

भारत सरकार
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
स्वास्थ्य सेवा महानिदेशालय
केन्द्रीय औषध मानक नियंत्रण संगठन
दक्षिण क्षेत्र
उप औषध नियंत्रक (भारत) का कार्यालय
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GOVERNMENT OF INDIA
Ministry of Health and Family Welfare
Directorate General of Health Services
Central Drugs Standard Control Organization
South Zone
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File No: 71/SZ/2016-17/ 1377

29.07.2016

To

The Drugs Controller General (India)
Directorate General of Health Services
FDA Bhavan, Kotla Road
New Delhi – 110 002

**Sub: Forwarding of Pending List for the Month of July - 2016 of
O/o. DDC (I), CDSCO, South Zone, Chennai – Reg.**

Ref: Directorate letter no. DCGI/MISC/2014(110) dated 08.09.2014

Sir,

Please find enclosed herewith the Pending list in respect of O/o. Deputy Drugs Controller (India), South Zone for the Month of July - 2016 for your information and kind perusal.

Yours faithfully,

for G. Rale
Dr. S. Manivannan
Deputy Drugs Controller (India)
CDSCO, South Zone, Chennai

Encl: As above.

BLOOD BANK INSPECTIONS PROPOSED BY THIS OFFICE
FOR THE STATE OF TAMIL NADU

S. No.	Name of the File	Inward No. (available with applicant)	Date of Receipt	Reason & Remarks
1.	M/s. Life Cell International Pvt. Ltd., Chennai – 127	2255	13/11/2014	Awaiting for instruction from the O/o. Drugs Controller General (India)
2.	M/s. Chettinad Hospital & Research Institute, Kanchipuram Dt	-	06/06/2016	The Joint inspection proposed in the month of August 2016
3.	M/s. Galaxy Hospitals, Tirunelveli.(Compliance Verification)	558	25/05/2016	Awaiting letter from SLA
4.	M/s. Government Hospital, Maduranthagan	1155	19/07/2016	Joint inspection proposed in the month of August 2016
5.	M/s. Krishna Blood bank & Research centre,Tirunelveli	714	10/06/2016	Joint inspection proposed in the month of August 2016
6.	M/s. Government Hospital, Tiruvannamalai	1015	06/7/2016	Joint inspection proposed in the month of August 2016
7.	M/s. Government ospital Mayiladuthurai	1025	08/07/2016	Joint inspection proposed in the month of August 2016
8.	M/s. A.A. Lab Services, Chennai	1061	13/07/2016	Re-joint inspection for verification of compliance proposed in the month of August 2016
9.	M/s. Government Stanley Medical College & Hospital,Chennai	1052	11/07/2016	Joint inspection proposed in the month of August 2016
10.	M/s. Sri Ramachandra University & Hospital,Chennai (Compliance verification)	1091	15/07/2016	Re-joint inspection for verification of compliance proposed in the month of August 2016
11.	M/s. Govt. Thiruvarur Medical College and Hospital, Thiruvarur	1183	25/07/2016	Under Scrutiny
12.	M/s. Government Headquarters Hospital, Dindigul	1178	25/07/2016	Under Scrutiny
13.	M/s. Govt. Head Quarters Hospital, Tiruppur	1179	25/07/2016	Under Scrutiny
14.	M/s. Govt. Kilpauk Medical College Hospital, Chennai	1177	25/07/2016	Under Scrutiny

15.	M/s. Madras Egmore Lions Blood Bank, Chennai	1205	26/07/2016	Re-joint inspection for verification of compliance proposed in the month of August 2016
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BLOOD BANK FILES PENDING FOR WANT OF BLOOD BANK REPLY FOR THE STATE OF TAMIL NADU

