP-HPLC method for determination of 'Gilteritinib' in tablet dosage form.	International Research journal of Pharmacy and Medical Science	Manuscript of the Article is under communication
4	Ms. Pratiksha Kharat Arun	HPTLC method for determination of 'Gilteritinib' in tablet dosage form.	International Research journal of Pharmacy and Medical Science	Manuscript of the Article is under communication
5	Ms. Shweta Shankar Yadav	Simultaneous estimation of "Fluticasone Furoate, umeclidinium Bromide And Vilanterol trifenate" in Nasal formulation by RP HPLC.	Journal AOAC.	Manuscript of the Article is under communication
6	Ms. Shweta Shankar Yadav	Simultaneous estimation of "Perindopril Erbumine, Indapamide And Amlodipine" in Tablet dosage form by RP HPLC.	Journal of Pharmaceutical analysis	Manuscript of the Article is under communication
7	Ms. Merin Thomas	Stability indicating RP-HPLC method for 'Tafamidis' in Capsule dosage form.	Journal of liquid chromatography and related technologies	Manuscript of the Article is under communication

8	Ms. Merin Thomas	HPTLC method for determination of 'Bromfenac' in Ophthalmic solution	Journal of Planar Chromatography	Manuscript of the Article is under communication
9	Mr. Adnankhan Jariwala	Simultaneous determination of 'Dydrogesteron and Estradiol' in Tablet dosage form by UPLC	Journal of liquid chromatography and related technologies	Manuscript of the Article is under communication
10	Mr. Adnankhan Jariwala	Simultaneous determination of 'Dydrogesteron and Estradiol' in Tablet dosage form by HPTLC	Journal of Planar Chromatography	Manuscript of the Article is under communication
11	Ms. Yogita Hari Nawle	Stability indicating RP-HPLC method for determination of 'Darolutamide' in tablet dosage Form	International Journal of pharmacy and Medical Science	Manuscript of the Article is under communication
12	Ms. Yogita Hari Nawle	HPTLC method for determination of 'Darolutamide' in tablet dosage Form	International Journal of pharmacy and Medical Science	Manuscript of the Article is under communication
13	Ms. Twinkle Gajanan Tarole	Stability indicating RP-HPLC method for determination of 'Molnupiravir' in Capsule dosage form.	Asian journal of pharmaceutical research	Manuscript of the Article is under communication
14	Ms. Priya Bhaskar Patil	HPLC method for determination of 'Rasagline' in tablet dosage form.	World Journal of Pharmaceutical research	Manuscript of the Article is under communication
15	Ms. Pushpani Parve	Stability indicating RP-HPLC method for the determination of "Ivabradine" in tablet dosage form.	International Journal of pharmacy and pharmaceuticals Sciences and research	Manuscript of the Article is under communication
16	Ms. Pushpani Parve	HPTLC method for the determination of "Dacomitinib" in tablet dosage form.	International Journal of pharmacy and pharmaceuticals Sciences and research	Manuscript of the Article is under communication
17	Ms. Sayali Patil	Stability indicating RP-HPLC method for the determination of 'Imidocab Dipropionate' in injection dosage form	World Journal of Pharmaceutical research	Manuscript of the Article is under communication
18	Ms. Sayali Patil	HPTLC method for the determination of 'Tafamidis' in Capsule dosage form	World Journal of Pharmaceutical research	Manuscript of the Article is under communication
19	Mr. Ashok Kumar/ MS. Umme Rab	UPLC method for simultaneous estimation of Hydroquinone, Oxybenzone and Octinoxate in Cream formulation	World Journal of Pharmaceutical research	Manuscript of the Article is under communication
20	Mr. Bhusan Sonawane, JLA	Simultaneous estimation of Methotrexate and Folic acid in Tablet Dosage form By HPTLC	World Journal of Pharmaceutical research	Manuscript of the Article is under communication
21	Mr. Rushikesh Ghuge	Stability indicating RP-HPLC method for the determination of 'Venetoclax' in Capsule dosage Form	Journal of Planar Chromatography	Manuscript of the Article is under communication
22	Ms. Komal Sawate	Stability indicating RP-HPLC method for the determination of 'Crisobarole' in ointment dosage form	World Journal of Pharmaceutical research	Manuscript of the Article is under communication
23	Ms. Komal Sawate	Stability indicating HPTLC method for the determination of 'Venetoclax' in Capsule dosage Form	World Journal of Pharmaceutical research	Manuscript of the Article is under communication



## H) Administration Section :

### 1) Revenue Generation:

The testing fee collected from stakeholders for analysis of Registration Samples and other samples as per Drugs & Cosmetics Act and Rules and deposited to the Government Account during the year 2021-22 amount aggregated **Rs. 25,38,435/-**.

### 2) Budget Utilisation:

As against the sanctioned budget of **Rs. 8,89,80,000/-** for the year 2021-22, the cumulative expenditure at the end of March - 2022 is **Rs. 8,37,35,664/-**.

**Total budget sanctioned for the Financial Year 2021 – 2022 and expenditure for the year from April – 2021 to March - 2022 is as follows.**

Sub Head	Budget Provision During the Year 21-22	Total Expenditure March 2022	Progressive Expenditure March 2022	Balance as on March 2022
	PLAN	PLAN	PLAN	PLAN
Salary	4,75,00,000	87,000	4,51,96,644	23,03,356
Wages	9,00,000	63,496	7,52,348	1,47,652
MT	5,00,000	22,295	3,81,217	1,18,783
TE	1,00,000	0	21,148	78,852
OE	2,20,00,000	13,70,523	2,13,60,526	6,39,474
PUB	4,00,000	9,951	3,60,932	39,068
S&M	60,00,000	4,45,236	57,94,289	2,05,711
MW	65,80,000	0	50,15,360	15,64,640
OC	5,00,000	1,69,454	4,72,891	27,109
M&E	45,00,000	24,27,202	43,80,309	1,19,691
TOTAL	8,89,80,000	45,95,157	8,37,35,664	52,44,336

### 3) Administrative Matters :

**The administration section regularly makes correspondence & follow ups on various pending issues in the laboratory in addition to the routine matters as listed below :**

- Submission of monthly Key Performance Indicator report
- Amendment in In-situ Promotion Rules 1990
- प्रयोगशालाकी 2021 की त्रैमासिक रिपोर्ट
- Proposal for maintenance of Horticulture work for the period of 2021-22
- Proposal for maintenance of Civil work
- Representation of Shri. Arjun Ghadge regarding regularization.
- Submission of monthly Key Performance Indicator report
- Drug Alert
- Approval for MOEI & Fans, Maintenance of pump sets, Sub-Section equipments and Compound lighting etc.
- Repatriation of Smt. Sneha R. Rajangali, UDC as Head Clerk on deputation basis at the CDSCO (WZ), Mumbai
- Repatriation of Smt. Bharani S.E. to the post of Jr. Scientific Assistant on deputation basis
- Details of eligible scientists to be considered for notification as Govt. Analyst
- Approval of Revalidation of fund of Civil work

