

Information provided under RTI Act. 2005 in – 2017-18

REGIONAL DRUGS TESTING LABORATORY, CENTRAL DRUGS STANDARD CONTROL
ORGANISATION, (Directorate General of Health services), Ministry of Health & Family Welfare, SECTOR-
39C, CHANDIGARH – 160036

➤ RTI Application No: 1

Receipt Date: 03.04.2017

Reply date: 17.04.2017

Sl. No.	Information Sought	Reply
1.	Advertisement was published in CDSCO Website for the recruitment of Ten Bench Chemist. Advertisement No 1. 01/08/2016-17/Admn./Cont. App./1997/16 dated 30.12.2016/	Yes
2.	How many marks were allocated to written test and interactive section.	The information sought cannot be shared with third party under section 8 (1)(J) of RTI Act. 2005
3.	Please provide the merit list (including marks obtained in the written test and interactive session) of selected candidates and waiting candidates?	<i>Annexure-3</i>
4.	Please provide the details of members sitting in the selection board.	1. Dr. R. A. Singh, Director, RDTL, Chandigarh-Chairman 2. Dr. Debasis Maiti, Senior Scientific Officer Gr.II, RDTL, Chandigarh-Member. 3. Sh.Vikram Singh, Administrative Officer, IMTECH, Chandigarh-Member.
5.	Please provide the selection list including final marks obtained by the candidates with following details. a) Name b)Previous experience c) Permanent address with District & State	The information sought cannot be shared with third party under section 8(1)(J) of RTI Act. 2005
6.	Kindly provide the list of shortlisted candidates including marks obtained in written test and interactive session.	Information in this regard is available on the CDSCO website


Annexure- 3

**List of candidates recommended by the committee for engagement
as bench chemist on contractual basis through
G.A. Digital Web Word, New Delhi**


Sr. No.	Roll No.	Entry No.	Name
1	1	BC-305	Aditi Nijhawan
2	2	BC-23	Arun Kumar
3	9	BC-105	Goldie Uppal
4	21	BC-103	Manoj Kumar
5	19	BC-55	Manjot Kaur
6	15	BC-4	Keshav Kumar
7	27	BC-3	Nitesh Kumar
8	11	BC-212	Gurmeet Kumari
9	3	BC-137	Chetna Kamboj
10	30	BC-24	Ravendra Kumar

Waiting List

1	12	BC-57	Gurpreet Singh
2	39	BC-28	Sumeet Sharma
3	40	BC-208	Sunil Katoch
4	10	BC-316	Gurjeet Kaur
5	20	BC-2	Manjusha Sharma
6	25	BC-85	Neha Tomar
7	37	BC-281	Shivali
8	28	BC-97	Pankaj Kumar
9	34	BC-134	Sachin Kumar
10	33	BC-45	Ruchi Dhiman


S.S.O. (Gr. -II),
RDTL, Chandigarh
(Member)


10/2/17
Sh. Vikram Singh
Administrative Officer
IMTECH, Chandigarh
(Member)


10/2/17
Director, RDTL,
Chandigarh
(Chairman)

➤ **RTI Application No: 2**

Receipt Date: 21.06.2017

Reply date: 21.06.2017

Sl. No.	Information Sought	Reply
a.	Total office of CDSCO taken on Rent in India	This Laboratory running from its own building.
b.	The total Rent payable annually or monthly, for all the Rented Premises, by the Government to the Owners of this offices	N.A. to this Laboratory
c.	The Rent payable for the office situated at CDSCO, Sea port Office, DGHS, Ministry of Health & Family Welfare, 9-91, National Highway – 17, Palaspe, JNPT Highway, Village Padeghar, Panvel, Padeghar, Maharashtra - 410206	N.A. to this Laboratory

➤ **RTI Application No: 3**

Receipt Date: 30.06.2017

Reply date: 30.06.2017

Sl. No.	Information Sought	Reply
a.	Please provide State wise (department wise) breakup of tentative vacancies for SSC CHSLE-2015 examination for the post of LDC in ministry of Health and Family Welfare	In this context, it is informed that there is no sanction post of LDC in this Laboratory. The tentative vacancies of SSC CHSLE - 2015 examination for the post of LDC treated as NIL.

Receipt Date: 28.08.2017

Reply date: 30.08.2017

Background:

Tender Details: Tender Document 4-5/2017-18/Security1596/17 Dated 07/07/2017 for quotation for Security Guard and Housekeeping Staff.

In the light of the above mentioned background, please provide the following information:

Sl. No.	Information Sought	Reply
1.	Name and details of the parties who submitted bid for the above mentioned tender.	1.M/s. NIPS Services Pvt. Ltd. 2.M/s. B.D Security Pvt. Ltd. 3. M/s. J Star Security Pvt. Ltd. 4.M/s. Terrier Utility Services Pvt. Ltd. 5.M/s. Guardian Security & Placement Services 6.M/s. Golden Eagle Security Services 7. M/s. Swaraj
2.	The Criteria for selection of the candidate for the tender.	As per tender document.
3.	The amount quoted by the winning candidate in tender.	Information cannot be provided as the case is still under process.
4.	The name of the winning candidate of the tender.	Information cannot be provided as the case is still under process.
5.	A copy of the minutes of the meeting in which the tender was decided.	Information cannot be provided as the case is still under process.
6.	Please provide a copy of rules vide which Labour compliance, including Bonus, Leave Compensatory Charges and Relieving Charges are mandatory compiled.	As per govt. rules applicable
7.	Please intimate whether the winning bidder has quoted these compliances in his financial bid and if not, why he was not disqualified.	Information cannot be provided as the case is still under process.

Receipt Date: 14.08.2017

Reply date: 07.09.2017

Sl. No.	Information Sought	Reply
1.	List of HPLCs with corresponding validation & calibration reports and log books, available in RDTL Chandigarh during the period from 01.06.2015 to 31.03.2017.	<p>List of HPLCs with their status of calibration is attached herewith as per Annexure- 'A'.</p> <p>Calibration reports, log books are confidential documents for internal use only and this will not serve any public interest and therefore, cannot be provided as per section 8(d) of RTI Act, 2005.</p>
2.	List of Reference Standard and impurities along with log book available in RDTL Chandigarh during the period from 01.06.2015 to 31.03.2016	<p>There were 30 reference standard and 9 impurities procured from IPC Ghaziabad.</p> <p>The log books are for the internal use and would not serve any Public interest and therefore, cannot be provided as per section 8(d) of RTI Act, 2005.</p>
3.	List of Qualified persons with their specimen signatures available in RDTL Chandigarh during the period from 01.06.2015 to 31.03.2016	<p>The list of total number of employee's month wise of the required period is enclosed herewith as per Annexure 'B'.</p> <p>Specimen signatures cannot be furnished in accordance with a provision of section 8 (j) RTI Act, 2005 as it will serve no public Interest and would cause unwarranted invasion of the privacy of the individual.</p>
4.	List of Staff engaged in testing of samples in RDTL Chandigarh during the period from 01.06.2015 to 31.03.2016, along with their qualification, experience and copies of their appointment letters.	<p>The list of technical staff engaged in testing of samples of the required period is enclosed herewith as per Annexure 'C'.</p> <p>Appointment letters/ other details cannot be furnished in accordance with the provision of section 8(j) of RTI Act, 2005 as it would serve no public interest & would cause unwarranted invasion of the privacy of the individuals.</p>

5.	List of weighing balance with corresponding validation & calibration reports and log books, available in RDTL Chandigarh during the period from 01.06.2015 to 31.03.2016	<p>There are 4 nos. of weighing balances and their status of calibration is given as per Annexure-‘D’.</p> <p>Calibration reports log books are confidential documents for internal use only. This would serve no public interest & therefore not provided as per Section 8 (d) of RTI Act, 2005.</p>
6.	List of Disintegration Apparatus with corresponding validation & calibration reports and log books, available in RDTL Chandigarh during the period from 01.06.2015 to 31.03.2016	<p>The list of 3 Disintegration Apparatus with their calibration status is given as per Annexure-‘E’.</p> <p>Calibration reports, log books are confidential documents for internal use only. This would serve no public interest and hence not provided as per section 8(d) of RTI Act, 2005.</p>
7.	Copies of Audit Reports in respect of Technical Audits of RDTL Chandigarh conducted by Internal Teams and External Agencies during the period from 01.01.2015 to 30.06.2016	<p>Internal and External Audit of the Lab. has been carried out as per NABL requirement.</p> <p>In accordance with the provision of Section 8(j) of RTI Act, 2005. It would serve no public interest & would cause unwarranted invasion of the privacy of the individual, therefore, the reports not provided.</p>
8.	List of HPLC columns available in RDTL Chandigarh during the period from 01.06.2015 to 31.03.2016.	The list of 57 columns is enclosed as per Annexure ‘F’.

