

## Information provided under RTI Act. 2005 in – 2023-24

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:** 31.03.2023

**Reply date:** 20.04.2023

Sl.No.	Information Sought	Reply
1.	To furnish me a copy of report for batch number CHC-1054 Mfd dt: 11/2021 Exp dt: 10/2023 of Steptococcus Faecalis, Clostridium Butyricum, Bacillus mesentericus and Lactic Acid Bacillus Capsules manufactured by M/s. Codec Healthcare Pvt. Ltd., NH. No. 74, Roorkee, Dehradun Highway, Kishanpur, Roorkee 247667 Haridwar (Uttarakhand).	The test reports sought by the applicant is exempted under Section 8(1) (h) of the RTI, Act, 2005. Further, this institute is bound by the fiduciary relationship of trust with the senders of the samples (Drugs, Cosmetics and medical devices) i.e. Drugs Inspectors and Drugs Officers. So, the information available to a person in his fiduciary relationship of trust cannot be disclosed under section 8(1) (e) of RTI Act, 2005.

### ➤ RTI Application No: 2

**Receipt Date:** 12.03.2023

**Reply date:** 03.05.2023

Sl.No.	Information Sought	Reply
1.	Has the CDSCO the policy to disclose the details of the complaints including the name address of the complainants, the particulars & copy of the complaints to the third party or whom against the complaint filed in CDSCO. If yes, provide the certified copies of the policy or such rules.	The reply is submitted by CDSCO, HQ
2.	Do the CDSCO or its subordinated offices or its officers disclosed the details including photo copy or certified copies of the complaints filled in the third party or to the person or the firm against the complaints has been filled. If yes, then, provide me the details to whom the copies or certified copies of such complaints provided by you.	No complaint of Sh. Vikas Tomar is received in RDTL, Chandigarh.

### ➤ RTI Application No: 3

**Receipt Date:** 21.08.2023

**Reply date:** 28.08.2023

Sl.No.	Information Sought	Reply
1.	Whether British Pharmacopeia Certified Reference Standard (BPCRS) was used to perform assay of Triamcinolone Acetonide BP in Triamcinolone Acetonide Cream BP between 01st January 2020 and 31 <sup>st</sup> December 2022? If yes please provide us the batch number, validity and traceability details of the British Pharmacopeia Certified Reference Standard (BPCRS) used.	Sample of Triamcinolone Acetonide Cream BP not received from 01.01.2020 to 31.12.2022.

2.	If British Pharmacopeia Certified Reference Standard (BPCRS) was not used, whether Working Standard was to perform assay of Triamcinolone Acetonide BP in Triamcinolone Acetonide Cream BP between 01 <sup>st</sup> January 2020 to 31 <sup>st</sup> December 2022? If yes, please provide us the procurement detail of primary standard batch number validity and traceability details	NA
3.	If British Pharmacopeia Certified Reference Standard (BPCRS) or working Standard was not used then provide us the method which was used to perform assay of Triamcinolone Acetonide BP in Triamcinolone Acetonide Cream BP between 01 <sup>st</sup> January 2020 and 31 <sup>st</sup> December 2022	NA

➤ **RTI Application No: 4**

**Receipt Date:** 06.09.2023

**Reply date:** 19.09.2023

Sl.No.	Information Sought	Reply
1.	Please provide me detailed information regarding the total number of RTI applications has been received in the last 06 months from the date of this application.	03 (three) RTI applications has been received during last six months.
2.	Please provide me the certified copies of all RTI applications has been received by CDSCO in the last 06 months from the date of this application. Please also provide me the certified copies of all RTI application replied by CDSCO.	NA
3.	Please enlighten me about the average time period for the disposal of RTI applications in the last 06 months from the date of this application.	11-12 days (admissible 30 days)
4.	Please enlighten me about the maximum time period has been taken for the disposal of RTI application in the last six months from the date of this application.	20 days

➤ **RTI Application No: 5**

**Receipt Date:** 22.09.2023

**Reply date:** 06.10.2023

Sl.No.	Information Sought	Reply
1.	How many Medical Device Officers have been appointed by the Central Government under Rule 23(1) if the said MDR?	Not applicable for RDTL Chandigarh

