



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
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File No. BIO/CT/24/000102

Dated: 23-05-2025

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 III study titled – “A Phase-3, Double-Masked, Two-Arm, Multiple Dose, Parallel Group, Randomized, Multicenter, Active-Controlled, Comparative Clinical Study to Evaluate the Efficacy, Safety and Immunogenicity of Aflibercept Intravitreal Injection and Eylea (Aflibercept) Intravitreal Injection in Patients with Diabetic Macular Oedema (DME).” Vide Protocol No. 0252-24 (Version: 2.1 dated 10-Mar-2025) - regarding

Ref. No.: Your Application No. BIO/CT04/FF/2024/44897 dated 16-08-2024 -reg

Sir,

With reference to your application No BIO/CT04/FF/2024/44897 dated 16-08-2024, 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) CSR shall be submitted to this office after completion of trial.
- (II) 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
- (III) 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;
- (IV) 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;
- (V) 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;
- (VI) 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.

- (VII) 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.
- (VIII) 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;
- (IX) 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.
- (X) 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.
- (XI) 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.
- (XII) 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.
- (XIII) 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.
- (XIV) 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.
- (XV) 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.
- (XVI) 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.
- (XVII) The sponsor and the investigator shall maintain the data integrity of the data generated during clinical trial.
- (XVIII) 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.

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

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 III study titled– **“A Phase-3, Double-Masked, Two-Arm, Multiple Dose, Parallel Group, Randomized, Multicenter, Active-Controlled, Comparative Clinical Study to Evaluate the Efficacy, Safety and Immunogenicity of Aflibercept Intravitreal Injection and Eylea (Aflibercept) Intravitreal Injection in Patients with Diabetic Macular Oedema (DME).”** Vide Protocol No. 0252-24 (Version: 2.1 dated 10-Mar-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: 23-05-2025

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

Annexure:**Details of new drug or investigational new drug:**

Names of the new drug or investigational new drug:	Aflibercept Solution for Injection 40mg/ml in Vial (r-DNA origin)		
Therapeutic class	Anti neovascularisation agents		
Dosage form:	Solution for intravitreal Injection		
Composition:	Each mL contains:		
	Name of Ingredients	Quantity (mg/mL)	
	Aflibercept drug substance, In house	40 mg	Active ingredient
	Sodium dihydrogen phosphate, monohydrate, USP, Ph. Eur., BP, IP	1.10 mg	Buffering agent
	Disodium hydrogen phosphate, heptahydrate USP, DAC	0.54 mg	Buffering agent
	Sucrose, Ph. Eur., In-house	50 mg	Stabilizer, tonicity modifier and bulking agent
	Sodium chloride, USP, Ph. Eur., BP, JP,IP, In-House	2.34 mg	Stabilizer and tonicity modifier
	Polysorbate 20, USP/NF, Ph. Eur., JP,IP, In-House	0.30 mg	Surfactant
	Hydrochloric acid#, NF, Ph. Eur., BP, JP,ChP, IP	q.s to pH6.20	To adjust pH
	Sodium hydroxide# NF, Ph. Eur., BP, JP,IP	q.s to pH6.20	To adjust pH
Water for injection, USP, Ph. Eur., IP	q.s. to 1.0 mL	Vehicle	
Indications:	Diabetic Macular Oedema		

Details of clinical trial site:

S. No.	Name and Address of Clinical Trial Site	Ethics Committee Details	Name of Principal Investigator
1.	K B Haji Bachooali Charitable Ophthalmic & E.N.T Hospital. Free Ophthalmic Hospital Society's, 58/60, Jehangir Merwanji street, Parel, Mumbai, 400012, Maharashtra, India	FOHS'S Institutional Ethics Committee K B hanji Bachooali Charitable Ophthalmic & E.N.T. Hospital, Free Ophthalmic Hospital's Society's 58/60, Jehangir Merwanji Street, Parel, Mumbai-400012, Maharashtra, India EC reg No.	Dr. Anand Subramanyam