- List of names of employees working in CDTL-Mumbai along with their addresses and mobile numbers.
- RTI Monthly return.
- Representation of Mrs. S. S. Chindarkar, OS for revised pay structure as per 7<sup>th</sup> CPC.
- Payment of wages to outsources persons during 2<sup>nd</sup> wave of COVID-19
- Application for the post of Director, Pharmacopoeia Commission for India Medicine and Research (PCIM&H), Ghaziabad
- Allowance to Non-medical Scientist covered under In-situ promotion
- Accordance of administrative approval and expenditure sanction
- Grievance related to alleged irregularities in recruitment process for the post of SLA and JLA
- Providing inputs for updating monitoring module in the JS's e-Samiksha website
- Proposal for filling up the Group A (Gazetted, Non-Ministerial), SSO-I post
- Observance of Grievance Redressal/ Pendency Disposal monthly report
- Grant of travelling allowance for transfer along with family to Shri. Ashish W. Yenkar
- Application for filling up one post of Director (RL), Group A Gazetted in Central Revenue Control Laboratory on Deputation basis
- Review of Mechanism to ensure probity among Govt. Servants
- Treatment/ regularization of hospitalization/ quarantine period during COVID-19 pandemic
- Notice of Hearing for appeal/ complaint
- APAR of Director
- Details of eligible officials to be considered for notification a Govt. Analyst for Cosmetics or Classes of cosmetics
- TA Contribution to candidate summoned for Interviews/ Personal Talks in UPSC
- Recruitment of JSA by Promotion/ transfer on deputation basis in CDTL-Mumbai
- Approval of LTC advance and Encashment
- प्रयोगशाला की 2021 की तिमाही बैठक की प्रगति रिपोर्ट
- Formulation of Budget proposals - RE 21-22 and BE 2022-23 in respect of Grant of Ministry of Health and Family welfare as on 31<sup>st</sup> March, 2021.
- Grant of Special casual leave on 9<sup>th</sup> June and 16<sup>th</sup> July and 22<sup>nd</sup> July 2021 due to heavy rain in the Mumbai suburban area and Unavailability of Transport (Reminder-I)
- APAR pages for the year 2020-21 for Dr. Raman Mohan Singh, Director, CDTL-Mumbai and
- Special campaign drive for disposal of pending matters during the period 2<sup>nd</sup> to 31<sup>st</sup> October 2021.
- Central Public Procurement Portal
- Assurance - Rajya Sabha unstarred question No. 208 for 24/04/2015 raised by Hon'ble member, Smt. Vandan Chavan sent to Parliament Cell regarding 'Implementation of National Litigation Policy'
- Considering request of dependent family member of deceased Govt. servants for appointment on Compassionate grounds
- Submission of quarterly return on actual expenditure incurred on pay and various types of regular central Govt. civilian employees and information in respect of posts and scale of pay
- Proposal for RRs to the post of AHT, OS, Stenographer Grade C, LIA, UDC and LDC.
- Verification of Caste certificates.
- 1 जुलाई से 30 सितंबर तक हिंदी के प्रभावी प्रयोग की स्थिति
- Invitation for Foundation Day Programme at CDTL-Mumbai as a Guest of Honour.
- Proposals for amendment of RRs to the post of Stenographer Grade C in CDTL-Mumbai.
- Information/ Proposal regarding posts under CDSCO getting vacant next year in CDTL-Mumbai
- Review of filling up the post in all laboratories at CDTL-Mumbai.
- Issued Offer of Appointment to the Post of LDC in CDTL-Mumbai to Shri. Manish and Shri. Parvesh Kumar.
- Forwarded Application of Smt. S. U. Warde, SSO-II for the post of SSO-I (Chemistry) Group 'A' Gazetted post on promotion basis
- Recruitment of JSA by promotion/ transfer on deputation basis in CDTL-Mumbai

- Amendment of RRs to the post of Superintendent, Stenographer Grade-I and Librarian in CDTL-Mumbai
- तृतीय राजभाषा कार्यान्वयन समिति की वर्ष 2021-22 की तिमाही बैठक की कार्यवृत्ति
- Application for Recruitment to the post of Director in Pharmacopeia Commission for Indian Medicine and Research and Homoeopath (PCIM&H), Ghaziabad on deputation basis
- 1 अक्टूबर से 31 डिसेंबर तक हिंदी के प्रभावी प्रयोग की स्थिति
- Requested to M/s. Sai Communication the supplier of manpower for providing the candidates along with Biodata for conducting interview at CDTL-Mumbai on 12<sup>th</sup> January 2022.
- Date of effect of In-situ promotion from S-I to S-II level - Dr. Raman Mohan Singh, Ex-Senior PSO, IPC Ghaziabad.
- हिंदी के प्रगामी प्रयोग के संबंध में 31 डिसेंबर 2021 को समाप्त प्रगति रिपोर्ट की समीक्षा
- Management audit of Vigilance Unit - Reg.
- Forwarded application for condonation of delay in exercising option for pay fixation on promotion to a post carrying higher responsibility of Smt. Aditi Bandre, JSA, CDTL-Mumbai
- Cancellation of appointment/ posting order to the post of LDC (L-13) selected through SSC (10+2) level examination 2018.
- Forwarded application for No Objection Certificate for Distance Education from Apex Professional University Arunachal Pradesh of Mr. Ashish W. Yenkar, JSA, CDTL-Mumbai
- Complaint against Anti Social Elements residing in front of Zonal FDA Bhawan, Mumbai
- Forwarded application for No Objection certificate for contesting election in residential CHS Ltd. for the post of Managing Committee member of Shri. Arun K. Nagarkar, JSA, CDTL-Mumbai
- Verification of Character and Antecedents of Candidate provisionally appointed to Civil post under Central Govt. of India
- Dilapidated/ dangerous condition of compound wall of CDTL-Mumbai at above said address behind BIT Chawl No. 2 & 4
- Information on the sanctioned strength of employees, number of person in position and vacant post.

#### 4) Recruitment :

- The laboratory has 01 Account Officer, 01 Consultant (Fin / Admin), 30 Bench Chemist, 04 Laboratory Assistant, 06 Data Entry Operator, 02 Office Assistant appointed on contractual basis through outsourcing agency. These are given suitable trainings before they are given independent work. The vacancies arise very often in these posts as they leave the organization for better opportunities regularly posts are filled through outsourcing agencies for which interviews are conducted in CDTL-Mumbai as & when required.

#### 5) Quantum of letters/emails received, dispatched/sent during the year was as under:

Dak received	Letters dispatched	E-mail received	E-mail sent
4,638	6,378	5,773	5,474



## I) Trainings :

### a) Webinar / Training :

Seminar & Internal training sessions are an integral part of the training schedule of the laboratory. In the era of COVID-19 social distancing these events were no longer an option & the authorities took to replace these events with other interactive events such as webinars. Following is the list of webinars circulated to the staff for upgrading their knowledge & keeping with the advancements.