Annexure-A

Regional Drugs Testing Laboratory-Chandigarh

List of HPLC Calibration (01.06.2015 to 31.03.2017)

(Annexure-A)

Sr.No	Name of the Equipment	Instrument ID	Model/Make	Date of Last Calibration During the above period	Calibration Due on	Preventive maintenance /Calibrated By
01	HPLC	RDTL-INS-01	2487/Waters	18.11.2016	17.05.2017	M/s Waters Chandigarh/Inhouse
02	HPLC	RDTL-INS-39	1200 Series/ Agilent	21.11.2016	20.05.2017	M/s Agilent New Delhi/Inhouse
03	HPLC	RDTL-INS-55	1100 Series/ Agilent	02.12.2016	01.06.2017	M/s Agilent New Delhi/Inhouse
04	HPLC	RDTL-INS-77	Flexar/ Perkin Elmer	04.11.2016	03.05.2017	M/s Perkin Elmer, Chandigarh
05	HPLC	RDTL-INS-78	Flexar/ Perkin Elmer	07.11.2016	06.05.2017	M/s Perkin Elmer, Chandigarh
06	HPLC	RDTL-INS-79	Flexar/ Perkin Elmer	04.11.2016	03.05.2017	M/s Perkin Elmer, Chandigarh
07	HPLC	RDTL-INS-80	Flexar/ Perkin Elmer	18.11.2016	17.05.2017	M/s Perkin Elmer, Chandigarh
08	HPLC	RDTL-INS-81	Flexar/ Perkin Elmer	28.11.2016	27.05.2017	M/s Perkin Elmer, Chandigarh
09	HPLC	RDTL-INS-82	Flexar/ Perkin Elmer	29.11.2016	28.05.2017	M/s Perkin Elmer, Chandigarh
10	HPLC	RDTL-INS-83	Flexar /Perkin Elmer	24.11.2016	23.05.2017	M/s Perkin Elmer, Chandigarh

Note- As per our SOP of HPLC the frequency of calibration is Six months \pm 15 days and all the HPLC are calibrated within said period i.e. 01.06.2015 to 31.03.2017.



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Annexure- B

Annexure-B

RDTL - CHANDIGARH LIST OF TOTAL STAFF FROM JUNE-2015 TO MARCH 2016

Sr. No.	Month	Total
1	Jun-15	41
2	Jul-15	67
3	Aug-15	66
4	Sep-15	65
5	Oct-15	63
6	Nov-15	63
7	Dec-15	65
8	Jan-16	66
9	Feb-16	66
10	Mar-16	65



RDTL - CHANDIGARH
LIST OF TECHNICAL STAFF FROM JUNE-2015 TO MARCH 2016

Sr. No.	Month	Technical Staff
1	Jun-15	31
2	Jul-15	56
3	Aug-15	56
4	Sep-15	55
5	Oct-15	53
6	Nov-15	54
7	Dec-15	55
8	Jan-16	56
9	Feb-16	56
10	Mar-16	55



Regional Drugs Testing Laboratory-Chandigarh

List of Weighing Balance Calibration (01.06.2015 to 31.03.2016)

(Annexure-D)

Sr.No	Name of the Equipment	Instrument ID	Model/Make	Date of Last calibration	Calibration Due on	Calibrated By
01	Weighing Balance	RDTL-INS-12	XR 205A/Precisa	05.06.2015	04.06.2016	External Calibration M/s from ICL Calibration and Testing Services, Panchkula and Daily calibration before use.
02	Weighing Balance	RDTL-INS-13	T-214/Denver	05.06.2015	04.06.2016	
03	Weighing Balance	RDTL-INS-45	CX 200/Citizen	05.06.2015	04.06.2016	
04	Weighing Balance	RDTL-INS-54	CX 200-/Citizen	05.06.2015	04.06.2016	


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Annexure-E**Regional Drugs Testing Laboratory-Chandigarh****List of Disintegration Apparatus Calibration (01.06.2015 to 31.03.2016)****(Annexure-E)**

Sr.No	Name of the Equipment	Instrument ID	Model/Make	Date of Last Calibration	Calibration Due on	Calibrated By
01	Disintegration Apparatus	RDTL-INS-38	VTD-AV/Veego	09.11.2015	08.05.2016	Inhouse
02	Disintegration Apparatus	RDTL-INS-74	VTD-AVP/Veego	15.09.2015	14.03.2016	Inhouse
03	Disintegration Apparatus for (Suppositries and Pessaries)	RDTL-INS-75	VTS-P/Veego	15.09.2015	14.03.2016	Inhouse


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Annexure-F				
LIST OF HPLC COLUMNS				
S. No.	COMPANY NAME	INTERNAL DIAMETER /LENGTH	COLUMN SR. NO.	ID NO.
1	PERKIN ELMER	4.6 mm X 250	914120270	RDTL/HPLC/C18/001
2	PERKIN ELMER	4.6 mm X 250	914110207	RDTL/HPLC/C18/002
3	PERKIN ELMER	4.6 mm X 250	914110199	RDTL/HPLC/C18/003
4	PERKIN ELMER	4.6 mm X 250	914110217	RDTL/HPLC/C18/004
5	PERKIN ELMER	4.6 mm X 250	914110205	RDTL/HPLC/C18/005
6	PERKIN ELMER	4.6 mm X 250	914110231	RDTL/HPLC/C18/006
7	PERKIN ELMER	4.6 mm X 250	914120260	RDTL/HPLC/C18/007
8	PERKIN ELMER	4.6 mm X 250	914110219	RDTL/HPLC/C18/008
9	PERKIN ELMER	4.6 mm X 150	914110290	RDTL/HPLC/C18/009
10	PERKIN ELMER	4.6 mm X 250	914110221	RDTL/HPLC/C18/010
11	PERKIN ELMER	4.6 mm X 250	914110215	RDTL/HPLC/C18/011
12	AGILENT	4.6 mm X 250	USUXA03491	RDTL/HPLC/C18/012
13	PERKIN ELMER	4.6 mm X 150	914110285	RDTL/HPLC/C18/013
14	PERKIN ELMER	4.6 mm X 250	914110212	RDTL/HPLC/C18/014
15	PERKIN ELMER	4.6 mm X 250	914120247	RDTL/HPLC/C18/015
16	PERKIN ELMER	4.6 mm X 150	914110286	RDTL/HPLC/C18/016
17	PERKIN ELMER	4.6 mm X 150	914110326	RDTL/HPLC/C18/017
18	PERKIN ELMER	4.6 mm X 150	914110295	RDTL/HPLC/C18/018
19	PERKIN ELMER	4.6 mm X 150	914110289	RDTL/HPLC/C18/019
20	PERKIN ELMER	4.6 mm X 250	914110263	RDTL/HPLC/C18/020
21	PERKIN ELMER	4.6 mm X 300	915030041	RDTL/HPLC/C18/021
22	AGILENT	4.6 mm X 150	USKH071113	RDTL/HPLC/C18/022
23	AGILENT	4.6 mm X 150	USKH069278	RDTL/HPLC/C18/023
24	AGILENT	4.6 mm X 250	USUXA03494	RDTL/HPLC/C18/024
25	AGILENT	4.6 mm X 250	USNH022074	RDTL/HPLC/C18/025
26	PERKIN ELMER	4.6 mm X 250	914110216	RDTL/HPLC/C18/026
27	PERKIN ELMER	4.6 mm X 250	914110223	RDTL/HPLC/C18/027
28	PERKIN ELMER	4.6 mm X 250	914120208	RDTL/HPLC/C18/028
29	PERKIN ELMER	4.6 mm X 150	914120064	RDTL/HPLC/C8/001
30	PERKIN ELMER	4.6 mm X 150	914120058	RDTL/HPLC/C8/002
31	PERKIN ELMER	4.0 mm x 250	914120306	RDTL/HPLC/C8/003
32	PERKIN ELMER	4.0 mm x 250	914120308	RDTL/HPLC/C8/004
33	PERKIN ELMER	4.0 mm x 250	914120315	RDTL/HPLC/C8/005
34	AGILENT	4.6 mm X 250	USAN000424	RDTL/HPLC/C8/006
35	AGILENT	4.6 mm X 150	USM0013482	RDTL/HPLC/C8/007
36	AGILENT	4.6 mm X 150	USM0013606	RDTL/HPLC/C8/008
37	AGILENT	4.6 mm X 150	USAN000409	RDTL/HPLC/C8/009
38	PERKIN ELMER	4.0 mm x 250	914120309	RDTL/HPLC/C8/010
39	PERKIN ELMER	4.0 mm x 250	914120311	RDTL/HPLC/C8/011
40	AGILENT	4.6 mm X 250	UST0015326	RDTL/HPLC/NH2/001
41	AGILENT	4.6 mm X 250	UST0015163	RDTL/HPLC/NH2/002
42	AGILENT	4.6 mm X 250	USYU005835	RDTL/HPLC/SIL/001
43	AGILENT	4.6 mm X 250	USYU005894	RDTL/HPLC/SIL/002
44	AGILENT	4.6 mm X 150	USBJ001616	RDTL/HPLC/CN/001
45	AGILENT	4.6 mm X 150	USBJ001772	RDTL/HPLC/CN/002
46	PERKIN ELMER	4.6 mm X 250	914120215	RDTL/HPLC/C18/029
47	PERKIN ELMER	4.6 mm X 150	914110294	RDTL/HPLC/C18/030
48	PERKIN ELMER	4.6 mm X 250	914110276	RDTL/HPLC/C18/031