		ECR/919/Inst/MH/2017/RR-22	
2.	Disha Eye Hospitals Pvt Ltd.14, grandTrunk road, Sheoraphuli, West Bengal - 712223	Disha Eye Hospitals Pvt Ltd Ethics Committee 88(63A), Gosh Para Road, Barrackpore,Kolkata-700120, West Bengal, India EC reg no. ECR/846/Inst/WB/2016/RR-19	Dr. Debdulal Chakraborty
3.	Comtrust Charitable Trust Eye Hospital Mini Bypass Road, Puthiyara PO, Calicut-673004, Kerala,India.	Institutional Ethics Committee Comtrust Charitable Trust Eye Hospital Puthiyara Calicut Kerala -673004, India EC reg no. ECR/1278/Inst/KL/2019	Dr. Prakash V S
4.	M & J Western Regional Institute Of OphthalmologyA Unit Of B J Medical College And Civil Hospital, Badiya Limbdi Char Rasta, New Civil Hospital Campus, Asarwa, Ahmedabad-380016, Gujarat,India	Institutional Ethics Committee-B J Medical College Of Civil Hospital B J Medical College Of Civil Hospital, Office Of Medical Superintendent Civil Hospital, Ahmedabad-380016, Gujarat, India. EC reg no. ECR/72/Inst/GJ/2013/RR-24	Dr. Somesh Aggarwal
5.	Dr. Rajendra Prasad Centre for Ophthalmic Sciences AIIMS Campus , Sri Aurobindo Marg,Ansari Nagar East. 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

6.	Chopda Medicare & Research Centre Pvt Ltd Mangnum 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. Anup Shah
7.	Netralaya Super Speciality Eye Hospital 1st Floor, Kaydee House ,Above Union bank of India, Opp. Gujarat gas, Parimal garden, Cross road, CG Road, Ahmedabad-380006, Gujarat, India	Swarnim Ethics Committee Netralaya Super Speciality Eye Hospital, 1st Floor, KaydeeHouse, Opp. Gujarat Gas, Parimal garden Cross Road, Ellis bridge, Ahmedabad-380006, Gujarat, India EC reg no. ECR/1922/Inst/GJ/2024	Dr. Parth Rana
8.	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
9.	Shanti Saroj Netralaya A.NGaikwad901/902, Beside Sundar Nagar, Anand Nursing Home road, off, Sangli, Miraj-416410, Maharashtra	EC-Saishwari Clinic Hospital for mental Health Saishwari Clinic-Hospital For Mental Health Yashwant CO. Op Housing Society Sangli Road, Miraj-416410Maharashtra EC reg no. ECR/1245/Inst/MH/2019	Dr. Sharad Bhomaj
10.	Narayana Nethralaya 121/C, Chord Road, 1st R Block Rajaji Nagar, Bangalore-560010, Karnataka	Narayana Nethralaya Ethics Committee Narayana Nethralaya, 121/C, Chord Road, 1st Block Rajaji Nagar, Bangalore-560010, Karnataka	Dr. Naresh Yadav

		<p>EC reg no.</p> <p>ECR/187/Inst/Kar/2013/RR-19</p>	
11.	<p>Nethra Eye Hospital No.8, 80 feet road, Poojaray Layout, RMV 2nd Stage, Sanjayagar, Bangalore- 560094</p>	<p>Pranav Diabetes Centre Ethics Committee Pranav Diabetes Centre, 57/1 Nanda Complex Rammurthy nagarmain Road, BanaswadiBengaluru-560043, Karnataka,India</p> <p>EC reg no</p> <p>ECR/1217/Inst/KA/2019/RR-22.</p>	<p>Dr. Sri Bhargava Natesh</p>
12.	<p>Netralayam-The Superspeciality Eye care Centre Shree Tower II, 2nd Floor ,RAA 36, Raghunathpur, VIP road, Kolkata, 700059, West Bengal,India</p>	<p>Netralayam Ethics Committee, Shree Tower II, 2nd Floor ,RAA 36, Raghunathpur, VIP road, Kolkata, 700059, West Bengal India</p> <p>EC reg no.</p> <p>ECR/1019/Inst/WB/2017/RR-21</p>	<p>Dr. Rupak Kanti Biswas</p>
13.	<p>R K Netralaya Eye Hospital Pvt Ltd D 63/10, B-1A, Dayal Enclave , Mahmoorganj Varanasi- 221010, Uttar Pradesh , India</p>	<p>Galaxy Hospital Ethics Committee Galaxy Lifecare Services Pvt Ltd. Plot No.4-7, Dayal Enclave,Mahmoorganj, Varanasi- 221010, Uttar Pradesh, India</p> <p>EC reg no.</p> <p>ECR/877/Inst/UP/2016/RR-20</p>	<p>Dr.Atul Sahu</p>