2.	Out of this, how many Medical Device Officers are with Pharmacy background or were earlier Drugs Inspector?	Not applicable for RDTL Chandigarh
3.	How many persons have been designated or appointed Medical Device Officer with Science or Engineering Background?	Not applicable for RDTL Chandigarh
4.	How many medical device manufacturing site have been inspected by the Central Government under Rule 23(1) of the said MDR by these Engineers / Scientists as Qualified Medical Officer?	Not applicable for RDTL Chandigarh
5.	How many persons have been designated or appointed as Medical Device Officer by the Central Government as per Rule 18(2) of the Medical Devices Rules, 2017 (MDR)?	Not applicable for RDTL Chandigarh
6.	How many samples have been taken for test / evaluation under Rule 70 (iii) of the said MDR?	Not applicable for RDTL Chandigarh
7.	How many enquiries and inspections have been conducted by each of the Medical Device Officer under Rule 70 (v) of the said MDR?	Not applicable for RDTL Chandigarh
8.	How many investigations have been carried out by each of the Medical Device Officer under Rule 70 (vi) of the said MDR?	Not applicable for RDTL Chandigarh
9.	How many Medical Devi. Testing Laboratories have been inspected by each of the Medical Device Officer under Rule 83(1) of the said MDR?	Not applicable for RDTL Chandigarh
10.	What other duties / functions / inspections / etc. have been carried out by each of the Medical Device Officer under the said MDR?	Not applicable for RDTL Chandigarh

➤ **RTI Application No: 6**

**Receipt Date:** 05.10.2023

**Reply date:** 12.10.2023

Sl.No.	Information Sought	Reply
1.	How many RTI were filed in this Public Authority in the Calendar Year 2022 (01 January to 01 December 2022)	12-RTI application received in the Calendar Year 2022 (01 January to 01 December 2022)

➤ **RTI Application No: 7**

**Receipt Date:** 14.11.2023

**Reply date:** 29.11.2023

Sl.No.	Information Sought	Reply
1.	How many RTI were filed in this Public Authority in the Calendar Year 2019 (01 January to 01 December 2019)	16-RTI application received in the Calendar Year 2019 (01 January to 01 December 2019)

➤ **RTI Application No: 8**

**Receipt Date:** 19.12.2023

**Reply date:** 28.12.2023

Sl.No.	Information Sought	Reply
1.	How many RTI were filed in this Public Authority in the Calendar Year 2017 (01 January 2017 to 31 December 2019)	11-RTI application received in the Calendar Year 2017 (01 January 2017 to 31 December 2017)

➤ **RTI Application No: 9**

**Receipt Date:** 12.12.2023

**Reply date:** 01.01.2024

Sl.No.	Information Sought	Reply
1	Last 2 years me central drugs standard control organization Chandigarh ne jo sample liye usaki jankari di jaye.	The information not belongs to RDTL Chandigarh
2	Jis Drug ka semple liye gaya usaki company ka name, address and result bhi bataya jaye.	The information sought cannot be shared with third party under Section 8(1)(J) of RTI Act 2005
3	Jis drug ka semple liya gaya or fail hua usme jo khami rahi usaki jankari di jaye.	Information already published in CDSCO website under drugs alert.
4	Aise drug ki jankari di jaye jinhe band karne ke liye health ministry ko sujhav diya gaya ho. (company name and jab kaha gaya usaki jankari)	The information not belongs to RDTL Chandigarh
5	Kuch din pahle leb me kuch cough syrup ke semple fail huye. Unki Company name or sempale me jo khami rahi usaki jankari di jaye.	Information already published in CDSCO website under drugs alert.
6	Leb me jin state se sempel chek hone ke liye aate he unki jankari daye or kis state ke sabse jayada sample fail huye yah bhi bataye.	Samples received from the following States- Ladakh (UT), Himachal Pradesh, Delhi (UT), Chandigarh (UT). Maximum number of samples found NSQ from Himachal Pradesh.