S. No	Name of the File	Inward No. (available with applicant)	Date of Receipt	Purpose	Reason & Remarks	
1.	M/s. Sivanthi Blood Bank, Nagercoil	2222	10/11/2014	Grant of Blood Bank licence for processing of Blood Components	Query raised for submission of NOC from SBTC.	
2.	M/s. The Coimbatore Biomedical Services Blood Bank, Coimbatore	74	11/04/2016	Grant of licence due to Change in Constitution		
3.	M/s. Shanthi Social Services (Blood Bank Division), Coimbatore	3180	05/02/2016	Renewal of licence for the period from 23.02.2016 to 22.02.2021		
4.	M/s. Suham Blood Bank, Madurai	3206	08/02/2016	Grant of licence		
5.	M/s. Lords Blood Bank, Nagercoil	1899	30/09/2015	Renewal of licence for the period from 31.08.2015 to 30.08.2020		
6.	M/s. Indian Blood Bank, Dindigul	2232	03/11/2015	Renewal of licence for the period from 26.10.2015 to 25.10.2020		
7.	M/s. Essar Blood Bank, Chengalpattu	3138	02/02/2016	Grant of licence for processing of WHB IP		
8.	M/s. Lions Club of Coimbatore Legend Blood Bank & Research Centre, Coimbatore	2925	13/01/2016	Renewal of licence for the period from 18.10.2015 to 17.10.2020		

9.	M/s. Tuticorin Blood Bank, Tuticorin	198	18/04/2016	Grant of licence due to Change of Premises, Constitution & Renewal of licence for the period 13.12.2015 to 12.12.2020.	
10.	M/s. The Blood Donors Charitable Trust, Cuddalore	64	11/04/2016	Renewal of licence for processing of Whole Human Blood I. P.	
11.	M/s. Bethel Blood Bank Services Trust, Tirunelveli Town	2626	21/12/2015	Renewal of licence for processing of Whole Human Blood I. P.	
12.	M/s. Apollo Speciality Hospital, Chennai	74	15/04/2015	Grant of licence for processing of Apheresis	Query raised for submission of documents & NOC from SBTC.
13.	M/s. Doctors Blood Bank & Research Centre, Trichy	1910	01/10/2015	Grant of Blood Bank licence for processing of Apheresis	
14.	St Thomas Blood Bank, Chennai	1114	15/07/2016	Renewal of Licence	
15.	M/s. Apollo Hospitals Enterprises Ltd, Chennai	2060	19/10/2015	Renewal of licence	
16.	M/s. Friends Blood Bank, Trichy	3240	11/02/2016	Grant of Blood Bank licence for processing of Apheresis	
17.	Ms. R.M.D. Blood Bank, Thiruvannamalai	686	07/06/2016	Grant of Blood Bank licence	
18.	M/s. Vikram Clinical Blood Bank, Theni	674	06/06/2016	Renewal of Blood Bank licence for WHB I.P.	
19.	M/s. Sai Blood Bank & Clinical Laboratory, Rajapalayam	2060	23/11/2015	Renewal of Blood Bank licence	Awaiting letter from State Licensing Authority.

BLOOD BANK INSPECTIONS PROPOSED BY THIS OFFICE
FOR THE STATE OF KERALA

S. No	Name of the File	Inward No. (available with applicant)	Date of Receipt	Reason & Remarks
1.	M/s. Upasana Hospital, Kollam	1045	11/07/2016	The Joint inspection proposed in the month of August 2016
2.	M/s. Government Medical College Hospital, Kottayam	965	01/07/2016	The Joint inspection proposed in the month of August 2016
3.	M/s. General Hospital, Neyyatinkara	1215	25/07/2016	Under Scrutiny
4.	M/s. Karuna Hospital & School of Nursing, Idukki Dist	1075	19/07/2016	Under Scrutiny

BLOOD BANK INSPECTIONS PROPOSED BY THIS OFFICE
FOR THE STATE OF PUDUCHERRY

S. No	Name of the File	Inward No. (available with applicant)	Date of Receipt	Reason & Remarks
1.	M/s. Sri Venkateshwara Medical College Hospital, Puducherry	3809	29/03/2016	Due to non availability of Drugs Inspector from SLA Joint Inspection Postponed to the month of August.
2.	M/s. Indira Gandhi Medical College, Puducherry	810	20/06/2016	Due to non availability of Drugs Inspector from SLA Joint Inspection Postponed to the month of August.
3.	M/s. Puducherry Private Hospital Association, Puducherry	3371	28/02/2016	Due to non availability of Drugs Inspector from SLA. Re-Joint inspection proposed in the month of August 2016 for verification of compliance