14.	Regional Institute of Ophthalmology Indira Gandhi Institute of Medical Sciences Sheikhpura, Patna-800014, Bihar, India	<p>Institutional Ethics Committee Indira Gandhi Institute Of Medical Sciences, Sheikhpura, Patna-800014, Bihar, India</p> <p>EC reg no. ECR/640/Inst/BR/2014/RR-20</p>	Dr. Abhishek Anand
15.	Lotus Eye Hospital and Institute Limited 770/12, Avinashi Road, Civil Aerodrome Post, Coimbatore-641014, Tamilnadu, India	<p>Institutional Human Ethics Committee PSG Institute of Medical Sciences and Research Post BoxNo.1674.Avinashi Road, Peelamedu, Coimbatore -641004, Tamilnadu, India</p> <p>EC reg no. ECR/252/Inst/TN/2013/RR-19</p>	Dr. Ashish Sharma
16.	Kashyap Memorial Eye Hospital Pvt Ltd Purulia Rd, near Dangratoli Chowk, Dangratoli, Nayatoli Ranchi (Jharkhand) 834001, India	<p>Institutional Ethics Committee Kashyap Memorial Eye Hospital Complex, Ethics Committee, puruliaroad Ranchi-834001Jharkhand India.</p> <p>EC reg no. ECR/1790/Inst/JH/2023</p>	Dr. Bibhuti Kashyap
17.	Netralok Retina Clinic 304/305 Golden Icon, Above Hyundai Showroom, Opp. Medilink Hospital, Nr. Shyamal Cross road, 132 Feet ring road, Setellite , Ahmedabad-15, Gujarat, India	<p>Ethics Committee of Navneet Memorial hospital Navneet Memorial Hospital, Opp. Sardar Patel, Seva samaj Hall, Navarangpura,Ahmedabad, Gujarat-380006</p> <p>EC reg no. ECR/1866/Inst/GJ/2023</p>	Dr. Mudit Bansal
18.	Sankara Eye Hospital Varthur Main Road,KundanahalliGate, Bangalore-560037,Karnataka,India	<p>Institutional Ethics Committee Sankara Eye Hospital, Varthur Main Road, Kundanahalli Gate, Bangalore-560037, Karnataka, India</p> <p>EC reg no. ECR/705/Inst/KA/2015/RR-21</p>	Dr. Payal Shah

19.	Regional Institute Of Ophthalmology Medical College & Hospital 88, College Street, Kolkata 700073, West Bengal, India	Institutional Ethics Committee Regional Institute Of Ophthalmology, 88, College Street, Kolkata-700073, West Bengal, India EC reg no. ECR/59/Inst/WB/2013/RR-19	Dr. Soumyadeep Majumdar
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To,

M/s Intas Pharmaceuticals Ltd.
Corporate House, Near Sola Bridge S.G. Highway,
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Subject: Application for grant of permission to conduct Phase III study titled – “A Phase-3, Double-Masked, Two-Arm, Multiple Dose, Parallel Group, Randomized, Multicenter, Active-Controlled, Comparative Clinical Study to Evaluate the Efficacy, Safety and Immunogenicity of Aflibercept Intravitreal Injection and Eylea (Aflibercept) Intravitreal Injection in Patients with Diabetic Macular Oedema (DME).” Vide Protocol No. 0252-24 (Version: 2.1 dated 10-Mar-2025) - regarding

Ref. No.: Your Application No. BIO/CT04/FF/2024/44897 dated 16-08-2024 -reg

Sir,

With reference to your application No BIO/CT04/FF/2024/44897 dated 16-08-2024, 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) CSR shall be submitted to this office after completion of trial.
- (II) 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
- (III) 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;
- (IV) 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;
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- (VII) 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.
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- (IX) 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.
- (X) 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.
- (XI) 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.
- (XII) 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.
- (XIII) 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.
- (XIV) 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.
- (XV) 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.
- (XVI) 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.
- (XVII) The sponsor and the investigator shall maintain the data integrity of the data generated during clinical trial.
- (XVIII) 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.

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

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 III study titled– **“A Phase-3, Double-Masked, Two-Arm, Multiple Dose, Parallel Group, Randomized, Multicenter, Active-Controlled, Comparative Clinical Study to Evaluate the Efficacy, Safety and Immunogenicity of Aflibercept Intravitreal Injection and Eylea (Aflibercept) Intravitreal Injection in Patients with Diabetic Macular Oedema (DME).”** Vide Protocol No. 0252-24 (Version: 2.1 dated 10-Mar-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