Sr. No.	Conducted by	Webinar Date	Topic
1	Spinco Biotech	21/04/21	Explore more complex biology with automated imaging of 3D assay models
2	Phenomenex	23/04/21	Solution from Vitamin analysis
3	Phenomenex	27/04/21	HPLC Troubleshooting (Identifying, Solving and Avoiding problems)
4	PerkinElmer	20/05/21	Method transfer in GCHS getting it right always



5	USP India	09/06/21 to 10/06/21	Education course on Method Development and Validation of Analytical procedures for Biologics webinar Attended by : Smt. Smita George (JSA) Smt. Anindita Nandi (JSA)
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6	USP India	17/06/21	Corrective and Preventive Action (CAPA) Attended by Dr. M. Vijayakumar (SSA) Smt. S.A. Navaratne (SSA)
7	USP India	29/06/21	Deviation Investigations including RCA Live webinar Attended by Smt. Akshata S. Paranjpe (SSA) Smt. Sujata S. Kaisare (SSA)

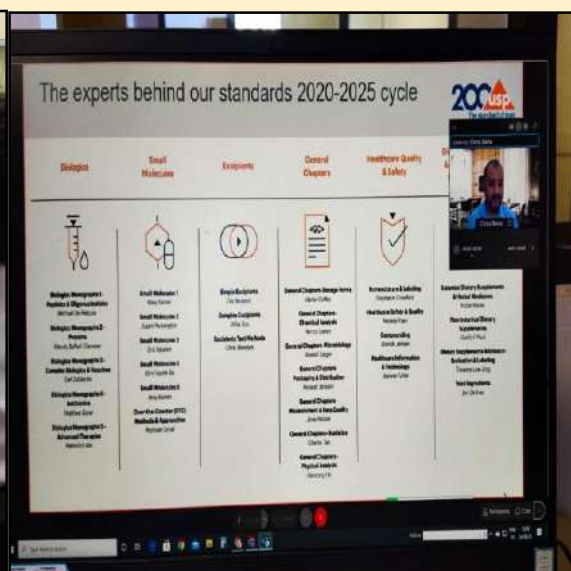


8	BIS-MHD	06/07/21	Standardization, Regulations and Testing of Medical Devices Attended by Smt. Sukhada A. Navaratne (SSA) Shri. Amol Akash (JSA) & Shri. Ramesh Jadhav (SLA)
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9	USP	07/07/21	Education course on Overview of USPNF
10	LGC - Mikromol team	07/08/21	Choosing the Right Reference Standard in Pharmaceutical Quality Control
11	CGHS	10/08/21	Insulin in Diabetes Mellitus
12	CGHS	24/08/21	Backache, Joint Pains and Role of Yoga
13	USP India	24/08/21	Heparin Series - Overview on USP Heparin Standards and Compendial Use







14	USP India	25/08/21	Qualification of Dissolution Testers: USP Performance Verification Test (PVT)
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15	USP	24/09/21	Webinar on overview on USP Heparin standards & Compendial USE
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16	Phenomenex	29/09/21	5 Star Webinar Topic on Chromatography - How to achieve FAST GC METHODS without altering the Resolution
17	USP	08/10/21	Introduction to USP reference standards
18	USP	21/10/21 to 22/10/21	Validation, Verification and Transfer of analytical procedures
19	QCI	27/10/21	Accreditation: Supporting Quality Infrastructure
20	USP	27/10/21 to 28/10/21	GMP audit of a Quality Control Laboratory - Requirements and best practices for industry Attended by Smt. S. U. Warde, SSO-II Smt. S. S. Kaisare, SSA Smt. S. A. Navaratne, SSA



21	IPC	23/11/21	Fundamentals of Dissolution
22	NBQP, QCI	09/12/21	Prof S. K. Joshi Laboratory Excellence Award and its requirement Attended by Dr. Raman Mohan Singh, Director Smt. S. U. Warde, SSO-II Smt. Komal S. Zingade, Lab Assistant





23	USP	08/02/22 to 10/02/22	Development and validation of dissolution procedures Attended by Shri. Pankaj Thakur, SLA & Shri. Ramesh Jadhav, SLA
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24	PCD19	09/03/22	India looking good: Safe and Quality Cosmetics
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- Attended two and half Days e-Learning Capacity Building Programme with administrative team of CDTL-Mumbai on "**General Financial Rules 2017**" hosted by National Productivity Council (NPC) India on 28<sup>th</sup> to 29<sup>th</sup> July 2021.

**Attended by:** 1) Smt. S. U. Warde (SSO-II)  
3) Shri. Suresh Madvi, UDC

2) Smt. Suranga S. Chindarkar, OS,  
4) Smt. Snehalata Trimbake, LDC etc.



- Attended Virtual capacity building workshop on **"Drug Susceptibility testing for newer drugs and use of Genome"** Attended by Smt. S. U. Warde, SSO-II along with her Biological team from 3<sup>rd</sup> to 5<sup>th</sup> August 2021 organised by **WHO Regional Office for South-East Asia**.



- Attended virtual meeting on **"To switch over from Physical File System to e-file System without further loss of time"** meeting chaired by DCG(I), CDSCO, DGHS on 18<sup>th</sup> August 2021.





- Attended **"Online training programme related to NPS issues"** organised by PAO, MHFW, Mumbai on 16<sup>th</sup> September 2021.

**Attended by** 1) Smt. Suranga S. Chindarkar, OS, 2) Smt. Snehalata Trimbake, LDC,  
3) Shri. M. K. Vidyadharan, Consultant Finance /Administration and  
4) Shri. Sudhir Kumar, Accounts Officer



- Attended virtual meeting **"ISO/TC 157/WG 3"** organised by ISO on 29<sup>th</sup> September 2021.

**Attended by** 1) Smt. S. U. Warde, SSO-II, 2) Smt. S. A. Navaratne, SSA,  
3) Shri. Amol Akash, JSA 4) Shri. Ramesh Jadhav, SLA



- Attended virtual meeting on **"Proposal for amendment in 'Heparin Sodium Injection' IP 2018 Monograph for Expert Opinion"** organised by IPC, Ghaziabad on 8<sup>th</sup> October 2021.

**Attended by :** 1) Smt. Sayali U. Warde, SSO-II, 2) Smt. Sujata S. Kaisare,  
3) Smt. Swati. S. Parikh, JSA, 4) Smt. Anindita Nandi, JSA  
5) Shri. Ramesh Jadhav, SLA.

- Attended virtual meeting on **"World Standards Day 2021"** celebration organised by BIS-MHD on 14<sup>th</sup> October 2021.

**Attended by :** 1) Smt. Sayali U. Warde, SSO-II, 2) Smt. Akshata S. Paranjpe, SSA,  
3) Smt. Sujata S. Kaisare, SSA, 4) Dr. Vijayakumar M., SSA  
5) Smt. Sukhada A. Navaratne, SSA.

