



**GOVERNMENT OF INDIA**  
**CENTRAL DRUGS STANDARD CONTROL**  
**ORGANISATION (Headquarter)**

(Directorate General of Health Services)  
Ministry of Health & Family Welfare

**FDA Bhavan**  
**ITO, Kotla Road**  
**New Delhi - 110002 (Delhi)**  
**Phone No.: 91-11-23216367**  
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**E-Mail : dci@nic.in**

**F.No. CT/25/000187**

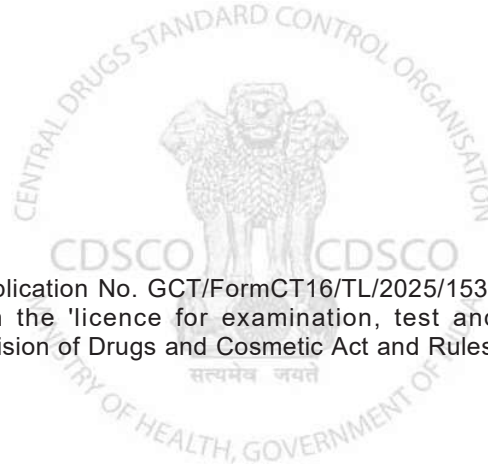
**Dated: 25-JUN-2026**

To

**M/s Glenmark**  
**Pharmaceuticals Ltd.**  
**B/2, MAHALAXMI**  
**CHAMBERS**  
**22, BHULA BHAI DESAI**  
**ROAD**  
**MUMBAI - 400026**  
**Maharashtra**

Sir,

With reference to your application No. GCT/FormCT16/TL/2025/153790 dated 15-DEC-2025, please find enclosed herewith the 'licence for examination, test and analysis' bearing No. **TL/CT/26/000124** under the provision of Drugs and Cosmetic Act and Rules to import the drug/drugs mentioned therein.



Yours faithfully,

**RAJEEV SINGH**  
**RAGHUVANSHI**

Digitally signed by RAJEEV  
SINGH RAGHUVANSHI  
Date: 2026.06.29 15:17:42  
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Licensing Authority

Copy together with a copy of Import License No. **TL/CT/26/000124**

Forwarded for information to:-

- All port offices

**Licence Number: TL/CT/26/000124**

**Ref File No. CT/187/25-DCG(I)**

**FORM CT-17**

(See rules 68, 69, 70, 71 and 72)

**LICENCE TO IMPORT NEW DRUG OR INVESTIGATIONAL NEW DRUG FOR THE PURPOSE OF CLINICAL TRIAL OR BIOAVAILABILITY OR BIOEQUIVALENCE STUDY OR FOR EXAMINATION, TEST AND ANALYSIS**

Licence Number: **TL/CT/26/000124**

1. The Central Licensing Authority hereby grant license to **M/s Glenmark Pharmaceuticals Ltd., B/2, Mahalaxmi Chambers 22, Bhula Bhai Desai Road, Mumbai (India) – 400026** to import new drug or investigational new drug for conduct of clinical trial as per **Protocol No. GSP 402-301 (SHR-A1811-315\_Extension) version 3.0 dated 18-Dec-2025** or for examination, test and analysis in the below mentioned clinical trial sites.[As per Annexure].

| Serial number | Name of the new drug or investigational new drug to be imported | Therapeutic class of New drug or investigational new drug | Quantity to be imported        |
|---------------|-----------------------------------------------------------------|-----------------------------------------------------------|--------------------------------|
| 1.            | Trastuzumab Rezetecan for Injection (SHR-A1811)<br>100 mg/vial  | Anticancer Drugs                                          | 2250 Vials (1 vial per carton) |

2. This licence is subject to the conditions prescribed in Chapter IX of the New Drugs and Clinical Trials Rules, 2019.
3. This licence shall, unless previously suspended or revoked, be in force for a period of three years from the date of its issuance.
4. Details of overseas manufacturer and manufacturing site under this licence.

| Name and address of manufacturer (full address with telephone, fax and e-mail address of the manufacturer)                                                               | Name and address of manufacturing site (full address with telephone, fax and e-mail address of the manufacturing site)                                                   |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| M/s Suzhou Suncadia Biopharmaceuticals Co., Ltd., No. 350 Fengli Street, Industrial Park, Suzhou, Jiangsu (China) - 215024 Telephone No.: 400-8283900 FAX: 0512-62625766 | M/s Suzhou Suncadia Biopharmaceuticals Co., Ltd., No. 350 Fengli Street, Industrial Park, Suzhou, Jiangsu (China) - 215024 Telephone No.: 400-8283900 FAX: 0512-62625766 |