COPP INSPECTIONS PROPOSED BY THIS OFFICE
FOR THE STATE OF TAMIL NADU

S. No	Name of the File	Inward No. (available with applicant)	Date of Receipt	Reason & Remarks
1.	M/s. Wardex Pharmaceuticals Pvt Ltd, Chennai	2595	16/12/2015	Manufacturer requested to postpone the inspection.
2.	M/s. B. Braun Medical India Pvt Ltd, Chengalpet	2583	15/12/2015	Manufacturer requested to postpone the inspection.
3.	M/s. Sterling Labs, Hosur	284	28/04/2015	Joint inspection proposed on 10 th & 11 th May 2016. Manufacturer requested to postpone the inspection.
4.	M/s. Global Calcium, Hosur (Unit III)	2611	17/12/2015	Joint inspection proposed on 12 th & 13 th May 2016. Manufacturer requested to postpone the inspection. Now the firm vide email dated 11.07.2016 requested for Joint inspection. The Joint inspection proposed in the month of August 2016
5.	M/s. Orchid Healthcare, Alathur (Plot No. B-77), Kancheepuram Dt.	2745	01/01/2016	Joint inspection Could not be conducted due to pre occupation of Drugs Inspector of SLA. Now it is proposed in the month of August 2016.
6.	M/s. Arvind Remedies, Chennai	2685	23/12/2015	Joint inspection proposed on 12.07.2016 & 13.07.2016. But, the Manufacturer requested to postpone the Joint Inspection.
7.	M/s. Hospira Healthcare India Pvt Ltd, Chennai	3184	09/02/2015	Joint inspection Could not be conducted due to pre occupation of Drugs Inspector of state. Now it is proposed in the month of August 2016.

8.	M/s. Orchid Healthcare, Irunkattukottai, Kancheepuram (Plot. B-5, B-6)	2747	01/01/2016	Joint inspection Could not be conducted due to pre occupation of Drugs Inspector of SLA. Now it is proposed in the month of August 2016.
9.	M/s. Mylan Laboratories, Hosur	2750	01/01/2016	The Joint inspection proposed in the month of August 2016
10.	M/s. Micro Labs Ltd, Hosur	2716	30/12/2015	The Joint inspection proposed in the month of August 2016
11.	M/s. Pharmafabricon (Unit-I), Madurai	1176	25/07/2016	Under Scrutiny

**COPP FILES PENDING FOR WANT OF MANUFACTURER REPLY
FOR THE STATE OF TAMIL NADU**

S. No	Name of the File	Inward No. (available with applicant)	Date of Receipt	Reason & Remarks
1.	M/s. Sara Pharmaceuticals, Nagercoil.	2508	04/12/2014	Application received on 04.12.2014. Query raised on 05.02.2015, Awaiting reply from the manufacturer.
2.	M/s. Alchymars, Alathur	2743	01/01/2016	Query raised for documents submission, Awaiting reply from the manufacturer.
3.	M/s. Nouveau Medicant (P) Ltd, Kancheepuram	3295	16/02/2016	Query raised for documents submission. Awaiting reply from the manufacturer.

COPP INSPECTIONS PROPOSED BY THIS OFFICE
FOR THE STATE OF PUDUCHERRY

S. No	Name of the File	Inward No. (available with applicant)	Date of Receipt	Reason & Remarks
1.	M/s. DAEIOU Pharmaceuticals (P) Ltd, Puducherry	565	13/05/2016	Due to non availability of Drugs Inspector from SLA Licensing Authority Joint Inspection Postponed to the month of August 2016.
2.	M/s. Goodman Pharmaceuticals Ltd, Puducherry.	2697	19/01/2016	Due to non availability of Drugs Inspector from SLA Licensing Authority Joint Inspection Postponed to the month of August 2016.