LIST OF HPLC COLUMNS

S.NO.	COMPANYNAME	INTERNAL DIAMETER/ LENGTH	COLUMN SR.NO.	ID NO.
49	WATERS	250 X 4.6 mm	055A35226510210	RDTL/HPLC/SIL/003
50	WATERS	250 X 4.6 mm	15031528510273	RDTL/HPLC/SIL/004
51	PERKIN	150 X 4.6 mm	914110283	RDTL/HPLC/C18/32
52	PERKIN	150 X 4.6 mm	914110325	RDTL/HPLC/C18/34
53	PERKIN	150 x 4.6 mm	914110284	RDTL/HPLC/C18/35
54	PERKIN	250 x 4.6 mm	914110264	RDTL/HPLC/C18/36
55	PERKIN	250 x 4.6 mm	914110355	RDTL/HPLC/Amino/37
56	PERKIN	250 x 4.6 mm	914120146	RDTL/HPLC/Silica/38
57	PERKIN	250 x 4.6 mm	914110335	RDTL/HPLC/Amino/39

Gurcharan
07/9/17

List of Impurities

LIST OF IMPURITIES
01.06.2015 TO 31.03.2016

SN	NAME OF IMPURITIES
1	Dicyandiamide
2	Guanine
3	Mesalamine impurity E
4	Mesalamine impurity H
5	Hydrocortisone
6	Efavirenz amino alcohol impurity
7	Efavirenz Quinoline impurity
8	Hydroxychloroquine sulphate
9	Diclofenac impurity A

Gurcharan
05/09/17

LIST OF REFERENCE STANDARD 01.06.2015 TO 31.3.16

S. No.	Name of RS	LOT NO.	QTY.
1	Alprazolam	IPRS/19/15	50 mg
2	Amoxycillin Trihydrate	IPRS/47/14	200 mg
3	Ascorbic Acid	177/09/10	1 Ampule
4	Betahistine	IPRS/122/12	200 mg
5	Caffeine	IPRS/122/14	200 mg
6	Cefuroxime Axetil	IPRS/24/15	200 mg
7	Cetirizine Hydrochloride	IPRS/69/14	200 mg
8	Chloroquine Phosphate	IPRS/58/12	200 mg
9	Clofazimine	IPRS/257/12	200 mg
10	Clonazepam	IPRS/124/12	200 mg
11	Divalproex Sodium	IPRS/93/12	200 mg
12	Diluted Nitroglycerin	USP	1 Ampule
13	Efavirenz	IPRS/236/12	200 mg
14	Ethinyl estradiol	IPRS/86/10	200 mg
15	Fexofenadine Hydrochloride	IPRS/03/11	200 mg
16	Flutamide	IPRS/12/13	200 mg
17	Gliclazide	IPRS/54/11	200 mg
18	Imatinib Mesylate	IPRS/118/12	200 mg
19	Lamivudine	IPRS/237/12	200 mg
20	Levocetirizine Hydrochloride	IPRS/72/14	200 mg
21	Paracetamol	IPRS/54/14	200 mg
22	Phenobarbitone	IPRS/17/12	200 mg
23	Phenytoin Sodium	IPRS/31/11	200 mg
24	Ranitidine Hydrochloride	IPRS/147/14	200 mg
25	Sulfamethoxazole	1740/92	1 Ampule
26	Tamsulosin Hydrochloride	IPRS/43/14	200 mg
27	Telmisartan	IPRS/78/14	200 mg
28	Thyroxine Sodium	IPRS/105/13	200 mg
29	Tramadol Hydrochloride	IPRS/136/14	200 mg
30	Triamcinolone	IPRS/17/10	200 mg

Gurchan
05/09/2017

➤ **RTI Application No: 6**

Receipt Date: 25.08.2017

Reply date: 07.09.2017

According to the Honourable Supreme Court order, the candidates of reserved category, who have received the benefits or exemptions given under the reservation, whether the number of reserved category candidates are equal or more to the unreserved candidate. They cannot get unreserved category seats. The candidates of that reserved category will be given job only in the reserved category.

Sl. No.	Information Sought	Reply
1.	Under the Right to information Act, 2005, I want to know that the above order of honourable Supreme Court has been followed by Ministry of Health and Family Welfare and Attached and Subordinate offices under the Ministry of Health and Family Welfare. If not followed, please provide me the reason behind this.	This office has not made any recruitment since the date of deliverance of order dated 06 th April, 2017 of Hon'ble Supreme Court and have followed the judgement.
2.	Under the Right to information Act, 2005, I want to know whether above order of Honourable Supreme Court will be follow in all other upcoming recruitment examinations conduct by Ministry of Health and Family Welfare and Attached and Subordinate offices under the Ministry of Health and Family Welfare or not.	

➤ **RTI Application No: 7**

Receipt Date: 01.09.2017

Reply date: 25.09.2017

Sl. No.	Question	Reply
1.	Please provide me the Flow Charts, Standard Operating Procedures, validation plan, IQ, OQ & PQ, followed by RDTL Chandigarh to analyse each & every sample of Drugs received by it for testing as per pharmacopoeias and as per label	Our Lab. follows standard operating procedure as per label claim like IP, BP, & USP applicable edition. The validation of IQ, OQ & PQ is carried as per quality manual.

	details.	In case of patent proprietary drugs, the method of analysis as per manufacture's specifications.
2.	Please provide me the details of purchases of Laboratory equipment, impurities, reference standards along with their validation, stability data and operational records of each reference standard and impurities, equipment year wise during last three years.	<p>The major lab instruments are purchased through our Ministry of Health and Family Welfare.</p> <p>Impurities and standard references were purchased from IPC Ghaziabad.</p> <p>The records are for the internal use and would not serve any Public interest and therefore, cannot be provided as per section 8(d) of RTI Act, 2005.</p>
3.	Please provide me the copy of audit reports of inspections of RDTL carried out under GLP (Good Laboratory Practices) by CDSCO Officers yearwise during last three year along with the CAPA Reports.	<p>Internal and External Audit of the Lab. has been carried out as per NABL requirement.</p> <p>In accordance with the provision of Section 8(j) of RTI Act, 2005. It would serve no public interest & would cause unwarranted invasion of the privacy of the individual, therefore, the reports not provided.</p>
4.	Please provide me the list of equipment installed for water used for test analysis by RDTL as per requirements of different pharmacopeia's for conducting dissolution test along with the details of the samples where required quality of water has not been used in analysis and the samples have been declared not of standard quality due to dissolution requirement of various pharmacopeia's.	<p>The quality of water type 1 is produced from water purification system installed in our lab.</p> <p>At present, our lab has three water purification systems, details attached as per Annexure- A.</p> <p>The quality of water is tested and monitor as per SOP & instruments are calibrated/ sanitized. We always use required quality of water in the analysis of samples.</p>

Annexure-A**Regional Drugs Testing Laboratory-Chandigarh****(Annexure-A)****List of Water Purification Systems**