5. The licensee shall maintain the record of imported new drug or investigational new drugs [As per Annexure].

Place: New Delhi

Date \_\_\_\_\_

**RAJEEV SINGH** Digitally signed by RAJEEV  
**RAGHUVANSHI** SINGH RAGHUVANSHI  
Date: 2026.06.29 15:17:53  
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(Dr. Rajeev Singh Raghuvanshi)  
Drugs Controller General (India) &  
Central Licensing Authority

**Annexure:**

Details of clinical trial site:

| S. No. | Name and address of clinical trial site                                                                      | Ethics Committee Details                                                                                                                                                                                                       | Name of Investigator |
|--------|--------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|
| 1.     | Bhagwan Mahaveer Cancer Hospital and Research Centre, Jawahar Lal Nehru Marg Jaipur Rajasthan - 302017       | Institutional Ethics Committee, Bhagwan Mahaveer Cancer Hospital & Research center, Jawaharlal Nehru Marg, Jaipur-302017<br><br>ECR/19/Inst/RJ/2013/RR-20                                                                      | Dr Deepak Gupta      |
| 2.     | Regional Cancer Centre, PO Box No. 2417, Medical College Campus Thiruvananthapuram Kerala - 695011           | Human Ethics Committee, RCC-Regional Cancer Centre, Medical College Campus, Thiruvananthapuram - 695011, Kerala<br><br>ECR/21/Inst/Ker/2013/RR-24                                                                              | Dr Lakshmi Haridas   |
| 3.     | TATA Memorial Hospital, Main Building, 3rd floor, Dr. Ernest Borges Road, Parel, Mumbai Maharashtra - 400012 | Institutional Ethics Committee 3rd floor, Main building, Tata Memorial Hospital, Tata Memorial Centre, Dr. Ernest Borges Marg, Parel (E), Mumbai-400012, Maharashtra, India.<br><br>IEC I:<br><br>ECR/170/Inst/MH/2013/RR-22,  | Dr Sudeep Gupta      |
| 4.     | TATA Memorial Hospital, Main Building, 3rd floor, Dr. Ernest Borges Road, Parel, Mumbai Maharashtra - 400012 | Institutional Ethics Committee 3rd floor, Main building, Tata Memorial Hospital, Tata Memorial Centre, Dr. Ernest Borges Marg, Parel (E), Mumbai-400012, Maharashtra, India.<br><br>IEC II:<br><br>ECR/414/Inst/MH/2013/ RR-24 | Dr Sudeep Gupta      |
| 5.     | Rajiv Gandhi Cancer Institute and Research Centre, Sector-5 Rohini Delhi Delhi - 110085                      | Institutional Review Board Rajiv Gandhi Cancer Institute and Research Centre, Sector V, Rohini, West Metro station Delhi, South West Delhi - 110085 India<br><br>ECR/10/Inst/DC/2013/RR-24                                     | Dr Sumit Goyal       |