COPP FILES PENDING FOR WANT OF MANUFACTURER REPLY
FOR THE STATE OF PUDUCHERRY

S. No	Name of the File	Inward No. (available with applicant)	Date of Receipt	Reason & Remarks
1.	M/s. Safetab Life Science, Puducherry	6145	13/03/2014	Application received on 13.03.2014. Query raised on 03.04.2014, Awaiting reply from the manufacturer.
2.	M/s. Micro Labs Ltd (Unit -III), Puducherry	2437	26/11/2015	Query raised, reply from the manufacturer not received.
3.	M/s. Universal Pharmaceuticals Ltd, Puducherry	2229	03/11/2015	Application received on 03.11.2015. Query raised on 12.11.2015, Awaiting reply from the manufacturer.

TESTING LABS FILES PROPOSED BY THIS OFFICE
FOR THE STATE OF TAMIL NADU

S. No	Name of the File	Inward No. (available with applicant)	Date of Receipt	Reason & Remarks
1.	M/s. Chennai Testing Laboratories Pvt Ltd, Chennai	681	08/06/2016	Application received on 08.06.2016. Query raised on 08.06.2016, Reply from Lab

				received on 27.06.2016. The Joint inspection proposed in the month of July 2016. Joint inspection Could not be conducted due to pre occupation of Drugs Inspector of SLA. Now it is proposed in the month of August 2016.
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**MEDICAL DEVICE FOR WANT OF MANUFACTURER REPLY
FOR THE STATE OF PUDUCHERRY**

S. No	Name of the File	Inward No. (available with applicant)	Date of Receipt	Reason & Remarks
1.	M/s. Nathan Healthcare, Puducherry	521	20/05/2016	Application received on 20.05.2016. Query raised on 24.06.2016, Awaiting reply from the manufacturer.

LVP FILES PROPOSED BY THIS OFFICE FOR THE STATE OF PUDUCHERRY

S. No	Name of the File	Inward No. (available with applicant)	Date of Receipt	Reason & Remarks
1.	M/s. Steril -Gene Life Sciences (P), Puducherry	574	27/05/2016	Joint inspection proposed on 04.07.2016 & 05.07.2016. But due to non availability of Drugs Inspector from SLA. Joint Inspection Postponed to the month of August.

**VACCINE FILES PENDING FOR WANT OF MANUFACTURER REPLY
FOR THE STATE OF TAMIL NADU**

S. No	Name of the File	Inward No. (available with applicant)	Date of Receipt	Reason & Remarks
1.	M/s. Mediclone Biotech Pvt Ltd, Chennai	1129	18/07/2016	Re-joint inspection proposed in the month of August 2016 for verification of compliance

BA/BE INSPECTIONS PROPOSED BY THIS OFFICE
FOR THE STATE OF TAMIL NADU

S. No	Name of the File	Inward No. (available with applicant)	Date of Receipt	Reason & Remarks
1.	M/s. Quest Life Sciences, Chennai	2360	19/11/2015	The Joint inspection proposed in the month of August 2016
2.	M/s. Micro Therapeutic Research Labs Pvt Ltd, Chennai	152	13/04/2016	Joint inspection proposed in the month of August 2016
3.	Notrox research Pvt Ltd, Salem	1037	11/07/2016	Joint inspection proposed in the month of August 2016

GRANT OF NOC TO OBTAIN LICENCE IN FORM 29
INSPECTIONS PROPOSED BY THIS OFFICE FOR THE STATE OF TAMIL NADU

S. No	Name of the File	Inward No. (available with applicant)	Date of Receipt	Reason & Remarks
1.	M/s. Levim Biotech LLP, Chennai	1071	18/07/2016	Under Scrutiny

GRANT OF NOC TO OBTAIN LICENCE IN FORM 29 FOR WANT OF MANUFACTURER
REPLY FOR THE STATE OF PUDUCHERRY

S. No	Name of the File	Inward No. (available with applicant)	Date of Receipt	Reason & Remarks
1.	M/s. BioGenomics Limited, Puducherry	743	14/06/2016	Application received on 14.06.2016. Query raised on 24.06.2016, Awaiting reply from the manufacturer.