Sr.No	Name of Equipment	Equipment ID No.	Sanitization/Calibration By
01	Elga Water Purification System	RDTL-INS-14	M/s Metrohm India Limited, Chandigarh/ Inhouse
02	Elga Water Purification System	RDTL-INS-15	M/s Metrohm India Limited, Chandigarh/ Inhouse
03	Thermo Scientific Water Purification System	RDTL-INS-103	M/s Labindia Analytical New Delhi/ Inhouse

**➤ RTI Application No: 8**

Receipt Date: 19.09.2017

Reply date: 06.10.2017

Sl. No.	Information Sought	Reply
1.	Details of all Survey Samples of drugs tested at your laboratory along with copies of respective Analysis Report during the period 01.09.2017 to 15.09.2017	<p>There were 74 Survey Samples reported from our Laboratory during the period from 01.09.2017 to 15.09.2017(<i>Summary Statement is given below</i>)*.</p> <p>The copies of analysis reports cannot be furnished in accordance with the provision of section 8(j) of RTI Act, 2005 as it would serve no public interest & would cause unwarranted invasion of the privacy of the individuals.</p>

**The comment in italics and within parenthesis is not contained in the original document. This is added here for the simplicity and easy to understand.*

Summary Statement

REGIONAL DRUGS TESTING LABORATORY
CENTRAL DRUGS STANDARD CONTROL ORGANISATION
(Directorate General of Health Services)
Ministry of Health & Family Welfare
Govt. of India
Sector-39 C, Chandigarh - 160036

SUMMARIZED STATEMENT(From 01/09/17 to 15/09/17)									
SNo.	Name of Analyst	Received	Disposed	Closing Balance	<30days	>30days <45days	>45days <60days	>60days	Remarks
Category:- LS - Legal Sample									
1	Ashok Sharma	49	1	48	48	0	0	0	
2	Dr Amit Kumar	46	1	45	45	0	0	0	
3	Hitesh Khare	64	4	60	60	0	0	0	
TOTAL		159	6	153	153	0	0	0	
Category:- SS - Survey Sample									
4	Ashok Sharma	57	14	43	43	0	0	0	
5	Dr Amit Kumar	58	26	32	32	0	0	0	
6	Hitesh Khare	70	34	36	36	0	0	0	
TOTAL		185	74	111	111	0	0	0	
GRAND TOTAL		344	80	264	264	0	0	0	

➤ **RTI Application No: 9**

Receipt Date: 16.11.2017

Reply date: 17.11.2017

Sir,

I had filed an application with PIO, Central Drug Testing Laboratory, Chandigarh dated 28.08.17 (Photo copy attached) seeking information under RTI Act, 2005. The reply dated 25.09.17 given is unsatisfactory (copy enclosed) grounds for the same is as under:-

Sl. No.	Question	Answer	Ground for Appeal	Reply
1.	Please provide me the Flow Charts, Standard Operating	Our Lab. follows standard operating procedure as per label claim like IP, BP, &	RDTL Chandigarh is a prestigious Govt. Institution, Highly specialized in Character.	A copy of the flow chart is enclosed herewith which is being adopted in this laboratory. (Annexure-1)

	<p>Procedures, validation plan, IQ, OQ & PQ, followed by RDTL Chandigarh to analyse each & every sample of Drugs received by it for testing as per pharmacopeia's and as per label details.</p>	<p>USP applicable edition.</p> <p>The validation of IQ, OQ & PQ is carried as per quality manual.</p> <p>In case of patent proprietary drugs, the method of analysis as per manufacture's specifications.</p>	<p>Its services are being availed by Govt. And its various specialized agencies on a regular basis to analysis drugs & medicines for its quality and standards. The common man of the country is deeply affected by the quality of the service rendered by such institutions. A slight Error or a mistake in this sensitive task of analysis and its resulted findings might render someone liable criminally or may ruin someone's trade of business. Such institutions are reviewing authorities and their verdict is considered final. Means there is no appeal against the findings of these institutions. Thus, the stake of the people being so high in relation to care operations of these institutions. It is desirable that its highly specialized task of analysis of drugs observes transparency and objectivity in its set</p>	<p>This Lab. follows standard operating procedure as per label claim like IP, BP, & USP applicable edition. The pharmacopeia's cannot be provided and are easily available and can be referred from the market /Library.</p> <p>In case of patent proprietary drugs, the methods of analysis are adopted as per manufactures specifications and standards are followed as per Drugs & Cosmetic Act. S.O.Ps, from the manufactures and Validation Plans are confidential documents of third party and it cannot be provided as per section 8(d) of RTI Act 2005.</p> <p>IQ, OQ & PQ are also provided by the respective vendors/suppliers of the instruments and accordingly cannot be provided under section 8(d) of the RTI Act 2005.</p> <p>The applicant mentioned "such institutions are reviewing authorities and their verdict is considered final" means there is no</p>
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			up, capabilities and operations and use of public funds. Hence, looking to the nature of the services rendered cannot be confidential documents for internal use only. Genuinely mistaken findings can be pardoned once, but what if the unfair practices have formed their roots in such institutions. That being so, the institution itself becomes an instrument that spreads injustice. The solution for this too is to have transparency in essential matters relating to the institution including its functioning.	appeal against the findings of these institutions. The information is not correct. The RDTL, Chandigarh is not appellant laboratory. Hence, there is a option to appeal against the findings of RDTL, Chandigarh.
2.	Please provide me the details of purchases of Laboratory equipment, impurities, reference standards along with their validation, stability data and operational records of each reference	<p>The major lab instruments are purchased through our Ministry of Health and Family Welfare.</p> <p>Impurities and standard references were purchased from IPC Ghaziabad.</p> <p>The records are for the internal use and would not serve any Public</p>	<p>Denial of information on reference standards/ impurities, equipments are violation of section 2(f) of the RTI Act 2005.</p> <p>In point B) the applicant has asked for details of the equipment in use in RDTL Chandigarh. Supply of this information would send a right and positive message to the public as</p>	<p>The major lab instruments are purchased through our Ministry of Health and Family Welfare/ HQ.</p> <p>As desired, a copy of major laboratory equipments purchased during the last three years is enclosed herewith. (Annexure-2).</p> <p>Standard references are purchased from IPC Ghaziabad and impurities are</p>

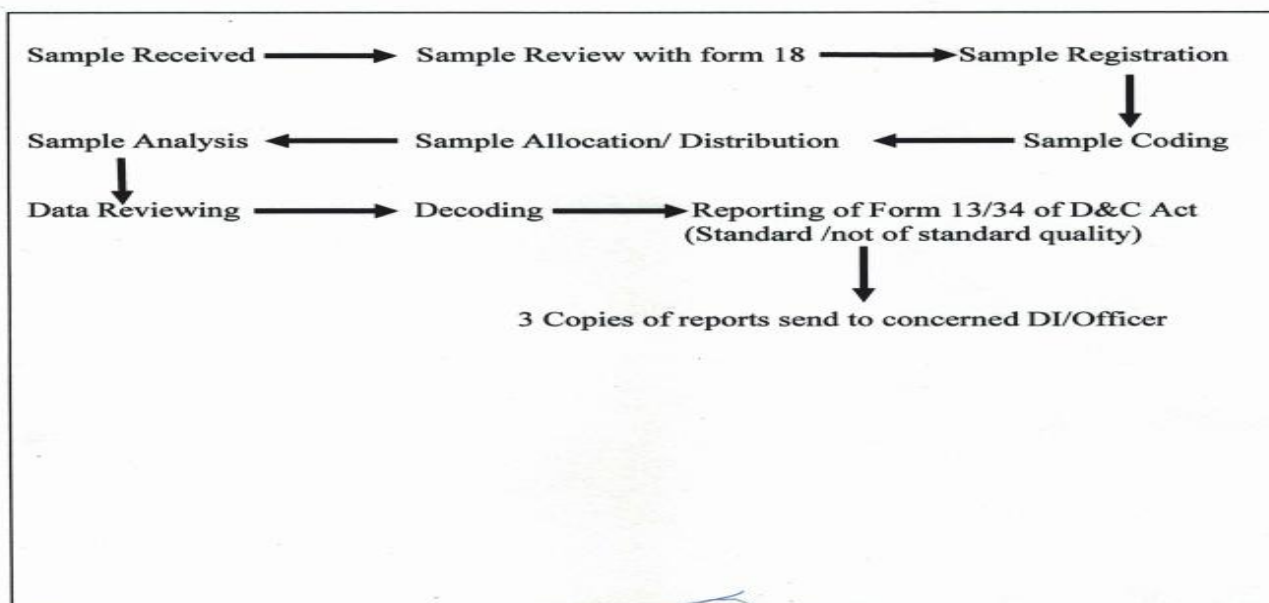
	standard and impurities, equipment year wise during last three years.	interest and therefore, cannot be provided as per section 8(d) of RTI Act, 2005.	to how advances the institution is. The institution has to be most up to date for the sake of accurate results. The pleas of confidentiality of withholding the information is just not tenable.	purchased according to availability. As desired, a copy of the reference standard is enclosed herewith (Annexure-3(A) and Annexure-3(B)). This lab strictly follows the expiry date mentioned on the label for the use of each Standard reference.
3.	Please provide me the copy of audit reports of inspections of RDTL carried out under GLP (Good Laboratory Practices) by CDSCO Officers year wise during last three year along with the CAPA Reports.	Internal and External Audit of the Lab. has been carried out as per NABL requirement. In accordance with the provision of Section 8(j) of RTI Act, 2005. It would serve no public interest & would cause unwarranted invasion of the privacy of the individual, therefore, the reports not provided.	Certain types of audit reports have been asked for. How can such audit reports be confidential? The flaws detected in the functioning of a Government body must come in public domain for the sake of transparency and public good. Hence it amount to denial of information.	Audits are carried out by NABL and copy of the continuation of accreditation mailed by NABL is attached herewith (Annexure-4).
4.	Please provide me the list of equipment installed for water used for test analysis by RDTL as per requirements of	The quality of water type 1 is produced from water purification system installed in our lab. At present, our lab has three water purification	The concern of the applicant is on the quality of water being used in RDTL Chandigarh for testing purposes. There Can be no denial that use of impure water in testing	The quality of water used for the testing purposes are type 1/ Purified water IP grade. Now according to the applicant's demand the water purification system and their installation sites are provided in the attached Annexure 5.