|     |                                                                                                                                                                                                                                                           |                                                                                                                                                                                                                              |                           |
|-----|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|
| 6.  | The Gujarat Cancer and Research Institute Civil Hospital, Asarwa Ahmedabad Gujarat                                                                                                                                                                        | GCRI/GCS Ethics Committee The Gujarat Cancer & Research Institute, M.P. Shah Cancer Hospital, Civil Hospital Campus, Asarwa, Ahmedabad -380 016, Gujarat, India<br><br>ECR/41/Inst/GJ/2013/RR-24                             | Dr Rajan Yadav            |
| 7.  | Tata medical center, Tata medical center 14 Major Arterial Road (EW) New Town, rajarhat kolkata West Bengal - 700156                                                                                                                                      | Institutional Review Board, Tata Medical Centre, 14- Major arterial Road (E-W) Rajrhat, New Town, , Kolkata, 700160<br><br>ECR/269/Inst/WB/2013/RR-24                                                                        | Dr Arnab Bhattacharjee    |
| 8.  | All India Institute of Medical Sciences, Ethics Committee, All India Institute of Medical Sciences, Room No. 102, 1 <sup>st</sup> Floor, Old O.T. Block, Ansari Nagar, New Delhi Delhi - 110029                                                           | AIIMS Ethics Committee, Room no- 710-711, 7th floor- NCA Building, Ansari Nagar, New Delhi - 110029, India<br><br>ECR/538/Inst/DL/2014/RR-25                                                                                 | Dr Sachin Khurana         |
| 9.  | Aster CMI Hospital, Aster CMI Hospital 43 2, New Airport Road, NH 7, Sahakara Nagar Hebbal Karnataka - 560092                                                                                                                                             | Aster CMI Hospital Institutional Ethics Committee Aster CMI Hospital, 43/2, New Airport Road, NH-7, Sahakara Nagar, Hebbal Bengaluru Bengaluru (Bangalore) Urban Karnataka - 560092 India<br><br>ECR/1084/Inst/KA/2018/RR-21 | Dr Velukuru Sai Vivek     |
| 10. | M. S. Ramaiah Medical College and Hospital, M. S. Ramaiah Medical College and Hospital, M S Ramaiah Nagar Mathikere Karnataka - 560054                                                                                                                    | Ethics Committee M S Ramaiah Medical College & Hospitals, M S Ramaiah Nagar, MSRIT Post-560054, Bangalore, Karnataka, India.<br><br>ECR/215/Inst/KA/2013/RR-22                                                               | Dr Santhosh Kumar Devadas |
| 11. | Omega Hospital, Omega Hospital, CHR Lane, Road Number 1, Seven Hills Colony Hyderabad Telangana - 500032                                                                                                                                                  | Institutional Ethics Committee, Omega Hospital, MLA colony, Road no.12, Banjara Hills, Hyderabad, Telangana, 500034<br><br>ECR/596/Inst/AP/2014/RR-22                                                                        | Dr Vindhya Vasini         |
| 12. | Sir H N Reliance Foundation Hospital and Research Hospital, Sir H N Reliance Foundation Hospital and Research Hospital, 3rd Floor Tower building, Medical Oncology department, Prarthana Samaj, Raja Rammohan Roy Rd, Girgaon Mumbai Maharashtra - 400004 | IEC of Sir H N Reliance Foundation Hospital and Research Centre, Raja Ram Mohan Roy Road, Prarthana Samaj, Mumbai City, Maharashtra- 400004 India<br><br>ECR/1389/Inst/MH/2020/RR-25                                         | Dr Sewanti Limaye         |

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| 13. | R.K. Birla Cancer Centre, Sawai Man Singh Medical College and Attached Hospitals, Department of Medical Oncology, R.K. Birla Cancer Centre, Sawai Man Singh Medical College and attached Hospitals, JLN Marg, Rajasthan, India. Jaipur Rajasthan - 302004 | Ethics Committee of SMS Medical College & Attached Hospital Office of Ethics Committee, Second Floor, New Academic Block, S.M.S. Medical College & Attached Hospital, J.L.N. Marg, Jaipur-302004, Rajasthan, India.<br><br>ECR/26/INST/RJ/2013/RR-24 | Dr Sandeep Kumar Jasuja |
| 14. | KIMS-Kingsway Hospitals, KIMS-Kingsway Hospitals, 44,Parwana Bhawan, Kingsway Nagpur Maharashtra - 440001                                                                                                                                                 | KIMS KINGSWAY HOSPITALS ETHICS COMMITTEE KIMS Kingsway Hospitals, 44, Parwana Bhawan, Kingsway, Nagpur-440001, Maharashtra, India<br><br>ECR/1269/Inst/MH/2025                                                                                       | Dr Saurabh Prasad       |
| 15. | Homi Bhabha Cancer Hospital and Research Centre, Plot no. 1, Medicity, New Chandigarh Mullanpur New Chandigarh Punjab - 140901                                                                                                                            | Institutional Ethics Committee Homi Bhabha Cancer Hospital And Research Centre, Department Of Radiodiagnosis, First Floor B Block, Medcity, New Chandigarh Mullanpur, SAS Nagar, Punjab - 140901 India<br><br>ECR/1988/Inst/PB/2024                  | Dr Seema Gulia          |
| 16. | Mahamana Pandit Madan Mohan Malviya Cancer Centre, Sundar Bagiya, Near Nariya Gate, Banaras Hindu University Campus Varanasi Uttar Pradesh - 221005                                                                                                       | IEC, MPMMCC and HBCH Varanasi Mahamana Pandit Madan Mohan Malaviya Cancer Centre, Sundar Bagiya, Near Nariya Gate, Banaras Hindu University Campus, Varanasi, Uttar Pradesh, 221005 India<br><br>ECR/1501/Inst/UP/2021                               | Dr Bipinsh Sansar       |
| 17. | Vardhman Mahavir Medical College and Safdarjung Hospital, Old Sports injury Centre, Medical oncology Block, VMMC and Safdarjung Hospital, Ansari Nagar West New Delhi Delhi - 110024                                                                      | Institutional Ethics Committee, VMMC and SJH, Ring Road, Ansari Nagar, New Delhi, South Delhi – 110024<br><br>ECR/593/Inst/DL/2014/RR-25                                                                                                             | Dr Kaushal kalra        |
| 18. | Sahyadri Super Specialty Hospital, Pune, Sahyadri Superspeciality Hospital, 163 Bhosale nagar, Hadapsar Pune Maharashtra - 411028                                                                                                                         | Sahyadri Hospitals Private Limited Ethics Committee Sahyadri Hospitals Private Limited Survey No 89 And 90 Plot No 54 Lokmanya Colony Kothrud, Pune, Maharashtra -411038 India<br><br>ECR/493/Inst/MH/2013/RR-24                                     | Dr Shona Milon Nag      |