- Attended virtual meeting of **"Expert Working Group - General Chapter"** organised by IPC, Ghaziabad on 25<sup>th</sup> October 2021.

**Attended by :** 1) Smt. Sayali U. Warde, SSO-II, 2) Smt. Sujata S. Kaisare, SSA,  
3) Dr. Vijayakumar M., SSA.



- Administrative team attended online meeting convened by Central Govt. Employees Welfare Coordination Committee, Mumbai with all Heads of Departments/ Officers of Govt. of India in and around Mumbai region regarding **"Holiday list for the Calendar year 2022"** on 25<sup>th</sup> November 2021.



- Virtual workshop on the topic **'Made in India for the World - BIS Contribution to International Standardization'** conducted by BIS on 23<sup>rd</sup> December 2021.  
**Attended by:** Smt. Sujata S. Kaisare, SSA.



- Attended “**Online e-Training on Safeguards in Public Procurement, General Financial Rule, GFR**” organized by National Productivity Council (NPC), Jaipur on 16<sup>th</sup> to 17<sup>th</sup> Feb, 2022.

**Attended by :** 1) Smt. Snehalata Trimbake, LDC & Administration and Technical Team

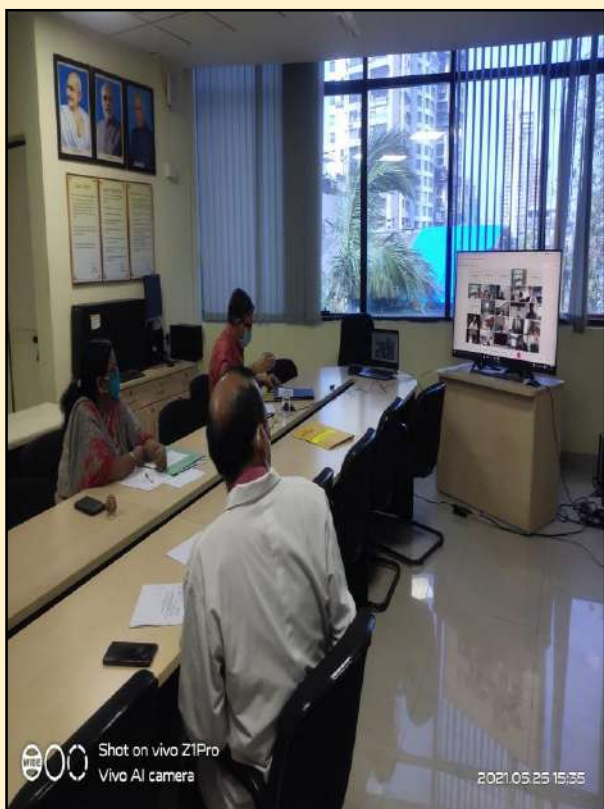


- Attended “**Training on Noting and Drafting**” organized by Regional Training Center, Mumbai on 25<sup>th</sup> Feb, 2022.

**Attended by :** Mr. Manish, LDC

### c) Meetings/ Virtual meetings attended by Director :

- Attended **TOLIC (Rajbhasha) meeting** through video conference hosted by Western Railway-Mumbai Central on 25<sup>th</sup> May 2021.





- Attended Virtual meeting of "**Approach to Alternative Microbiological Methods**" hosted by IPC on 1<sup>st</sup> July 2021 along with members of IP cell of CDTL-Mumbai.



- Attended "**47<sup>th</sup> meeting of the Scientific Body of the IPC**" organised by IPC, at IPC Ghaziabad on 3<sup>rd</sup> July 2021.





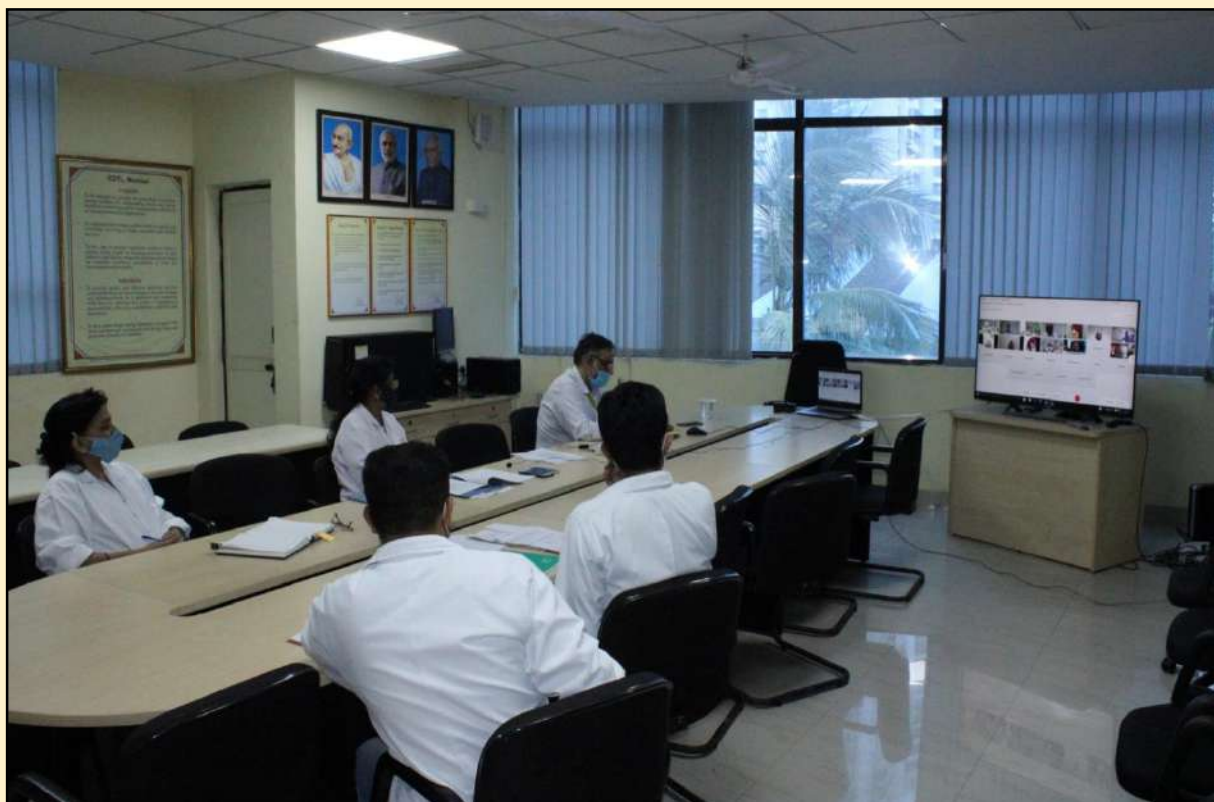
- Attended **DPC meeting** at GMSD, Mumbai on 8<sup>th</sup> July 2021.



- Attended Virtual meeting of **"Expert Working Group - General Chapter"** hosted by IPC on 23<sup>rd</sup> July 2021 along with members of IP cell of CDTL-Mumbai.