different pharmacopeia's for conducting dissolution test along with the details of the samples where required quality of water has not been used in analysis and the samples have been declared not of standard quality due to dissolution requirement of various pharmacopeia's.	systems, details attached as per Annexure- A. The quality of water is tested and monitor as per SOP & instruments are calibrated/ sanitized.	may lead to tainted results. Disclosure about the quality of water in use and the equipment in place for the purpose would enhance the confidence of people in the Government Institution and trust in their findings.	From this information, the concerned of the applicant should be mitigated.
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Annexure-1

Annexure-1

SAMPLE FLOW CHART IN RDTL



LIST OF INSTRUMENTS INSTALLED AT RDTL CHANDIGARH

Sr.No	Financial Year	Name of Major Instruments	Quantity	Purchased Through
01	2014-15	1.HPTLC	01	HLL
		2.Melting Point	01	RDTL
		3.UV-Visible Spectrophotometer	02	HLL
		4.HPLC	07	HLL
		5.FTIR	01	HLL
02	2015-16	1. Dissolution Apparatus Manual	01	RDTL
		2.Dissolution Apparatus Auto-sampler	01	HLL
03	2016-17	1.TOC-Analyser	01	HLL
		2.Digital Polarimeter	01	HLL
		3.Water Purification System	01	HLL
		4.Auto Potentiometric Titrator	01	HLL
		5.Liquid Particle Counter	01	HLL
		6.B.O.D.Incubator	02	RDTL
		7.Bacteriological Incubator	01	RDTL
		8.Hot air Oven	01	RDTL
		9.Microscope	01	RDTL
		10. HPHV Steam Sterilizer	01	CPWD
		11. Vertical Autoclave	01	CPWD
		12.Laminar Air Flow	03	CPWD
		13. Bio Safety Cabinet	01	CPWD

LIST OF REFERENCE STANDARD YEAR 2015

Sr. No.	Name of Reference standard	Purchased from	Date of Receiving	Vial No.
1	Ceftriaxone Sodium	IPC Ghaziabad	13/05/15	RDTL/RS/44/1
2	Azithromycin	IPC Ghaziabad	14/05/15	RDTL/RS/17/1
3	Alfuzosin Hydrochloride	IPC Ghaziabad	14/05/15	RDTL/RS/18/1
4	Moxifloacin	IPC Ghaziabad	14/05/15	RDTL/RS/105/1
5	MethylPrednisolone	IPC Ghaziabad	14/05/15	RDTL/RS/106/1
6	Famciclovir	IPC Ghaziabad	14/05/15	RDTL/RS/112/1
7	Ofloxacin	IPC Ghaziabad	14/05/15	RDTL/RS/115/1
8	Aceclofenac	IPC Ghaziabad	26/05/15	RDTL/RS/67/1
9	Aspirin	IPC Ghaziabad	26/05/15	RDTL/RS/69/1
10	Albendazole	IPC Ghaziabad	27/05/15	RDTL/RS/68/1
11	Cloxacillin Sodium	IPC Ghaziabad	27/05/15	RDTL/RS/70/1
12	Cephalexin	IPC Ghaziabad	27/05/15	RDTL/RS/71/1
13	Chloramphenicol	IPC Ghaziabad	27/05/15	RDTL/RS/72/1
14	Chloroquine Sulphate	IPC Ghaziabad	27/05/15	RDTL/RS/74/1
15	Domperidone Maleate	IPC Ghaziabad	27/05/15	RDTL/RS/75/1
16	Dicloxacillin Sodium	IPC Ghaziabad	27/05/15	RDTL/RS/76/1
17	Doxepin Hydrochloride	IPC Ghaziabad	27/05/15	RDTL/RS/77/1
18	Indomethacin	IPC Ghaziabad	27/05/15	RDTL/RS/84/1
19	Metronidazole	IPC Ghaziabad	27/05/15	RDTL/RS/103/1
20	Piroxicam	IPC Ghaziabad	27/05/15	RDTL/RS/133/1
21	Amoxycillin Trihydrate	IPC Ghaziabad	02/06/15	RDTL/RS/7/2
22	Fexofenadine Hydrochloride	IPC Ghaziabad	02/06/15	RDTL/RS/61/2
23	Gliclazide	IPC Ghaziabad	02/06/15	RDTL/RS/104/2
24	Triamcinolone	IPC Ghaziabad	02/06/15	RDTL/RS/145/2
25	Tamsulosin Hydrochloride	IPC Ghaziabad	02/06/15	RDTL/RS/163/1
26	Phenobarbitone	IPC Ghaziabad	16/06/15	RDTL/RS/164/1
27	Caffine	IPC Ghaziabad	22/06/15	RDTL/RS/165/1
28	Chloroquine Phosphate	IPC Ghaziabad	22/06/15	RDTL/RS/166/1
29	Paracetamol	IPC Ghaziabad	19/08/15	RDTL/RS/129/2
30	Ranitidine Hydrochloride	IPC Ghaziabad	19/08/15	RDTL/RS/135/2
31	Cetirizine Hydrochloride	IPC Ghaziabad	19/08/15	RDTL/RS/167/1
32	Ethinylestradiol	IPC Ghaziabad	12/09/15	RDTL/RS/56/2
33	Flutamide	IPC Ghaziabad	12/09/15	RDTL/RS/168/1
34	Lamivudine	IPC Ghaziabad	12/09/15	RDTL/RS/169/1
35	Imatinib Mesylate	IPC Ghaziabad	12/09/15	RDTL/RS/170/1
36	Efavirenz	IPC Ghaziabad	12/09/15	RDTL/RS/171/1
37	Thyroxine Sodium	IPC Ghaziabad	12/09/15	RDTL/RS/172/1
38	Clofazimine	IPC Ghaziabad	12/09/15	RDTL/RS/173/1
39	Diluted Nitroglycerin	Intas Dehradun	30/10/15	RDTL/RS/174/1

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LIST OF REFERENCE STANDARD YEAR 2016