➤ **RTI Application No: 10**

**Receipt Date:** 05.01.2024

**Reply date:** 25.01.2024

Sl.No.	Information Sought	Reply
1	1. Last 2 years me central drugs standard control organization Chandigarh ne jo sample liye usaki jankari di jaye.	Information does not belong to RDTL Chandigarh
2	2. Jis Drug ka semple liye gaya usaki company ka name, address and result bhi bataya jaye.	The information as is desired by the applicant cannot be provided as mentioned below:

		<ul style="list-style-type: none"> <li>This institute is bound by the fiduciary relationship of trust with the senders of the samples (Drugs, Cosmetics and medical devices), i.e. Drugs Inspectors and Drugs Officers. This office is used to charge the testing fees for samples as per Schedule “B” of Drugs and Cosmetics Act 1940 and Rules 1945 there under. Providing the test reports of samples directly or indirectly to the persons, other than its sender may incur a large financial loss for this institute, as this institute is used to charge fees for testing and submission of test reports of the samples as mentioned earlier. So, the information available to a person in his fiduciary relationship of trust cannot be disclosed under section 8 (1) (e) of RTI Act, 2005.</li> <li>Providing the desired information cannot be used to serve the large public interest. This lists of legal failed samples are regularly being uploaded under the Drug Alert of the CDSCO website, i.e. <a href="http://www.cdsc.gov.in">www.cdsc.gov.in</a> (Notification-Alert). One of the most common and important purposes of this Drugs Alert is to disseminate the information rapidly into a maximum possible extent of common people to alert them about the drugs, cosmetics and medical devices, which are not safe and fit for use. So the information which cannot serve the large public interest cannot be provided taking the risk of financial loss of this Government Institute.</li> <li>Moreover, the requested information pertains to ‘third party’ information, disclosure of which would cause unwarranted invasion of the privacy or can harm the competitive position of the individual pharmaceutical companies/Manufacturers and has no relationship to any public activity or interest. So, the requested information is denied u/s 11(1) and 8(1) (j).</li> </ul>
3	3. Jis drug ka semple liya gaya or fail hua usme jo khami rahi usaki jankari di jaye.	Information already published in CDSCO website under drugs alert.
4	4. Aise drug ki jankari di jaye jinhe band karne ke liye health ministry ko sujhav diya gaya ho. (company name and jab kaha gaya usaki jankari)	The information does not belong to RDTL Chandigarh

5	5. Kuch din pahle leeb me kuch cough syrup ke semple fail huye. Unki Company name or sempale me jo khami rahi usaki jankari di jaye.	Information already published in CDSCO website under drugs alert.
6	6. Leeb me jin state se semple chek hone ke liye aate he unki jankari daye or kis state ke sabse jayada sample fail huye yah bhi bataye.	Sample received from the following States- Ladakh (UT), Himachal Pradesh, Delhi (UT, Chandigarh (UT).The information of failed samples is already published in CDSCO website under Drugs Alert.