**Licence Number: TL/CT/26/000124****Ref File No. CT/187/25-DCG(I)**

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| 19. | Chittaranjan National Cancer Institute, Chittaranjan National Cancer Institute, Street Number 299, DJ Block, Action Area 1 D, Newtown Kolkata West Bengal - 700160                     | Institutional Ethics Committee, Chittaranjan National Cancer Institute, 37, S.P. Mukherjee Road, Kolkata 700026, West Bengal, India<br><br>ECR/241/Inst/WB/2013/RR-25                                            | Dr Chandrani Mallik       |
| 20. | Sankalp Speciality Hospital, Sankalp Speciality Hospital, Dhanvantari Marg, Vallabh Nagar, Behind Chhan Hotel, Mumbai Agra Highway, Mumbai Naka Nashik Maharashtra -422009             | Sankalp Speciality Hospital Ethics Committee Sankalp Speciality Hospital, Dhanvantari Marg, Behind Chhan Hotel, Mumbai Agra Highway, Mumbai Naka, Nashik-422009, Maharashtra, India<br><br>ECR/2221/Inst/MH/2026 | Dr Bhushan Tapiram Nemade |
| 21. | Indrayani Hospital and Cancer Institute, Alandi-Chakan Road, -412105, Maharashtra, India Pune Maharashtra - 412105                                                                     | Narsimha Saraswati Medical Foundation Ethics Committee Indrayani Hospital And Cancer Institute, Alandi-Chakan Road Alandi Devachi Pune Maharashtra - 412105<br><br>ECR/1121/Inst/MH/2018/RR-21                   | Dr Asma Sadique Pathan    |
| 22. | Max Super Speciality Hospital A unit of Crosslay Remedies Ltd, Max Super Speciality Hospital A unit of Crosslay Remedies Ltd. W-3, Sector-1, Vaishali Ghaziabad Uttar Pradesh - 201012 | Intitutional Ethics Committee Max Super Speciality Hospital, Vaishali (A Unit of Crosslay Remedies Ltd.), W-3, Sector-1, Vaishali, Ghaziabad, UP-201012<br><br>ECR/360/Inst/UP/2013/RR-24                        | Dr Gopal Sharma           |
| 23. | Malabar Cancer Centre Post Graduate Institute of Oncology Sciences and Research-PGIOSR, Moozhikkara P.O, Thalassery Kannur Kerala - 670103                                             | Institutional Ethics Committee Malabar Cancer Centre, Moozhikkara P.O Kodyeri Thalassery Kannur Kerala - 670103 India.<br><br>ECR/780/Inst/KL/2015/RR-21                                                         | Dr Nandini Devi R         |
| 24. | MNJ Institute of Oncology and Regional Cancer Centre, Red Hills, Lakdikapul Hyderabad Telangana - 500004                                                                               | MNJ Institute of Oncology and Regional Cancer Centre Ethics Committee MNJ Institute Of Oncology And RCC Lakdikapool Red Hills, Hyderabad Telangana - 500004 India<br><br>ECR/227/Inst/AP/2013/RR-24              | Dr Parimkayala Radhika    |

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