Sr. No.	Name of Reference standard	Purchased from	Date of Receiving	Vial No.
1	Sulfamethoxazole	CDL Kolkata	06/02/16	RDTL/RS/187/1
2	Ascorbic Acid	CDL Kolkata	06/02/16	RDTL/RS/188/1
3	Alprazolam	IPC Ghaziabad	18/02/16	RDTL/RS/175/1
4	Betahistine HCL	IPC Ghaziabad	18/02/16	RDTL/RS/176/1
5	Cefuroxime Axetil	IPC Ghaziabad	18/02/16	RDTL/RS/177/1
6	Clonazepam	IPC Ghaziabad	18/02/16	RDTL/RS/178/1
7	Divalproex Sodium	IPC Ghaziabad	18/02/16	RDTL/RS/179/1
8	Phenytoin Sodium	IPC Ghaziabad	18/02/16	RDTL/RS/181/1
9	Telmisartan	IPC Ghaziabad	18/02/16	RDTL/RS/182/1
10	Tramadol HCL	IPC Ghaziabad	18/02/16	RDTL/RS/183/1
11	Potassium Clavulnate	IPC Ghaziabad	17/05/16	RDTL/RS/184/1
12	Amoxycillin Trihydrate	CDL Kolkata	31/05/16	RDTL/RS/7/3
13	Atenolol	CDL Kolkata	31/05/16	RDTL/RS/9/2
14	Isoniazid	CDL Kolkata	31/05/16	RDTL/RS/85/2
15	Metaformin Hydrochloride	CDL Kolkata	31/05/16	RDTL/RS/93/2
16	Diazepam	CDL Kolkata	31/05/16	RDTL/RS/185/1
17	Amoxycillin Trihydrate	CDL Kolkata	02/06/16	RDTL/RS/7/4
18	Aspirin	CDL Kolkata	02/06/16	RDTL/RS/69/2
19	Mebendazole	CDL Kolkata	02/06/16	RDTL/RS/186/1
20	Bromhexine Hydrochloride	CDL Kolkata	13/06/16	RDTL/RS/20/2
21	Aspirin	CDL Kolkata	13/06/16	RDTL/RS/69/3
22	Chloramphenicol	CDL Kolkata	13/06/16	RDTL/RS/72/2
23	Riboflavin	CDL Kolkata	13/06/16	RDTL/RS/189/1
24	Ascorbic Acid	GLAXO SMITH	13/07/16	RDTL/RS/188/2
25	Rabeprazole Sodium	IPC Ghaziabad	18/07/16	RDTL/RS/190/1
26	Ibuprofen	IPC Ghaziabad	18/07/16	RDTL/RS/191/1
27	Ibuprofen	IPC Ghaziabad	18/07/16	RDTL/RS/191/2
28	Cefaclor	IPC Ghaziabad	18/07/16	RDTL/RS/192/1
29	Omeprazole	IPC Ghaziabad	18/07/16	RDTL/RS/193/1
30	Clopidogrel Bisulphate	IPC Ghaziabad	18/07/16	RDTL/RS/194/1
31	Gemifloxacin Mesylate	IPC Ghaziabad	18/07/16	RDTL/RS/195/1
32	Chlordiazepoxide	IPC Ghaziabad	18/07/16	RDTL/RS/196/1
33	Fenofibrate	IPC Ghaziabad	18/07/16	RDTL/RS/197/1
34	Nicotinamide	IPC Ghaziabad	18/07/16	RDTL/RS/198/1
35	Guaiphenesin	IPC Ghaziabad	18/07/16	RDTL/RS/199/1
36	Betamethasone	IPC Ghaziabad	18/07/16	RDTL/RS/200/1
37	Phenylephrine Hydrochloride	IPC Ghaziabad	18/07/16	RDTL/RS/201/1
38	Tinidazole	IPC Ghaziabad	18/07/16	RDTL/RS/202/1
39	Nitrazepam	IPC Ghaziabad	18/07/16	RDTL/RS/203/1
40	Clotrimazole	IPC Ghaziabad	18/07/16	RDTL/RS/204/1
41	Miconazole Nitrate	IPC Ghaziabad	18/07/16	RDTL/RS/205/1
42	Calcium Pantothenate	IPC Ghaziabad	18/07/16	RDTL/RS/206/1
43	Prednisolone	Sigma Aldrich	18/10/16	RDTL/RS/207/1
44	Celecoxib	IPC Ghaziabad	21/12/16	RDTL/RS/209/1

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LIST OF REFERENCE STANDARD YEAR 2017

Sr. No.	Name of Reference standard	Purchased from	Date of Receiving	Vial No.
1	Gliclazide	IPC Ghaziabad	24.05.2017	RDTL/RS/104/3
2	Metoprolol Tartrate	IPC Ghaziabad	24.05.2017	RDTL/RS/101/2
3	Ranitidine Hydrochloride	IPC Ghaziabad	24.05.2017	RDTL/RS/135/3
4	Mefenamic acid	IPC Ghaziabad	24.5.2017	RDTL/RS/225/1
5	Tranexamic acid	IPC Ghaziabad	24.05.2017	RDTL/RS/223/1
6	Lorazepam	IPC Ghaziabad	24.05.2017	RDTL/RS/219/1
7	Homoatropine Hydrobromide	IPC Ghaziabad	24.05.2017	RDTL/RS/222/1
8	Azathioprine	IPC Ghaziabad	24.05.2017	RDTL/RS/221/1
9	Ondansetron	IPC Ghaziabad	24.05.2017	RDTL/RS/224/1
10	Flavoxate Hydrochloride	IPC Ghaziabad	24.05.2017	RDTL/RS/218/1
11	Ondansetron Hydrochloride	IPC Ghaziabad	24.05.2017	RDTL/RS/220/1
12	Doxycycline Hcl	IPC Ghaziabad	24.05.2017	RDTL/RS/217/1
13	Amitriptyline Hydrochloride	IPC Ghaziabad	24.05.2017	RDTL/RS/01/02
14	Clonazepam	IPC Ghaziabad	24.05.2017	RDTL/RS/178/2
15	Promethazine Theoclate	IPC Ghaziabad	24.05.2017	RDTL/RS/215/1
16	Nortriptyline Hcl	IPC Ghaziabad	24.05.2017	RDTL/RS/216/1
17	Pregabalin	IPC Ghaziabad	24.05.2017	RDTL/RS/214/1
18	Tramadol HCL	IPC Ghaziabad	24.05.2017	RDTL/RS/183/2
19	Griseofulvin	IPC Ghaziabad	24.05.2017	RDTL/RS/211/1
20	Salbutamol Sulphate	IPC Ghaziabad	24.05.2017	RDTL/RS/212/1
21	Meloxicam	IPC Ghaziabad	24.05.2017	RDTL/RS/213/1
22	Metoprolol Tartrate	IPC Ghaziabad	24.05.2017	RDTL/RS/101/2
23	Levosulbutamol Sulphate	IPC Ghaziabad	15.06.2017	RDTL/RS/231/1
24	Irbesartan	IPC Ghaziabad	15.06.2017	RDTL/RS/230/1
25	Celecoxib	IPC Ghaziabad	15.06.2017	RDTL/RS/209/2
26	Etophylline	IPC Ghaziabad	15.06.2017	RDTL/RS/232/1
27	Metoprolol Succinate	IPC Ghaziabad	15.06.2017	RDTL/RS/233/1
28	Domperidone	IPC Ghaziabad	15.06.2017	RDTL/RS/47/2

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29	Homoatropine methylbromide	IPC Ghaziabad	15.06.2017	RDTL/RS/226/1
30	Quindochlor	IPC Ghaziabad	15.06.2017	RDTL/RS/227/1
31	Aciclovir	IPC Ghaziabad	15.06.2017	RDTL/RS/13/2
32	Quetiapine Fumarate	IPC Ghaziabad	15.06.2017	RDTL/RS/229/1
33	Clarithromycin	IPC Ghaziabad	15.06.2017	RDTL/RS/25/3
34	Theophylline	IPC Ghaziabad	15.06.2017	RDTL/RS/228/1
35	Clarithromycin	IPC Ghaziabad	15.06.2017	RDTL/RS/25/3
36	Olmesartan Medoxomil	IPC Ghaziabad	08.08.2017	RDTL/RS/236/1
37	Ketorolac Tromethamine	IPC Ghaziabad	08.08.2017	RDTL/RS/237/1
38	Levocetirizine HCL	IPC Ghaziabad	08.08.2017	RDTL/RS/238/1
39	Mannitol	IPC Ghaziabad	08.08.2017	RDTL/RS/239/1
40	Racecadotril	IPC Ghaziabad	08.08.2017	RDTL/RS/240/1
41	Hydroxyzine Hcl	IPC Ghaziabad	08.08.2017	RDTL/RS/241/1
42	Ivermectin	IPC Ghaziabad	08.08.2017	RDTL/RS/242/1
43	Menthol	IPC Ghaziabad	08.08.2017	RDTL/RS/243/1
44	Methylparaben	IPC Ghaziabad	08.08.2017	RDTL/RS/244/1
45	Norfloxacin	IPC Ghaziabad	08.08.2017	RDTL/RS/245/1
46	Piracetam	IPC Ghaziabad	08.08.2017	RDTL/RS/246/1
47	Ursodeoxycholic acid	IPC Ghaziabad	08.08.2017	RDTL/RS/247/1
48	Sildenafil Citrate	IPC Ghaziabad	08.08.2017	RDTL/RS/248/1
49	Heparin Sodium	CDL Kolkata	06.09.2017	RDTL/RS/249/1
50	Mifepristone	IPC Ghaziabad	03.11.2017	RDRL/RS/251/1
51	Levonorgestrel	IPC Ghaziabad	03.11.2017	RDRL/RS/252/1
52	Olanzapine	IPC Ghaziabad	03.11.2017	RDRL/RS/253/1
53	Leflunamide	IPC Ghaziabad	03.11.2017	RDRL/RS/254/1
54	Ezetimibe	IPC Ghaziabad	03.11.2017	RDRL/RS/255/1
55	Linezolid	IPC Ghaziabad	03.11.2017	RDRL/RS/256/1
56	Ampicillin Trihydrate	IPC Ghaziabad	03.11.2017	RDRL/RS/257/1
57	Promethazine Hcl	IPC Ghaziabad	03.11.2017	RDRL/RS/258/1
58	Furazolidone	IPC Ghaziabad	03.11.2017	RDRL/RS/259/1
59	Temozolomide	IPC Ghaziabad	03.11.2017	RDRL/RS/260/1