➤ **RTI Application No: 11**

**Receipt Date:** 19.01.2024

**Reply date:** 23.02.2024

Sl.No.	Information Sought	Reply																																																		
1.	Copy of protocol no RDTL/STP/E10 in detail applied for test of EG and /or DEG by RDTL. Chandigarh	Copy of protocol no RDTL/STP/E10 is attached.																																																		
2.	<div>B.Date of actual test of following drug samples manufactured by my company with documentary evidence.</div> <table><tr><th>Name of Drugs</th><th>BATCH NO.</th></tr><tr><td>DOK-1 MAKS SIROP</td><td>DXS2210</td></tr><tr><td>DOK-1 MAKS SIROP</td><td>DXS2104</td></tr><tr><td>DOK-1 MAKS SIROP</td><td>DXS2004</td></tr><tr><td>GLYCERIN IP/USP</td><td>G20209-1A</td></tr><tr><td>PROPYLENE GLYCOL IP/BP</td><td>FOO455UG</td></tr><tr><td>DOK-1 MAKS SIROP</td><td>DXS2207</td></tr><tr><td>DOK-1 MAKS SIROP</td><td>DXS2208</td></tr><tr><td>DOK-1 MAKS SIROP</td><td>DXS2209</td></tr><tr><td>DOK-1 MAKS SIROP</td><td>DXS2109</td></tr><tr><td>DOK-1 MAKS SIROP</td><td>DXS2205</td></tr><tr><td>DOK-1 MAKS SIROP</td><td>DXS2105</td></tr><tr><td>DOK-1 MAKS SIROP</td><td>DXS2201</td></tr><tr><td>DOK-1 MAKS SIROP</td><td>DXSH2201</td></tr><tr><td>DOK-1 MAKS SIROP</td><td>DXS2106</td></tr><tr><td>DOK-1 MAKS SIROP</td><td>DXS2206</td></tr><tr><td>DOK-1 MAKS SIROP</td><td>DXS2107</td></tr><tr><td>DOK-1 MAKS SIROP</td><td>DXS2202</td></tr><tr><td>DOK-1 MAKS SIROP</td><td>DXS2203</td></tr><tr><td>DOK-1 MAKS SIROP</td><td>DXSH2202</td></tr><tr><td>DOK-1 MAKS SIROP</td><td>DXS2108</td></tr><tr><td>AMBRONOL SYRUP</td><td>AAS2201</td></tr><tr><td>AMBRONOL SYRUP</td><td>AAS2103</td></tr><tr><td>AMBRONOL SYRUP</td><td>AAS2202</td></tr><tr><td>AMBRONOL SYRUP</td><td>AAS2204</td></tr></table>	Name of Drugs	BATCH NO.	DOK-1 MAKS SIROP	DXS2210	DOK-1 MAKS SIROP	DXS2104	DOK-1 MAKS SIROP	DXS2004	GLYCERIN IP/USP	G20209-1A	PROPYLENE GLYCOL IP/BP	FOO455UG	DOK-1 MAKS SIROP	DXS2207	DOK-1 MAKS SIROP	DXS2208	DOK-1 MAKS SIROP	DXS2209	DOK-1 MAKS SIROP	DXS2109	DOK-1 MAKS SIROP	DXS2205	DOK-1 MAKS SIROP	DXS2105	DOK-1 MAKS SIROP	DXS2201	DOK-1 MAKS SIROP	DXSH2201	DOK-1 MAKS SIROP	DXS2106	DOK-1 MAKS SIROP	DXS2206	DOK-1 MAKS SIROP	DXS2107	DOK-1 MAKS SIROP	DXS2202	DOK-1 MAKS SIROP	DXS2203	DOK-1 MAKS SIROP	DXSH2202	DOK-1 MAKS SIROP	DXS2108	AMBRONOL SYRUP	AAS2201	AMBRONOL SYRUP	AAS2103	AMBRONOL SYRUP	AAS2202	AMBRONOL SYRUP	AAS2204	<div>The information as is desired by the applicant cannot be provided as mentioned below;</div> <div><ul style="list-style-type: none"><li>This institute is bound by the fiduciary relationship of trust with the senders of the samples (Drugs, Cosmetics and medical devices), i.e. Drugs Inspectors and Drugs Officers, so the information available to a person in his fiduciary relationship of trust cannot be disclosed under section 8 (1) (e) of RTI Act, 2005.</li><li>More So, the requested information pertains to ‘third party’ information, disclosure of which would cause unwarranted invasion of the privacy or can harm the competitive position of the individual pharmaceutical Companies/Manufacturers and has no relationship to any public activity or interest. So, the requested information is denied u/s 11(1) and 8 (j).</li><li>As per Section 25(3) of The Drugs and Cosmetics Act 1940 and Rule there under, any document purporting to be a report signed by a government Analyst under this Chapter shall be evidence of the facts stated therein, and evidence shall be conclusive unless the person from the sample was taken or the person whose name, address and other particulars have been disclosed.</li><li>Providing the desired information cannot be used to serve the large public interest.</li></ul></div>
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3.	Please also provide me copies of covering letters with which these reports were dispatched.	<ul style="list-style-type: none"> <li>As per Rule 46 of Drugs and Cosmetic Act 1940 and rule thereunder, after the test or analysis has been completed, government analyst shall forthwith supply to the inspector a report in triplicate in Form 13. Hence the disclosure of the claimed documents neither mandatory nor carry any value.</li> </ul>
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➤ **RTI Application No: 12**

**Receipt Date:** 18.03.2024

**Reply date:** 01.04.2024

Sl.No.	Information Sought	Reply																																																		
1.	Copy of protocol no RDTL/STP/E10 in detail applied for test of EG and /or DEG by RDTL. Chandigarh	Copies of Protocol already supplied by CPIO.																																																		
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➤ **RTI Application No: 13**