- Attended webinar of **"Respiratory Disorders & Role of Yoga"** hosted by CGHS on 27<sup>th</sup> July 2021.
- Attended **"Seventeenth meeting of Obstetric Gynecological Instruments and Appliances Sectional Committee, MHD 03"** through video conferencing organised by MHD-BIS on 6<sup>th</sup> August 2021.





- Attended the **"Meeting with DDG (Store) to review and discuss on certain issues of GMSD, Mumbai"** at MSO R K Puram, New Delhi on 17<sup>th</sup> August 2021.
- Attended **"Review meeting under the Chairmanship of DG, Dte. GHS, to discuss the status of action taken by MSO/GMSDs for amendment of Recruitment Rules and filling up the vacant posts etc."** at Nirman Bhawan, New Delhi on 17<sup>th</sup> August 2021.



- Attended virtual meeting on **"Reform in Drugs Testing"** organised by Office of DGHS on 18<sup>th</sup> August 2021.



- Attended virtual meeting on **"To switch over from Physical File System to e-file System without further loss of time"** meeting convened by Dy. Director Admn. (D) CDSCO, DGHS, at New Delhi on 18<sup>th</sup> August 2021.





- Attended Virtual Meeting under the Chairmanship of JS (RM) "to review the performance of all the GMSDs in order to firm up of possible solutions for improvement in the functioning of GMSD", organized by DGHS and MSO on 24<sup>th</sup> August 2021.



- जी.एम.एस.डीकी त्रैमासिक राजभाषा समिति की बैठक मे २६ ऑगस्ट २०२१ को भाग लिया।



- Conducted **MRM of GMSD, Mumbai** on 26<sup>th</sup> August, 2021.



- Chaired Video conferencing meeting regarding the **"Technical Committee to hand holding NTTLs"** hosted by NTTL, New Delhi on 3<sup>rd</sup> September 2021.



- राजभाषा कार्यान्वयन समिति वर्ष 2021-22 की द्वितीय त्रैमासिक बैठक समिति के सदस्यों तथा सभी अनुभाग प्रभारी के साथ 06/09/2021 को संपन्न हुई ।





- Attended virtual meeting to discuss "**Request for clarification regarding Smokeless Tobacco Products**" organised by FAD 4, BIS under the chairmanship of Dr. L Swasticharan, Addl. DDG, DGHS, New Delhi on 7<sup>th</sup> September 2021.



- Attended virtual meeting on "**National Technical Advisory Committee Meeting**" under the chairmanship of Dr. Kunwar Sen, Addl DG, Dte.GHS, MoHFW on 9<sup>th</sup> September, 2021.





- Attended 2<sup>nd</sup> virtual meeting to discuss **"Request for clarification regarding Smokeless Tobacco Products"** organised by FAD 4, BIS under the chairmanship of Dr. L Swasticharan, Addl. DDG, DGSH, New Delhi on 13<sup>th</sup> September 2021.



- Attended the virtual **"The Launch event of Prof. S. K. Joshi Laboratory Excellence Award 2021"** organised by Quality Council of India on 16<sup>th</sup> September 2021.



- Attended virtual **"Valedictory Ceremony National Pharmacovigilance Week"** organised by NCC-PvPI, IPC, on 23<sup>rd</sup> September 2021.

- सरकारी चिकित्सा सामग्री भंडार के हिंदी पखवाड़ा पुरष्कार वितरण एवं समापन समारोह 28 सेप्टेंबर 2021 संपन्न हुई।



- Attended virtual meeting "ISO/TC 157/WG 3" organised by ISO on 29<sup>th</sup> September 2021.





- Attended virtual meeting of Constitution of a Committee to technically guide the National Tobacco Testing Laboratories (NTTLs) regarding **"Disposal of Tobacco products/ Waste after testing in the NTTLs and their possible environmental burden and solutions"** organised by NTTL, New Delhi on 21<sup>st</sup> October 2021.

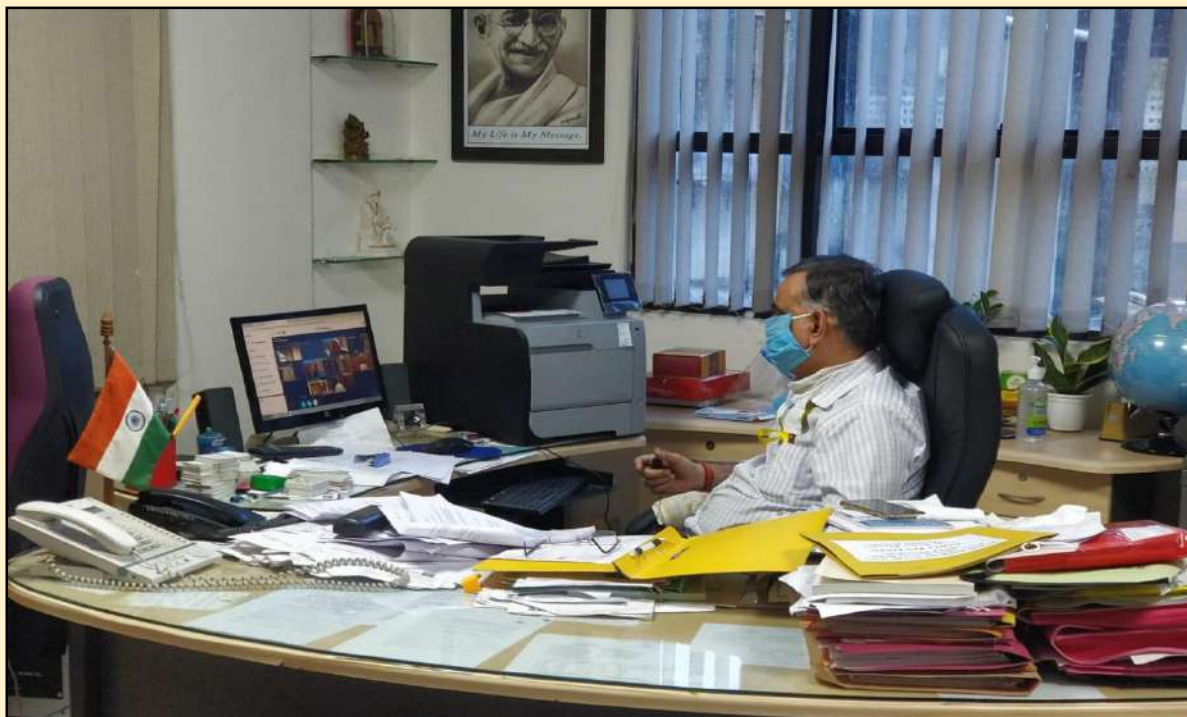


- Attended meeting with Dy. Director General (Store), MSO, **"to review and discuss on certain issues of GMSD, Mumbai"** at R K Puram, New Delhi on 22<sup>nd</sup> October 2021.
- राजभाषा कार्यान्वयन समिति वर्ष 2021-22 की त्रैमासिक बैठकसरकारी चिकित्सा सामग्री भंडार के समिति के सदस्यों साथ 27 अक्टोबर 2021 को संपन्न हुई।
- नगर राजभाषा कार्यान्वयन समिति (केंद्रीय सरकारी कार्यालय) , मुंबई की छमाही बैठक सरकारी चिकित्सा सामग्री भंडार के समिति के सदस्यों के साथ 29 अक्टोबर 2021 को संपन्न हुई ।





- Chaired virtual second sub-committee meeting on "**Phytochemical Reference Substances (PRS) and Botanical Reference Substances (BRS) development**" organised by IPC, Ghaziabad on 29<sup>th</sup> October 2021.



