Government of India
Central Drugs Standard Control Organisation (Headquarter)
(Directorate General of Health Services)
FDA Bhavan, ITO, Kotla Road
New Delhi - 110002 (Delhi)
Phone No.: 91-11-23216367
Fax No.: 91-11-23236973
E-Mail: dci@nic.in

File No. BIO/CT/24/000143 Dated: 10.06.2025

To,

M/s Intas Pharmaceuticals Ltd.
Corporate House, Near Sola Bridge S.G. Highway,
Thaltej Ahmedabad (India) – 380054

Subject: Application for grant of permission to conduct Phase II/III study titled – "A Phase 2/3, Randomized, Double-Masked, Parallel Group, Multicentre, Comparative Clinical Study to Evaluate the Efficacy, Safety, Pharmacokinetics and Immunogenicity of Intas Bevacizumab and Ranibizumab Intravitreal Injection in Participants with Neovascular (wet) Age- Related Macular Degeneration" vide Protocol No. 0235-24, Version No. 3.0 dated 02 April 2025 - regarding
Ref. No.: Your Application No. BIO/CT04/FF/2024/46114 dated 28-10-2024 -reg

Sir,

With reference to your application No BIO/CT04/FF/2024/46114 dated 28-10-2024, please find enclosed herewith the permission in Form CT-06 for conduct of subject clinical trial under the provisions of New Drugs and Clinical Trial Rules, 2019.

The permission granted by the Central Licensing Authority to conduct clinical trial under this Chapter shall be subject to following conditions, namely:

(I) Firm should submit results of the Phase II clinical study to CDSCO after completion of the study.
(II) CSR shall be submitted to this office after completion of trial
(III) Clinical trial at each site shall be initiated after approval of the clinical trial protocol and other related documents by the Ethics Committee of that site, registered with the Central Licensing Authority under rule 8
(IV) Where a clinical trial site does not have its own Ethics Committee, clinical trial at that site may be initiated after obtaining approval of the protocol from the Ethics Committee of another trial site; or an independent Ethics Committee for clinical trial constituted in accordance with the provisions of rule 7:

Provided that the approving Ethics Committee for clinical trial shall in such case be responsible for the study at the trial site or the centre, as the case may be:

Provided further that the approving Ethics Committee and the clinical trial site or the bioavailability and bioequivalence centre, as the case may be, shall be located within the same city or within a radius of 50 kms of the clinical trial site;

(V) In case an ethics committee of a clinical trial site rejects the approval of the protocol, the details of the same shall be submitted to the Central Licensing Authority prior to seeking approval of another Ethics Committee for the protocol for conduct of the clinical trial at the same site;

(VI) The Central Licensing Authority shall be informed about the approval granted by the Ethics Committee within a period of fifteen working days of the grant of such approval;

(VII) Clinical trial shall be registered with the Clinical Trial Registry of India maintained by the Indian Council of Medical Research before enrolling the first subject for the trial.

(VIII) Clinical trial shall be conducted in accordance with the approved clinical trial protocol and other related documents and as per requirements of Good Clinical Practices Guidelines and the provisions of these rules.

(IX) Status of enrolment of the trial subjects shall be submitted to the Central Licensing Authority on quarterly basis or as appropriate as per the duration of treatment in accordance with the approved clinical trial protocol, whichever is earlier;

(X) Six monthly status report of each clinical trial, as to whether it is ongoing, completed or terminated, shall be submitted to the Central Licensing Authority electronically in the SUGAM portal.

(XI) In case of termination of any clinical trial the detailed reasons for such termination shall be communicated to the Central Licensing Authority within thirty working days of such termination.

(XII) Any report of serious adverse event occurring during clinical trial to a subject of clinical trial, shall, after due analysis, be forwarded to the Central Licensing Authority, the chairperson of the Ethics Committee and the institute where the trial has been conducted within fourteen days of its occurrence as per Table 5 of the Third Schedule and in compliance with the procedures as specified in Chapter VI.

(XIII) In case of injury during clinical trial to the subject of such trial, complete medical management and compensation shall be provided in accordance with Chapter VI and details of compensation provided in such cases shall be intimated to the Central Licensing Authority within thirty working days of the receipt of order issued by Central Licensing Authority in accordance with the provisions of the said Chapter.

(XIV) In case of clinical trial related death or permanent disability of any subject of such trial during the trial, compensation shall be provided in accordance with Chapter VI and details of compensation provided in such cases shall be intimated to the Central Licensing Authority within thirty working days of receipt of the order issued by the Central Licensing Authority in accordance with the provisions of the said Chapter.

(XV) The premises of the sponsor including his representatives and clinical trial sites, shall be open for inspection by officers of the Central Licensing Authority who may be accompanied by officers of the State Licensing Authority or outside experts as authorized by the Central Licensing Authority, to verify compliance of the requirements of these rules and Good Clinical Practices Guidelines, to inspect, search and seize any record, result, document, investigational product, related to clinical trial and furnish reply to query raised by the said officer in relation to clinical trial.