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Annexure 3 (A)

55	Betamethasone dipropionate	IPC Ghaziabad	03.11.2017	RDRL/RS/261/1
56	Acetazolamide	IPC Ghaziabad	03.11.2017	RDRL/RS/262/1
57	S-Amlodipine Besylate	IPC Ghaziabad	03.11.2017	RDRL/RS/263/1
58	Thiamine Mononitrate	IPC Ghaziabad	03.11.2017	RDRL/RS/264/1
59	Phenobarbitone Sodium	IPC Ghaziabad	03.11.2017	RDRL/RS/265/1
60	Prednisone Tablet RS	IPC Ghaziabad	04.11.2017	RDRL/RS/266/1

Annexure 3(B)

Annexure 3(B)

List of Impurities Year 2015			
Sr.No	Name of Impurities	Purchased from	Date of Receiving
1	Paracetamol		
	4-Aminophenol	IPC Ghaziabad	28.05.2015
	4-Chloroacetanilide	IPC Ghaziabad	28.05.2015
	Dicyandiamide	IPC Ghaziabad	16.06.2015
2	Hydrocortisone	SRL	25.07.2015

List of Impurities Year 2016

Sr. No	Name of Impurities	Purchased from	Date of
1	Paracetamol		
	4-Aminophenol	IPC Ghaziabad	18.07.2016
	4-Chloroacetanilide	IPC Ghaziabad	18.07.2016
	Dicyandiamide	IPC Ghaziabad	18.07.2016
2	Secnidazole		
	2-methyl-5-Nitro Imidazole	IPC Ghaziabad	18.07.2016
3	Cetirizine Hydrochloride		
	Impurity A	IPC Ghaziabad	18.07.2016
4	Estriol Impurity		
	16-Epiestriol	Sigma Aldrich	18.10.2016
5	Estriol Impurity		
	16-Epiestriol	Sigma Aldrich	18.10.2016
6	Diclofenac Sodium		
	1-(2,6-Dichlorophenyl)Oxindole	Tokyo Chemical Industries	7.12.2016
7	Cetirizine Hydrochloride	Tokyo Chemical Industries	7.12.2016
	4-Chlorobenzhydryl Piperazine	Tokyo Chemical Industries	7.12.2016
8	7-Aminodesacetoxycephalosporanic Acid	Tokyo Chemical Industries	7.12.2016
9	4-Hydroxy-D-2-Phenylglycine	Tokyo Chemical Industries	7.12.2016
10	3-Methylflavone-8-carboxylic Acid	Tokyo Chemical Industries	7.12.2016

List of Impurities Year 2017

Sr. No.	Name of Impurities	Purchased from	Date of Receiving
1	Cefdroxil		
	Impurity-A	IPC Ghaziabad	24.05.2017
2	Cefroxime Axetil		
	E-isomar	IPC Ghaziabad	24.05.2017
3	Clotrimazole		
	Impurity-E	IPC Ghaziabad	24.05.2017
	Impurity-D	IPC Ghaziabad	24.05.2017
4	Ondansetran Hydrochloride		
	2-Methyl Imidazole	IPC Ghaziabad	24.05.2017
5	Azithromycin		
	Impurity-A	IPC Ghaziabad	24.05.2017
6	2-Methyl-4(5)-Nitro Imidazole	Sigma Aldrich	02.01.2017
7	4-Chloroacetanilide	Sigma Aldrich	2.01.2017

(Annexure-4)



National Accreditation Board for Testing and Calibration Laboratories

(A Constituent Board of Quality Council of India)



NABL/T-2988/03/17

27.03.2017

Dr.R.A.Singh
Director
Regional Drugs Testing Laboratory
Central Drugs standard Control Organisation
Directorate General of Health Services
Ministry of Health & Family welfare
Government of India
Sector 39-C, Chandigarh-160036
Tel:0172 2688239 ; Fax:0172 2636316
Email ID: rdtchd@cdsco.nic.in



Subject: Continuation of accreditation

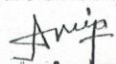
Dear Sir,

The surveillance report of your laboratory was evaluated and NABL is pleased to inform you the continuation of accreditation in accordance with ISO/IEC 17025:2005 in the field of Chemical testing as per the scope and authorized signatories recommended by the assessment team.

Please note that your Accreditation certificate no. T-3840 is valid till-09.03.2018, you are required to apply six months in advance to avoid break in accreditation cycle.

Being an accredited laboratory of NABL you must fulfill all the Terms and Conditions laid down in our document NABL-131. You are requested to follow NABL-133 (current issue) for using NABL symbol.

Yours sincerely,


Anuja Anand
Joint Director
anuja@nabl.qci.in

Regional Drugs Testing Laboratory-Chandigarh**(Annexure-5)****List of Water Purification Systems**

Sr.No	Name of Equipment	Equipment ID No.	Section	Sanitization/Calibration By
01	Elga Water Purification System	RDTL-INS-14	Cosmetic Lab	M/s Metrohm India Limited, Chandigarh/ Inhouse
02	Elga Water Purification System	RDTL-INS-15	Cosmetic Lab	M/s Metrohm India Limited, Chandigarh/ Inhouse
03	Thermo Scientific Water Purification System	RDTL-INS-103	General Instrument Lab	M/s Labindia Analytical New Delhi/ Inhouse

➤ **RTI Application No: 10**

Receipt Date: 07.12.2017

Reply date: 11.12.2017


Sl. No.	Information Sought	Reply
1.	बताने का कष्ट करें कि विभिन्न मंत्रालयों/विभागों में अनुबंध पर रखे गए/ कार्य कर रहे कर्मचारियों/ अधिकारियों की कार्य अवधि और मानदेय/वेतन सहित उनकी सूची देने का कष्ट करें।	The Technical, Admin, Accounts & Security staffs are recruited on contract basis is through private service providers. The details is given as per Annexure-A
2.	इन कर्मचारियों/ अधिकारियों की पंजीकृत नियोजित एजेंसियों के नाम व पते सहित सूची तथा उन्हें मिलने वाले कमीशन ब्योरा दें।	The agencies providing services are namely 1. M/s Impressive Data Services Pvt.Ltd., Admin office-633, D1, Durga Home Shalimar Garden Ext.1. GZB(U.P). The commission payable to this agency Rs.70/- per employee/Month for Technical, Admin and Account Staff 2. M/s Guardian Security & Placement services, SCO No.114, 1 st Floor, Sector-47-C, Chandigarh for security & Housekeeping staff. The commission payable to this agency is 2% of wages per employee/Month.
3.	बताने का कष्ट करें कि पांच वर्ष से रिक्त पड़े पदों पर नियुक्ति की नीति की जानकारी दें। विभिन्न मंत्रालयों/विभागों में ऐसे कितने रिक्त पद हैं। पद व रिक्त अवधि सहित इनकी सूची दें। बताने का कष्ट करें कि ऐसे पांच साल से रिक्त चले आ रहे समाप्त किए गए पदों की सूची देने का कष्ट करें।	There has been no vacancy which has been lying vacant for the last 5 years therefore the abolishment of vacant post is not applicable.
4.	विभिन्न मंत्रालयों/ विभागों वैसे कर्मचारियों और अधिकारियों की जानकारी देने का कष्ट करें कि जिनका पद तो कुछ और है उनसे काम कुछ और लिया जा रहा है। कार्यकाल व वेतन सहित ऐसे कर्मचारियों व अधिकारियों की सूची दें।	There is no such case, where the work performance given by the employees are different against the requirement of their respective posts. However, additional jobs have been assigned whenever required.
5.	विभिन्न मंत्रालयों/विभागों में काम करने वाले अनुबंध पर रखे गये कर्मचारियों/अधिकारियों से संबंधित शिकायतों पर की गई कारवाई का ब्योरा दें।	No complaint has been received and therefore no action was required.