- Attended 48<sup>th</sup> virtual meeting of the Scientific Body of the Indian Pharmacopoeia Commission (IPC) under the chairmanship of Prof. N. K. Ganguly organised by IPC, Ghaziabad on 8<sup>th</sup> January 2022.



- Attended meeting through zoom on **43<sup>rd</sup> Annual Day Tentative Programme (Online)** organised by ICMR, NICPR, Noida on 14<sup>th</sup> January 2022.



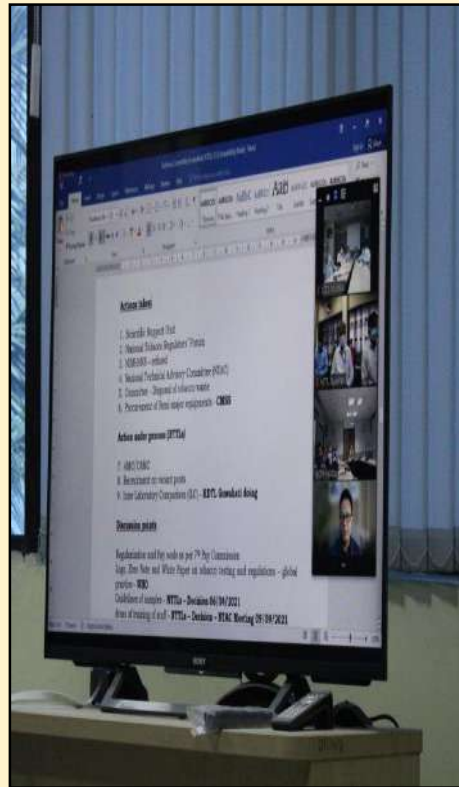
- Attended **35<sup>th</sup> Meeting of Cosmetics Sectional Committee, PCD 19 in Joint session with PCD:1, PCD:2, PCD:3 and PCD:4 subcommittees** organized by BIS through Video conference on 24<sup>th</sup> February 2022.

**Attended by :** 1) Dr. Raman Mohan Singh, Director, 2) Smt. Sujata S. Kaisare, SSA & 3) Smt. Swati S. Parikh, JSA.





- Attended zoom meeting regarding the “**Technical committee to handhold NTTLs**” under the Chairmanship of Dr. Shalini Singh, Director, NTTL of NICPR with NTTL team on 4<sup>th</sup> March 2022.



- Attended meeting to review and discuss on "**GMSD Administrative, Infrastructure Development, Renovation of GMSD Mumbai Building and other issues**" with Dy. Director General (St.), Medical Store Organization at New Delhi on 7<sup>th</sup> March 2022.



## Other activities :

### ➤ Quality testing in the times of COVID-19 pandemic :

A situation declared as emerging pathogen by the WHO has occurred and as with many other organisations, CDTL-Mumbai too has been impacted by the COVID 19 pandemic. Strong communication and motivation has been an important step towards helping the staff through the changes and challenges of the COVID 19 situation.

CDTL-Mumbai comes under essential services and hence was directed to regularly function to render facility of testing life saving drugs and medicines. The management and staff banded together and strived to stem the tide of the outbreak. Laboratory is a place where innovation strives. To ensure the laboratory is safe for the staff, extra precautions to minimise the risk of spread of the infection and surface contamination was implemented. The laboratory strictly followed guidelines laid down by the Ministry of Health & Family Welfare, at the same time abided by the NABL norms. The laboratory has instituted new operating decisions and **principles & new protocol for protection of personnel is followed.**

In this year, laboratory has received the samples of life saving Antiviral drug Remdesivir Bulk and its parenteral preparations from Indian manufacturers which were analysed on urgent basis including the weekly off days by the team of analysts for the welfare of COVID 19 patients.



➤ **IMS Recertification Audit (ISO 9001:2015, ISO 14001:2015 & ISO 45001:2018) held on 02<sup>nd</sup> to 04<sup>th</sup> June 2021 :**

CDTL-Mumbai had the IMS (ISO 9001:2015, ISO 14001:2015 and ISO 45001:2018) recertification audit on 2<sup>nd</sup> to 4<sup>th</sup> June 2021. Few hints & recommendations as suggested by the auditor were addressed & corrective action taken.





- **NABL (ISO/IEC - 17025 : 2017) Audit held on 21<sup>st</sup> to 22<sup>nd</sup> June 2021 :**  
CDTL-Mumbai successfully faced the NABL Reaccreditation Audit scheduled on 21<sup>st</sup> and 22<sup>nd</sup> June 2021.



## ➤ Celebrated 7<sup>th</sup> International Yoga Day on 21<sup>st</sup> June 2021 :

CDTL-Mumbai and NTTL-Mumbai celebrated International Yoga Day on 21<sup>st</sup> June 2021. To mark the importance of Yoga in one's life Honorable Prime Minister has proposed and implemented International Yoga Day since 2015.

International Yoga Day 2021 theme is “Yoga for well-being”. All the world is passing through the challenge of COVID-19 pandemic and almost every country has imposed lockdown in a certain form. In this situation, it is hard or impossible for people to remain mentally and physically fit and healthy. People are suffering from anxiety and depression even if the lockdown is getting softer in some parts of the country.

Yoga, a spiritual discipline, is based on an extremely subtle science and focuses on bringing harmony between mind and body. Dr. Raman Mohan Singh and Smt. Akshata S. Paranjpe deliberated on the significance of yoga and explained that YOGA works on one's body, mind, emotion and energy. They demonstrated various asanas and the staff performed it with enthusiasm. The instructors appealed to the staff to incorporate the exercises and co exist with the rest of nature in mutual understanding and respect.