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

Annexure:**Details of new drug or investigational new drug:**

Names of the new drug or investigational new drug:	Aflibercept Solution for Injection 40mg/ml in Vial (r-DNA origin)		
Therapeutic class	Anti neovascularisation agents		
Dosage form:	Solution for intravitreal Injection		
Composition:	Each mL contains:		
	Name of Ingredients	Quantity (mg/mL)	
	Aflibercept drug substance, In house	40 mg	Active ingredient
	Sodium dihydrogen phosphate, monohydrate, USP, Ph. Eur., BP, IP	1.10 mg	Buffering agent
	Disodium hydrogen phosphate, heptahydrate USP, DAC	0.54 mg	Buffering agent
	Sucrose, Ph. Eur., In-house	50 mg	Stabilizer, tonicity modifier and bulking agent
	Sodium chloride, USP, Ph. Eur., BP, JP,IP, In-House	2.34 mg	Stabilizer and tonicity modifier
	Polysorbate 20, USP/NF, Ph. Eur., JP,IP, In-House	0.30 mg	Surfactant
	Hydrochloric acid#, NF, Ph. Eur., BP, JP,ChP, IP	q.s to pH6.20	To adjust pH
	Sodium hydroxide# NF, Ph. Eur., BP, JP,IP	q.s to pH6.20	To adjust pH
Water for injection, USP, Ph. Eur., IP	q.s. to 1.0 mL	Vehicle	
Indications:	Diabetic Macular Oedema		

Details of clinical trial site:

S. No.	Name and Address of Clinical Trial Site	Ethics Committee Details	Name of Principal Investigator
1.	K B Haji Bachooali Charitable Ophthalmic & E.N.T Hospital.Free Ophthalmic Hospital Society's, 58/60,Jehangir Merwanji street, Parel, Mumbai, 400012, Maharashtra, India	FOHS'S Institutional Ethics Committee K B hanji Bachooali Charitable Ophthalmic & E.N.T. Hospital, Free Ophthalmic Hospital's Society's 58/60,Jehangir Merwanji Street, Parel, Mumbai-400012, Maharashtra, India EC reg No.	Dr. Anand Subramanyam

		ECR/919/Inst/MH/2017/RR-22	
2.	Disha Eye Hospitals Pvt Ltd.14, grandTrunk road, Sheoraphuli, West Bengal - 712223	Disha Eye Hospitals Pvt Ltd Ethics Committee 88(63A), Gosh Para Road, Barrackpore,Kolkata-700120, West Bengal, India EC reg no. ECR/846/Inst/WB/2016/RR-19	Dr. Debdulal Chakraborty
3.	Comtrust Charitable Trust Eye Hospital Mini Bypass Road, Puthiyara PO, Calicut-673004, Kerala,India.	Institutional Ethics Committee Comtrust Charitable Trust Eye Hospital Puthiyara Calicut Kerala -673004, India EC reg no. ECR/1278/Inst/KL/2019	Dr. Prakash V S
4.	M & J Western Regional Institute Of OphthalmologyA Unit Of B J Medical College And Civil Hospital, Badiya Limbdi Char Rasta, New Civil Hospital Campus, Asarwa, Ahmedabad-380016, Gujarat,India	Institutional Ethics Committee-B J Medical College Of Civil Hospital B J Medical College Of Civil Hospital, Office Of Medical Superintendent Civil Hospital, Ahmedabad-380016, Gujarat, India. EC reg no. ECR/72/Inst/GJ/2013/RR-24	Dr. Somesh Aggarwal
5.	Dr. Rajendra Prasad Centre for Ophthalmic Sciences AIIMS Campus , Sri Aurobindo Marg,Ansari Nagar East. 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

6.	Chopda Medicare & Research Centre Pvt Ltd Mangnum 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. Anup Shah
7.	Netralaya Super Speciality Eye Hospital 1st Floor, Kaydee House ,Above Union bank of India, Opp. Gujarat gas, Parimal garden, Cross road, CG Road, Ahmedabad-380006, Gujarat, India	Swarnim Ethics Committee Netralaya Super Speciality Eye Hospital, 1st Floor, KaydeeHouse, Opp. Gujarat Gas, Parimal garden Cross Road, Ellis bridge, Ahmedabad-380006, Gujarat, India EC reg no. ECR/1922/Inst/GJ/2024	Dr. Parth Rana
8.	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
9.	Shanti Saroj Netralaya A.NGaikwad901/902, Beside Sundar Nagar, Anand Nursing Home road, off, Sangli, Miraj-416410, Maharashtra	EC-Saishwari Clinic Hospital for mental Health Saishwari Clinic-Hospital For Mental Health Yashwant CO. Op Housing Society Sangli Road, Miraj-416410Maharashtra EC reg no. ECR/1245/Inst/MH/2019	Dr. Sharad Bhomaj
10.	Narayana Nethralaya 121/C, Chord Road, 1st R Block Rajaji Nagar, Bangalore-560010, Karnataka	Narayana Nethralaya Ethics Committee Narayana Nethralaya, 121/C, Chord Road, 1st Block Rajaji Nagar, Bangalore-560010, Karnataka	Dr. Naresh Yadav