**Receipt Date:** 13.03.2024

**Reply date:**01.04.2024

<b>Sl.No.</b>	<b>Information Sought</b>	<b>Reply</b>
1.	A copy of ALL INDIA common seniority List of Group A and Group B (Gazetted) staff under the laboratories of CDSCO including CDL, Kolkata/CDTL- Mumbai, Chennai, Indore and Hyderabad/RDTL- Chandigarh and Guwahati, Indore and Hyderabad /RDTL-Chandigarh and Guwahati, and 8 Minilabs.	All India common seniority list of Group A and Group B (Gazetted) staff is not available with the RDTL Chandigarh.
2.	A copy of recruitment rules for Associate Pharmaceuticals Chemist, CDL, <b>Kolkata</b> .	The information not belongs to RDTL, Chandigarh

➤ **RTI Application No: 14**

**Receipt Date:** 15.03.2024 **Reply**

**date:**20.03.2024

<b>Sl.No.</b>	<b>Information Sought</b>	<b>Reply</b>
1.	What is the annual drug testing capacity (samples/year) of each CDSCO drug testing laboratory as of 2023? Please provide a break-up of the capacity based on the tests that the laboratory is certified to perform.e.g., Assay, Dissolution, impurity Profile, Stability etc.	As on date, there no order for annual drug testing capacity for this laboratory. Based on the receipt of samples, on priority basis, report will be released. And there is no breakup of the capacity based on the tests for the laboratory to perform.



	2. How many drug samples were annually sought to be tested by each CDSCO laboratory between 01 January 2019 and 31 December 2023? Of these, how many passed, failed, and are still pending for testing?	<div>This laboratory received and tested the drugs samples between 01st January 2019 and 31<sup>st</sup> December 2023, are as follows:-</div> <table><tr><th>Year (01/01/2019 to 31/12/2023)</th><th>Total Number of samples Tested</th><th>Total Number of samples Passed</th><th>Total Number of samples Failed</th><th>Total Number of samples Pending</th></tr><tr><td>2019</td><td>4119</td><td>3962</td><td>157</td><td>Nil</td></tr><tr><td>2020</td><td>2346</td><td>2207</td><td>139</td><td>Nil</td></tr><tr><td>2021</td><td>2961</td><td>2849</td><td>112</td><td>Nil</td></tr><tr><td>2022</td><td>2724</td><td>2629</td><td>95</td><td>Nil</td></tr><tr><td>2023</td><td>2756</td><td>2565</td><td>191</td><td>Nil</td></tr><tr><td><b>Total</b></td><td><b>14906</b></td><td><b>14212</b></td><td><b>694</b></td><td><b>Nil</b></td></tr></table>	Year (01/01/2019 to 31/12/2023)	Total Number of samples Tested	Total Number of samples Passed	Total Number of samples Failed	Total Number of samples Pending	2019	4119	3962	157	Nil	2020	2346	2207	139	Nil	2021	2961	2849	112	Nil	2022	2724	2629	95	Nil	2023	2756	2565	191	Nil	<b>Total</b>	<b>14906</b>	<b>14212</b>	<b>694</b>	<b>Nil</b>
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3.	What is the maximum number of samples each drug inspector is directed to collect per month for testing?	This information not belongs to RDTL, Chandigarh.																																			
4.	How many inspections of manufacturing facilities and testing laboratories (with no. of Public and Private break-up) were conducted annually between 01 January 2019 and 31 December 2023?	This information not belongs to RDTL, Chandigarh.																																			
5.	How many prosecutions were launched annually between 01 January 2019 and 31 December 2023? How many prosecutions were concluded during this period?	This information not belongs to RDTL, Chandigarh.																																			

➤ **RTI Application No: 15**

**Receipt Date:** 22.03.2024 **Reply date:** 08.04.2024

Sl.No.	Information Sought	Reply
1	Please provide me the details about the list of Standard operating procedure are currently effective in Central Drugs Testing Laboratory, Kolkata as per Schedule L-1, Good laboratory practices and requirements of Premises and equipments Drugs and cosmetic rules, 1945.	The sought information not belongs to this Laboratory.
2	Please provide me the uncontrolled copy of standard operating procedure related to Handling and investigating of Not of Standard quality drugs currently following in Central Drugs	The sought information not belongs to this Laboratory.

	Testing Laboratory, Kolkata	
3	I request you to share the uncontrolled copy of SOP for handling of Not of standard quality Samples prepared by the Director, RDTL, Chandigarh and Director, CDTL, Chennai as mentioned in Agenda no.1, Report of 51st meeting of drugs consultative committee held on 09 <sup>th</sup> June, 2017 at New Delhi.	The sought information is not available with this Laboratory.