6.	बताने का कष्ट करें कि विभिन्न मंत्रालयों/विभागों में पंजीकृत सेवा प्रदायी कंपनियों के अतिरिक्त भी अनुबंध पर कर्मचारियों व अधिकारियों की नियुक्ति की गई है अगर हां तो इनकी सेवा कस संचालन जिन नियमों के तहत किया जा रहा है, उनकी जानकारी दें।	The official/officers have been recruited only through the agencies with whom agreements have been made.
7.	अनुबंध श्रमिक (विनियमन एवं उन्मूलन) अधिनियम, 1970 की धारा 12, 10, और 7 की पूरी तरह विभिन्न मंत्रालयों/विभागों का पालन करने की जानकारी देने का कष्ट करें।	No labour has been recruited by this office so far directly/through registered agency.
8.	विभिन्न मंत्रालयों/ विभागों द्वारा अनुबंध पर रखने के लिए अनुबंध श्रमिक (विनियमन एवं उन्मूलन) अधिनियम, 1970 की धारा 2(1) (जी) के तहत प्रधान नियोक्ताओं की सूची पता व पद सहित देने का कष्ट करें। साथ ही यह भी बताएं कि किन किन कार्यों के लिए कर्मचारी व अधिकारी अनुबंध पर रखे गए हैं। इन कार्यों में अनुबंध पर लोगों को रखने के लिए सक्षम प्राधिकारी द्वारा गजट नोटिफिकेशन जारी करने की जानकारी दें।	As mentioned above, no labourer has been recruited. Therefore, details cannot be provided.

Annexure-A

ANNEXURE-A				
Regional Drugs Testing Laboratory				
Detail of Employess recruited through the M/s Impressive Data Services Pvt. Ltd., Admin office- 633, D1, Durga Home Shalimar Garden Ext.1. GZB(U.P)				
Sr.no	Post	No. of Technical Staff/Others	Wages/Salary Per Month	Date of Joining
1	Bench Chemist	14	26250	04.10.2017
2	Bench Chemist	15	25000	04.10.2017
3	Data Entry Operators	5	17916	04.10.2017
4	Lab Asistant	5	16468	04.10.2017
5	Office Assitant	5	16468	04.10.2017
6	Consultants	3	31500	04.10.2017

Detail of Employess recruited through the M/s Guardian Security & Placement services, SCO No.114, 1st Floor, Sector-47-C, Chandigarh				
Sr.No	Post	No. of Technical Staff/Others	Wages/Salary Per Month	Date of Joining
1	Security Supervisor	1	16978	01.10.2017
2	Security Guard	5	15418	01.10.2017
3	House Keeping	5	11648	01.10.2017


G.P.I.O.

➤ **RTI Application No: 11**

Receipt Date: 15.12.2017

Reply date: 01.01.2018

Sl. No.	Information Sought	Reply
1.	Please provide us the copies of test reports of all products declared Misbranded for any shortcoming observed in the Label of the machine during last five years, viz. 2013-14, 2014-15, 2015-16, 2016-17 and 2017-18	This Laboratory has not declared any products (Drugs & Cosmetics) as misbranded till date. Therefore, the reports of the misbranded product cannot be provided. However, this laboratory has been declaring the products as not of standard quality (NSQ) and the list of NSQ samples are being loaded to the website cdsco.nic.in under the head “Drug Alert” every month.

➤ **RTI Application No: 12**

Receipt Date: 19.02.2018

Reply date: 21.02.2018

Sl. No.	Information Sought	Reply
1.	Please provide us the copies of test reports of all products declared Misbranded for any shortcoming observed in the Label of the machine during last five years, viz. 2013-14, 2014-15, 2015-16, 2016-17 and 2017-18	In this connection, it is stated that this office had earlier received your letter dated 11.12.2017 having same contents of your above letter and was replied vide this office letter no. 1-18/2017-18/Admn/RTI/03/18 dated 01.01.2018. Accordingly, the postal order no. 18G-291416 for Rs.20/- (Twenty only) received vide above letter is returned herewith.

➤ **RTI Application No: 13**

Receipt Date: 21.02.2018

Reply date: 26.02.2018

Sl. No.	Information Sought	Reply
1.	As on date 01.12.2017 How many Special Casual Leaves are admitted to Central Government Employees with disabilities.	No disable Central Govt. employee has been working in this laboratory and therefore, required information is not applicable to us.
2.	As on Date 01.12.2017 How many Central Government Employees with Disabilities working.	No disable Central Govt. employee has been working in this laboratory and therefore, required information is not applicable to us.
3.	As On Date 01.12.2017 Kindly Provide me category wise breakup details of Persons with disabilities working Central Government service.	No disable Central Govt. employee has been working in this laboratory and therefore, required information is not applicable to us.

➤ **RTI Application No: 14**

Receipt Date: 09.03.2018

Reply date: 12.03.2018

I have been using Teneligliptin tablets 20 mg (Tablets) mfd by Cadila Healthcare Ltd in blister packs. I find Day 1 to Day 15 at the back side over the tablets.		
Sl. No.	Information Sought	Reply
1.	I may be informed the reason/justification for mentioning the day and whether contents in each tablet vary based on day.	Reply of this para has already been given by ADC (I) & CPIO vide his letter no. Z-28020/47/2018-DC dated 27.02.2018
2.	Since days are mentioned whether it needs to be taken for a limited period.	As mentioned above
3.	The number of samples of this drug drawn for analysis, tested, reported std and reported not of std quality during 2015_16, 2016_17.	It is informed that this laboratory has not received the sample for testing during the desired period i.e. 2015-16 and 2016-17.

Z-28020/47/2018-DC
Directorate General of Health Services
Office of DCG (I)
(RTI CELL)



FDA Bhawan, Kotla Road,
New Delhi

Date: 27/02/18

To,

Sh. R. Lalitha,
62, Flat 3C, CDS Chennaipattinam,
Ammamet,
Kanchipuram Dt,
Pin: 603108,

Sub: Information under RTI Act, 2005 - Reg.

Sir,

Please refer to your RTI application no. Nil dated 22.01.2018 received in this office on 01.02.2018 regarding information under RTI Act, 2005.

In this regard, the point wise reply is as below:

Point no. 1 to 2: The sought information is clarification/opinion/interpretation not covered under section 2 (f) of RTI Act, 2005.

Point no. 3: Your RTI application is being transferred under section 6(3) of RTI Act, 2005 to the CPIO, Central Drug testing Laboratory, CDSCO with the request to provide the available information directly to the applicant under intimation to this office.

Yours Faithfully,

(Jayant Kumar)

Assistant Drugs Controller (I) & CPIO

Copy to:-

1. The CPIO, Central Drugs Laboratory, 3, Kyd Street, Kolkata - 700 016
2. The CPIO, Central Drugs Testing Laboratory, CDSCO, Zonal FDA Bhavan, GMSD Compound, Bellasis Road, Mumbai Central, Mumbai 400 008.
3. The CPIO, Central Drug Testing Laboratory, Govt. of India, 37, Naval Hospital Road, Periamet, Campus G.M.S.D., Chennai - 600 003
4. The CPIO, Central Drug Testing Laboratory, CDSCO, Zonal office Hyderabad, CDSCO BHAVAN, Beside T.B. & Demonstration Centre, S.R. Nagar, Hyderabad - 500038, A.P.
5. The CPIO, Regional Drugs Testing Laboratory, Directorate General of Health Services, Six Miles, Guwahati-781 037 (Assam)
6. The CPIO, Regional Drugs Testing Laboratory, Sector 39-C, Chandigarh 160036

Address of first appellate authority is as below:

Sh. A. K. Pradhan,
Deputy Drugs Controller (India),
FDA Bhawan, Opp. Mata Sundri College,
Kotla Road, New Delhi - 110002.

2017-18		
Sl. No.	Total No. of RTI Received	Total No. of RTI Replied
1.	14	14