(XVI) The laboratory owned by any person or a company or any other legal entity and utilised by that person to whom permission for clinical trial has been granted used for research and development, shall be deemed to be registered with the Central Licensing Authority and may be used for test or analysis of any drug for and on behalf of Central Licensing Authority.

(XVII) The Central Licensing Authority may, if considered necessary, impose any other condition in writing with justification, in respect of specific clinical trials, regarding the objective, design, subject population, subject eligibility, assessment, conduct and treatment of such specific clinical trial.

(XVIII) The sponsor and the investigator shall maintain the data integrity of the data generated during clinical trial.

(XIX) It may kindly be noted that merely granting permission to conduct clinical trial with the drug does not convey or imply that based on the clinical trial data generated with the drug permission to market this drug in the country will automatically be granted to you.

Yours faithfully,

RAJEEV SINGH RAGHUVANSHI

Digitally signed by RAJEEV SINGH RAGHUVANSHI
Date: 2025.06.10 17:43:33 +05'30'

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)
Licensing Authority

File No. BIO/CT/24/000143

FORM CT-06

(See rules 22, 25, 26, 29 and 30)

PERMISSION TO CONDUCT CLINICAL TRIAL OF NEW DRUG OR INVESTIGATIONAL NEW DRUG

The Central Licensing Authority hereby permits M/s Intas Pharmaceuticals Ltd. Corporate House, Near Sola Bridge S.G. Highway, Thaltej Ahmedabad (India)- 380054 to conduct Phase II/III study titled – **"A Phase 2/3, Randomized, Double-Masked, Parallel Group, Multicentre, Comparative Clinical Study to Evaluate the Efficacy, Safety, Pharmacokinetics and Immunogenicity of Intas Bevacizumab and Ranibizumab Intravitreal Injection in Participants with Neovascular (wet) Age-Related Macular Degeneration"** vide Protocol No. 0235-24, Version No. 3.0 dated 02 April 2025 in the below mentioned clinical trial sites.

2. Details of new drug and clinical trial site [as per Annexure].

3. This permission is subject to the conditions prescribed in part A of Chapter V of the New Drugs and Clinical Trials Rules, 2019 under the Drugs and Cosmetics Act, 1940.

4. It may kindly be noted that merely granting permission to conduct clinical trial with the drug does not convey or imply that based on the clinical trial data generated with the drug permission to market this drug in the country will automatically be granted to you.

Place: New Delhi
Date: 10.06.2025

RAJEEV SINGH RAGHUVANSHI

Digitally signed by RAJEEV SINGH RAGHUVANSHI
Date: 2025.06.10 17:45:13 +05'30'

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)
Central Licensing Authority

Annexure:

Details of new drug or investigational new drug:

<table>
<tr><td>Names of the new drug or investigational new drug:</td><td>Bevacizumab Solution for Injection 25 mg/mL (Vial 5.75 mg/0.23 mL) (rDNA origin)</td></tr>
<tr><td>Therapeutic class</td><td>Anti-Neovascularization agents</td></tr>
<tr><td>Dosage form:</td><td>Solution for Injection (Intravitreal Injection)</td></tr>
<tr><td>Composition:</td><td>Each 0.23 mL vial contains:
Bevacizumab 5.75 mg (25 mg/mL).

<table><tr><th>Ingredients</th><th>Quantity (mg/mL)</th></tr><tr><td>Bevacizumab drug substance In house</td><td>25 mg</td></tr><tr><td>Monosodium dihydrogen phosphate, monohydrate USP, Ph. Eur., JP, IP</td><td>5.8 mg</td></tr><tr><td>Disodium hydrogen phosphate, anhydrous USP, Ph. Eur.</td><td>1.2 mg</td></tr><tr><td>α, α - Trehalose dihydrate USP</td><td>60 mg</td></tr><tr><td>Polysorbate 20 USP, Ph. Eur., IP, JP</td><td>0.4 mg</td></tr><tr><td>Ortho Phosphoric acid USP, Ph. Eur., JP, IP</td><td>q.s to pH 6.20</td></tr><tr><td>Sodium hydroxide USP, Ph. Eur., JP, IP</td><td>q.s to pH 6.20</td></tr><tr><td>Water for Injection USP, Ph. Eur., IP</td><td>q.s. to 1.0 mL</td></tr></table></td></tr>
<tr><td>Indication:</td><td>For treatment of neovascular (wet) age-related macular degeneration (nAMD).</td></tr>
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Details of clinical trial sites:

S. No.	Name and Address of Clinical Trial Site	Ethics Committee Details	Name of Principal Investigator
1	M & J Western Regional Institute Of Ophthalmology A Unit Of B J Medical Collage and Civil Hospital, Badiya Limdi Char Rasta, New Civil Hospital Campus Asarwa, Ahmedabad-380016, Gujarat, India.	Institutional Ethics Committee - B J Medical Collage and Civil Hospital B J Medical Collage and Civil Hospital, office of medical superintendent civil hospital, Ahmedabad-380016, Gujarat, India. **EC reg No.** ECR/72/Inst/GJ/2013/RR-24	Dr. Puja Negi
2	Chopda Medicare & Research Centre Pvt. Ltd Magnum Heart Institute, 3/5 Patil Lane No.1, Laxmi Nagar, Near K B H Vidyalaya, Canada Corner, Nashik-422005, Maharashtra, India.	Magna-care Ethics Committee Chopda Medicare And Research Centre Pvt Ltd, Magnum Heart Institute, Canada Corner, Nashik, Maharashtra-422005, India **EC reg No.** ECR/79/Inst/MH/2013/RR-24	Dr. Shah Anup Vijaykumar
3	Shivam Retina Clinic and Eye Hospital HG-1 A, ITC Building, Majura Gate, Ring Road, Surat- 395001 Gujarat, India.	Unity Hospital Ethics Committee Unity Trauma Centre and ICU, N-4 Janki Park Society Aai Mata Road, Parvat Patiya Surat, Gujarat- 395010 India. **EC reg No.** ECR/1226/Inst/GJ/2019	Dr. Shobhana Mange
4	Dr. Rajendra Prasad Centre for Ophthalmic Sciences, All India Institute of Medical Science, Ansari Nagar, New Delhi -110029, India	Institutional Ethics Committee All India Institute of Medical Sciences, Old OT Block, Room No.102, AIIMS Hospital, Ansari Nagar, Delhi-110029 India. **EC reg No.** ECR/538/Inst/DL/2014/RR-20	Dr. Vinod Kumar

S. No.	Name and Address of Clinical Trial Site	Ethics Committee Details	Name of Principal Investigator
5	Netralaya Super Speciality Eye Hospital, 1st Floor K D House, Above Union Bank, Opp. Gujarat Gas, Parimal Garden Cross Road, C.G. Road, Ahmedabad- 380006, Gujarat, India.	Swarnim Ethics Committee Netralaya Super Speciality Eye Hospital, 1st floor, KayDee House, Opp, Gujarat Gas, Parimal Garden Cross Road, Ellis bridge Ahmedabad- 380006, Gujarat, India. **EC reg No.** ECR/1922/Inst/GJ/2024	Dr. Rana Parth Jagdish Kumar
6	Disha Eye Hospitals Pvt Ltd 14,Grand Trunk Road, Sheoraphuli , West Bengal, 712223.	Disha Eye Hospital Pvt Ltd Ethics Committee 88(63A),Ghosh Para Road, Barrackpore Kolkata, North 24 Parganas, West Bengal 700120, India **EC reg No.** ECR/846/Inst/WB/2016/RR-19	Dr. Debdulal Chakraborty
7	Regional Institute of Ophthalmology Medical College & Hospital, 88, College Street, Kolkata-700073, West Bengal, India	Institutional Ethics Committee for Human Research, Medical College, Kolkata Medical College, Kolkata 88, College Street, Kolkata-700073, West Bengal, India **EC reg No.** ECR/287/Inst/WB/2013/RR-24	Dr. Soumyadeep Majumdar
8	Narayana Nethralaya, 121/C, Chord Road, 1st R Block, Rajaji Nagar, Bangalore-560010, Karnataka, India	Narayana Nethralaya Ethics Committee, Narayana Nethralaya, 121/C, Chord Road, 1stR Block, Rajaji Nagar, Bangalore-560010,Karnataka, India **EC reg No.** ECR/187/Inst/Kar/2013/RR-24	Dr. Chaitra Jayadev
9	Dr. Agarwal's Healthcare Limited, D 63/10, B-1 A, Dayal Enclave, Mahmoorganj, Varanasi-221010, Uttar Pradesh, India	Yakshit Independent Ethics Committee, Yakshit Independent Ethics Foundation, Plot No. 8/15 Bhadaini, Varanasi-221001, Uttar Pradesh, India **EC reg No.** ECR/381/Indt/UP/2023	Dr. Atul Kumar Sahu
10	Netralok Retina Clinic, 304-305, Golden Icon, Above Hyundai Showroom, Opp. Medilink Hospital, Nr. Shyamal CrossRoads, 132 Ft. Ring Road, Satellite, Ahmedabad-380015, Gujarat, India	Ethics Committee of Navneet Memorial Hospital,Navneet Memorial Hospital,Opp. Sardar Patel Seva Samaj Hall, Navrangpura, Ahmedabad-380006, Gujarat, India **EC reg No.** ECR/1866/Inst/GJ/2023	Dr. Mudit Bansal