PENDING LIST OF NOC FOR DUAL USE FILES

S. No.	Name of the File	Inward No. (Available with applicant)	Date of Receipt	Reason & Remarks
NIL				

PENDING LIST OF NOC FOR FORM - 29 FILES

S. No.	Name of the File	Inward No. (Available with applicant)	Date of Receipt	Reason & Remarks
NIL				

PENDING LIST OF NOC FOR EXPORT - NOC FILES

S. No.	Name of the File	Inward No. (Available with applicant)	Date of Receipt	Reason & Remarks
NIL				

PENDING LIST OF NOC FOR TEST LICENCE (FORM - 11) FILES

S. No.	Name of the File	Inward No. (Available with applicant)	Date of Receipt	Reason & Remarks
1.	M/s. Mylan Laboratories Limited, Bangalore	TL/Form12/SZ/2016/380	04/07/2016	Query raised. Reply from the applicant yet to be received
2.	M/s. Strides Shasun Limited, Bangalore	TL/Form12/SZ/2016/483	07/07/2016	Query raised. Reply from the applicant yet to be received

3.	M/s. Mylan Laboratories Limited, Bangalore	TL/Form12/SZ /2016/651	13/07/2016	Query raised. Reply from the applicant yet to be received
4.	M/s. Mylan Laboratories Limited, Bangalore	TL/Form12/SZ /2016/656	13/07/2016	Query raised. Reply from the applicant yet to be received
5.	M/s. Apotex Research Private Limited, Bangalore	TL/Form12/SZ /2016/679	13/07/2016	Query raised. Reply from the applicant yet to be received
6.	M/s. Mylan Laboratories Limited, Bangalore	TL/Form12/SZ /2016/592	11/07/2016	Query raised. Reply from the applicant yet to be received
7.	M/s. Mylan Laboratories Limited Bangalore	TL/Form12/SZ /2016/729	14/07/2016	Query raised. Reply from the applicant yet to be received
8.	M/s. Apotex Research Private Limited, Bangalore	TL/Form12/SZ /2016/717	15/07/2016	Query raised. Reply from the applicant yet to be received
9.	M/s. Mylan Laboratories Limited, Bangalore	TL/Form12/SZ /2016/826	14/07/2016	Query raised. Reply from the applicant yet to be received
10.	M/s. Strides Shasun Limited, Bangalore	TL/Form12/SZ /2016/846	15/07/2016	Query raised. Reply from the applicant yet to be received
11.	M/s. Strides Shasun Limited, Bangalore	TL/Form12/SZ /2016/1040	19/07/2016	Query raised. Reply from the applicant yet to be received
12.	M/s. Strides Shasun Limited, Bangalore	TL/Form12/SZ /2016/1043	19/07/2016	Query raised. Reply from the applicant yet to be received
13.	M/s. Medreich Limited, Bangalore	TL/Form12/SZ /2016/841	15/07/2016	Query raised. Reply from the applicant yet to be received
14.	M/s. Micro Labs Limited, Bangalore	TL/Form12/SZ /2016/1090	20/07/2016	Query raised. Reply from the applicant yet to be received
15.	M/s. Micro Labs Limited, Bangalore	TL/Form12/SZ /2016/1088	20/07/2016	Query raised. Reply from the applicant yet to be received
16.	M/s. Apotex Research Private Limited, Bangalore	TL/Form12/SZ /2016/618	12/07/2016	Query raised. Reply from the applicant yet to be received
17.	M/s. Apotex Research Private Limited, Bangalore	TL/Form12/SZ /2016/759	15/07/2016	Query raised. Reply from the applicant yet to be received
18.	M/s. Apotex Research Private Limited, Bangalore	TL/Form12/SZ /2016/628	12/07/2016	Query raised. Reply from the applicant yet to be

				received
19.	M/s. Actavis Pharma Development Centre, Chennai	TL/Form12/SZ /2016/1346	25/07/2016	Query raised. Reply from the applicant yet to be received
20.	M/s. Strides Shasun Limited, Bangalore	TL/Form12/SZ /2016/1241	22/07/2016	Query raised. Reply from the applicant yet to be received
21.	M/s. Strides Shasun Limited, Bangalore	TL/Form12/SZ /2016/1235	22/07/2016	Query raised. Reply from the applicant yet to be received
22.	M/s. Par Formulations Private Limited, Chennai	TL/Form12/SZ /2016/1227	21/07/2016	Query raised. Reply from the applicant yet to be received