

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

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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* *Dr. S. Manivannan*

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, Maduranthagam	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.	Query raised for submission of documents & NOC from SBTC.
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	
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	Awaiting letter from State Licensing Authority.
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	

**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	<b>Manufacturer requested to postpone the inspection.</b>
2.	M/s. B. Braun Medical India Pvt Ltd, Chengalpet	2583	15/12/2015	<b>Manufacturer requested to postpone the inspection.</b>
3.	M/s. Sterling Labs, Hosur	284	28/04/2015	Joint inspection proposed on 10 <sup>th</sup> & 11 <sup>th</sup> May 2016. <b>Manufacturer requested to postpone the inspection.</b>
4.	M/s. Global Calcium, Hosur (Unit III)	2611	17/12/2015	Joint inspection proposed on 12 <sup>th</sup> & 13 <sup>th</sup> May 2016. <b>Manufacturer requested to postpone the inspection.</b> 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	<b>Joint inspection Could not be conducted due to pre occupation of Drugs Inspector of SLA.</b> 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. <b>But, the Manufacturer requested to postpone the Joint Inspection.</b>
7.	M/s. Hospira Healthcare India Pvt Ltd, Chennai	3184	09/02/2015	<b>Joint inspection Could not be conducted due to pre occupation of Drugs Inspector of state.</b> 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. Pharmafabiricon (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, Puduchery	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. <b>Joint inspection Could not be conducted due to pre occupation of Drugs Inspector of SLA.</b> 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. <b>But due to non availability of Drugs Inspector from SLA. Joint Inspection Postponed to the month of August.</b>

**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