Smt. Akshata S. Paranjpe also emphasized that the regular practice of pranayama : strengthens lungs, increases immunity & improves overall health at this time of Corona Pandemic. She deliberated on the need to raise awareness on climate action through practicing yoga which can provide a solution to the changes in the climate, global warming, as it creates harmony between ourselves and nature. She also explained about the health benefits of Yoga. The seminar ended with B.K.S. Iyengars quote-

**“YOGA IS THAT LIGHT ,WHICH, IF YOU CAN LIGHT ONCE, WILL NEVER GET DIMMED, THE MORE YOUR PRACTICE, THE BRIGHTER THE FLAME WILL BE”**









- **Audit of the accounts organised by Office of the Director General of Audit (Central) - Indian Audit and Accounts Department (CAG) and conducted by audit team Ms. Reena Ahuja (Sr. Audit Officer), Mr. Parvej Ahmed (Assistant Audit Officer) & Mr. Shamin Akhtar, Assistant Audit Officer from 29<sup>th</sup> June 2021 to 14<sup>th</sup> July 2021:**









## ➤ Independence Day Celebration on 15<sup>th</sup> August 2021:

The Independence Day of India, was celebrated religiously throughout the country. It was celebrated with great enthusiasm at CDTL-Mumbai to commemorate 75 years of India's Independence. These celebrations was based on the "**Azadi Ka Amrut Mahotsav**". It was on this day that India attained independence after a long struggle by some great freedom fighters.

CDTL-Mumbai & NTTL-Mumbai staff gathered together for flag hoisting ceremony. Some of the staff members gave inspirational speeches and some sang patriotic songs. The theme of Independence Day 2021 is "**Nation First, Always First**". Hence the speeches focused on the scarifies made by our freedom fighter and the glorious path laid down for generations by them.

Indeed, it was a day of joy, a day to love and respect our country and make it a better place for Indians to live and experience the freedom, peace and unity in diversity.





➤ **Visit of Dr. Kartikeya Dhanda, Director, Textiles Committee Laboratory, Ministry of Textiles on 21<sup>st</sup> September 2021.**

Dr. Kartikeya Dhanda, Director, Textiles Committee Laboratory, Ministry of Textiles, Govt. of India was invited to the laboratory. His visit was motivating for the staff. He gave an engaging speech in which he appreciated the good efforts taken CDTL-team in maintaining the quality standards of the laboratory. He said each one of us is helping in building quality of the nation. He said the laboratory's efforts in continued improvement by participating in PT/ILC programs is enabling the laboratory in achieving it's vision of delivering quality results.









➤ **Visit for Guidance & verification of furniture items/workstations and electrical installations fixed in the new building of CDTL-Indore on 5<sup>th</sup> to 7<sup>th</sup> Oct, 2021 :**

As directed by Head Quarters, Dr. Vijayakumar M. SSA, visited CDTL, Building, Indore for directing and guiding the agency in fixing/ placing furniture and workstation etc. & for monitoring and verifying the same work in CDSCO's Central Drugs Testing Laboratory (CDTL) Building at Indore from 5<sup>th</sup> to 7<sup>th</sup> October 2021.

➤ **हिंदी पखवाड़ा 14 से 28 सितंबर 2021 तक मनाया गया:**

14 सितंबर को संपूर्ण भारत में हिंदी दिवस बहुत ही उत्साह के साथ मनाया जाता है। हिंदी को इस दिन भारत की आधिकारिक भाषा के रूप में अपनाया गया था। भारत सरकार, गृह मंत्रालय, राजभाषा विभाग द्वारा हिंदी भाषा को प्रोत्साहन देने के लिए हिंदी पखवाड़ा का आयोजन करने को प्रोत्साहित किया जाता है।

वर्तमान समय में कोविड महामारी को ध्यान में रखते हुए एवं भारत सरकार, गृह मंत्रालय के द्वारा जारी दिशा निर्देशों का पालन करते हुए कार्यालय में हर वर्ष की तरह इस वर्ष भी 14 से 28 सितंबर 2021 तक हिंदी पखवाड़ा मनाया गया। हिंदी पखवाड़ा के दौरान विभिन्न प्रतियोगिताओं का आयोजन किया गया। 15 सितंबर को लिखित निबंध प्रतियोगिता का आयोजन किया गया। जिसमें कर्मचारियों द्वारा पुरे उत्साह के साथ भाग लिया गया। अंततः दिनांक 28 सितंबर को हिंदी पखवाड़ा का पुरस्कार वितरण एवं समापन समारोह का आयोजन किया गया।

इस वर्ष हमारे मुख्य अतिथि श्रीमान मोहन सिंह मेहता जी अधीक्षण अभियंता (सिविल) पश्चिम एवं दक्षिण क्षेत्र आकाशवाणी व दूरदर्शन, प्रसार भारती मुंबई और चेन्नई को हिंदी पखवाड़ा समापन समारोह एवं पुरस्कार वितरण हेतु सादर आमंत्रित किया गया था। प्रत्येक प्रतियोगिताओं के विजेताओं को नगद पुरस्कार एवं प्रशस्ति पत्र प्रदान किये गये। हिंदी पखवाड़े में एक अद्वितीय राष्ट्रीय स्वाद था।













### ➤ Dussehra Celebration on 14<sup>th</sup> October 2021 :

Instrument Puja or Astra Puja was celebrated in CDTL-Mumbai on 14<sup>th</sup> October 2021. In the cross cultural development that has revolutionized the society, the ethos of old religious order is retained by worship of all the machines, instruments, computers in the laboratory.

All the instruments & tools were cleaned & worshipped and the entire staff celebrated the day ardently.





➤ **Vigilance Awareness Week 2021 observed from 26<sup>th</sup> October to 1<sup>st</sup> November 2021 :**

The Central Vigilance Commission, as part of its efforts to create awareness against the menace of corruption and to promote ease of public life and to achieve a corruption free society, observes Vigilance Awareness Week every year.

CDTL-Mumbai and NTTL-Mumbai are celebrating Vigilance Awareness Week from 26<sup>th</sup> October to 1<sup>st</sup> November 2021.

The theme for the Vigilance Awareness this year is **“Independent India @ 75: Self Reliance with Integrity”**. Vigilance is of 3 types Preventive, Participative and Punitive. Preventive vigilance involves studying the organization, its policies and its people and implementing effective measures so that they do not become vulnerable to corruption. Punitive is being watchful, to detect lapses. Participative is the involvement or participation of all stakeholders and well wishers in the vigilance programme e.g. Whistle blower policy.

CDTL-Mumbai had scheduled a weeklong Vigilance Awareness Week. Various activities were organised as per the instructions issued by the MoHFW and received from CDSO HQs. The entire staff stood together to take the Integrity pledge. The awareness week campaign affirms our commitment to the promotion of integrity through citizen participation.



➤ **Special Campaign drive for disposal of pending matters on Swachhta Abhiyan during the period 2<sup>nd</sup> to 31<sup>st</sup> October 2021 :**

Swachhata Abhiyan was undertaken from 2<sup>nd</sup> to 31<sup>st</sup> October 2021 as per the directives of the Ministry of Health and Family Welfare. The laboratory staff was actively involved in maintaining cleanliness of the building and premises. As a part of **Swachhata Abhiyan the old, rusted, equipments (dead stock) accumulated in the basement and old records** were segregated for disposal as per the Govt. of India policy. The committees/ sub-committees were formed for this task. All these items were disposed off by following e-auction process and the amount collected Rs. 94,500/- was deposited in Govt. of India account.