		<p>EC reg no.</p> <p>ECR/187/Inst/Kar/2013/RR-19</p>	
11.	<p>Nethra Eye Hospital No.8, 80 feet road, Poojaray Layout, RMV 2nd Stage, Sanjayagar, Bangalore- 560094</p>	<p>Pranav Diabetes Centre Ethics Committee Pranav Diabetes Centre, 57/1 Nanda Complex Rammurthy nagarmain Road, BanawadiBengaluru-560043, Karnataka,India</p> <p>EC reg no</p> <p>ECR/1217/Inst/KA/2019/RR-22.</p>	<p>Dr. Sri Bhargava Natesh</p>
12.	<p>Netralayam-The Superspeciality Eye care Centre Shree Tower II, 2nd Floor ,RAA 36, Raghunathpur, VIP road, Kolkata, 700059, West Bengal,India</p>	<p>Netralayam Ethics Committee, Shree Tower II, 2nd Floor ,RAA 36, Raghunathpur, VIP road, Kolkata, 700059, West Bengal India</p> <p>EC reg no.</p> <p>ECR/1019/Inst/WB/2017/RR-21</p>	<p>Dr. Rupak Kanti Biswas</p>
13.	<p>R K Netralaya Eye Hospital Pvt Ltd D 63/10, B-1A, Dayal Enclave , Mahmoorganj Varanasi- 221010, Uttar Pradesh , India</p>	<p>Galaxy Hospital Ethics Committee Galaxy Lifecare Services Pvt Ltd. Plot No.4-7, Dayal Enclave,Mahmoorganj, Varanasi- 221010, Uttar Pradesh, India</p> <p>EC reg no.</p> <p>ECR/877/Inst/UP/2016/RR-20</p>	<p>Dr.Atul Sahu</p>

14.	Regional Institute of Ophthalmology Indira Gandhi Institute of Medical Sciences Sheikhpura, Patna-800014, Bihar, India	<p>Institutional Ethics Committee Indira Gandhi Institute Of Medical Sciences, Sheikhpura, Patna-800014, Bihar, India</p> <p>EC reg no. ECR/640/Inst/BR/2014/RR-20</p>	Dr. Abhishek Anand
15.	Lotus Eye Hospital and Institute Limited 770/12, Avinashi Road, Civil Aerodrome Post, Coimbatore-641014, Tamilnadu, India	<p>Institutional Human Ethics Committee PSG Institute of Medical Sciences and Research Post BoxNo.1674.Avinashi Road, Peelamedu, Coimbatore -641004, Tamilnadu, India</p> <p>EC reg no. ECR/252/Inst/TN/2013/RR-19</p>	Dr. Ashish Sharma
16.	Kashyap Memorial Eye Hospital Pvt Ltd Purulia Rd, near Dangratoli Chowk, Dangratoli, Nayatoli Ranchi (Jharkhand) 834001, India	<p>Institutional Ethics Committee Kashyap Memorial Eye Hospital Complex, Ethics Committee, puruliaroad Ranchi-834001Jharkhand India.</p> <p>EC reg no. ECR/1790/Inst/JH/2023</p>	Dr. Bibhuti Kashyap
17.	Netralok Retina Clinic 304/305 Golden Icon, Above Hyundai Showroom, Opp. Medilink Hospital, Nr. Shyamal Cross road, 132 Feet ring road, Setellite , Ahmedabad-15, Gujarat, India	<p>Ethics Committee of Navneet Memorial hospital Navneet Memorial Hospital, Opp. Sardar Patel, Seva samaj Hall, Navarangpura,Ahmedabad, Gujarat-380006</p> <p>EC reg no. ECR/1866/Inst/GJ/2023</p>	Dr. Mudit Bansal
18.	Sankara Eye Hospital Varthur Main Road,KundanahalliGate, Bangalore-560037,Karnataka,India	<p>Institutional Ethics Committee Sankara Eye Hospital, Varthur Main Road, Kundanahalli Gate, Bangalore-560037, Karnataka, India</p> <p>EC reg no. ECR/705/Inst/KA/2015/RR-21</p>	Dr. Payal Shah

19.	Regional Institute Of Ophthalmology Medical College & Hospital 88, College Street, Kolkata 700073, West Bengal, India	Institutional Ethics Committee Regional Institute Of Ophthalmology, 88, College Street, Kolkata-700073, West Bengal, India EC reg no. ECR/59/Inst/WB/2013/RR-19	Dr. Soumyadeep Majumdar
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