As per O.M. No. I.25015/01/2021-IWSU, dt. 04/10/2021, all the matters pending at Head Quarters/Ministry level/ were communicated so that they are cleared/ disposed off within this period. The before and after photographs were uploaded on the website [www.cd.nhp.gov.in](http://www.cd.nhp.gov.in) on daily basis.

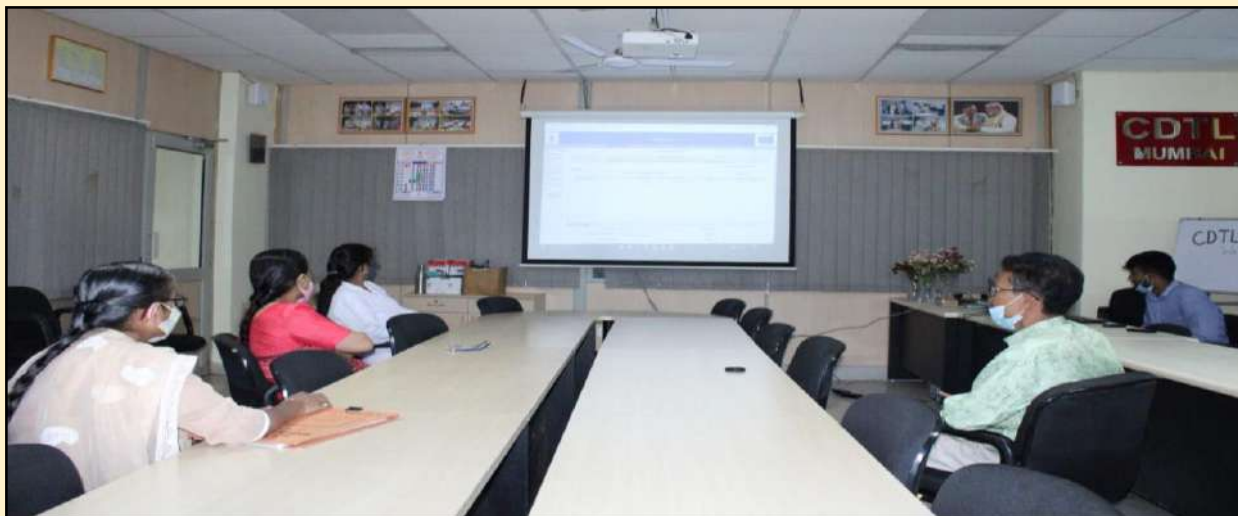
**Old, rusted, equipments (dead stock) accumulated in the basement and old records were segregated for disposal and disposed off by following e-auction process through Tenderwizard**





No.	Brief	Before Photograph	After Photograph
1	Terrace cleaning		
2	Back side premises Cleaning		
3	Garden Cleaning		
4	Administration Section cleaning - 2 <sup>nd</sup> floor		
5	Sample Warden Section - 2 <sup>nd</sup> floor		
6	Cleaning of 4 <sup>th</sup> Floor Lobby		

- **Auction on 27<sup>th</sup> October 2021 for disposal of old/ Damaged/ Irreparable equipments furniture, electronic etc. items under e-Auction by Tenderwizard M/s. ITC Limited, New Delhi and disposal work done by M/s. Envirocare Recycling Pvt. Ltd.**



#### ➤ **Inspection :**

As directed by DCG (I), Smt. S. U. Warde, SSO-II carried out the "**Inspection of State Drugs Laboratories in the State of Maharashtra for the Strengthening of State Drug Regulatory System - Further Continuation of the scheme**" at FDA, Bandra (E), Mumbai from 22<sup>nd</sup> Nov 2021 to 23<sup>rd</sup> Nov 2021 along with other team members : Representative of MoH&FW, New Delhi, Dy. Drugs Controller CDSCO, West Zone Mumbai and his representative and Representative of FDA Maharashtra State.

- **Visit of team of Haffkine Institute for setting up NABL accredited laboratory at Haffkine Institute on 7<sup>th</sup> December 2021 :**





## ➤ Republic Day celebration on 26<sup>th</sup> January 2022 :

CDTL-Mumbai celebrated the 73<sup>rd</sup> Republic Day with great éclat as part of the Azadi Ka Amrit Mahotsav commemorating 75 years of independence. The staff took pride in glorifying and celebrating the spirit of unity. The gathered members hoisted and saluted the National Flag and pledged themselves to upholding the honour, integrity, diversity and uniqueness India. Director, Dr. Raman Mohan Singh delivered inspirational speech and the entire staff sang the National anthem. It was an occasion to reaffirm our commitment to the unity in diversity, fraternity and equality. They paid tribute to the members of the armed forces, who gave up their life for the country.

The staff dispersed with the image of the fluttering tricolour in their minds.





➤ **Fire fighting training organised by Oasis Engineers at CDTL premises on 3<sup>rd</sup> February 2022 and attended by staff :**









➤ **त्रैमासिक हिंदी कार्यशाला –**

हिंदी राजभाषा सी. डी. टी. एल. मुंबई एवं जी. एम. एस. डी. मुंबई कार्यालय के राजभाषा समिति के तत्वाधान में हिंदी कार्यशाला का आयोजन दिनांक 25/03/2022 को हुआ। हिंदी कार्यशाला के मुख्य अतिथि डॉ. सुशिल कुमार शर्मा, उप महाप्रबंधक (राजभाषा) पश्चिम रेलवे, मुंबई तथा डॉ. रमन मोहन सिंह, अध्यक्ष राजभाषा समिति व निदेशक, सी. डी. टी. एल. मुंबई की उपस्थिति में राजभाषा 'हिंदी' से संबंधित नियमों तथा कार्यालयीन पत्राचार में आनेवाले कठिनाईयों एवं वर्तनी इत्यादि पर प्रकाश डाला गया।





The organizational chart for the Directorate of Chemicals, Government of Karnataka, is structured as follows:

- Director** and **Dy. Director** are at the top level.
- The Directorate is divided into two main wings:
  - Technical Wing**
    - Chemical Division**
      - Sample Warden Section
      - Reference Substance Section
      - Wet Chemistry Section
      - Instrumentation Section
      - Analytical R & D Section
    - Biological Division**
      - Microbiology Section
      - Medical Device Section
      - Cosmetics Section
      - Quality Assurance Section
  - Administration Wing**
    - Administration Division**
      - Establishment & Account Section
      - Stores Section
      - Library & Information Section
      - Utility and Security
- Administration strength** is a separate box at the bottom right.
- Staff Strength Summary:**
  - Technical Wing:**
    - Chemical Division:** Permanent Staff (38), Contractual Staff (34), Total = 72.
    - Biological Division:** Permanent Staff (13), Contractual Staff (10), Total = 23.
  - Administration Wing:**
    - Administration Division:** Daily Wages staff (3), Out sourcing Staff (17), Total = 20.
- Total Strength: 115** (72 + 23 + 20).
- Permanent staff: 51** (38 + 13).
- Contractual staff: 44** (34 + 10).
- Outsourcing staff/Daily Wages: 20** (3 + 17).