

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 Licencing Authority hereby permits **M/s GlaxoSmithKline Pharmaceuticals Limited, GSK House, Dr. Annie Besant Road, Worli, Mumbai - 400030** to conduct clinical trial of the new drug or investigational new drug as per Protocol No. 209682 (Amendment 01), dated 27.08.2019 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.

Place: New Delhi
Date:

(Dr. V. G. Somani)
Drugs Controller General (India)
Central Licencing Authority

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

Names of the new drug or investigational new drug:	Mepolizumab Powder for Solution for Injection				
Therapeutic class:	Humanized monoclonal antibody				
Dosage form:	Lyophilized Powder for Solution for Injection in vial				
Composition:	S. No.	Ingredients	Specifications	Quantity per Vial	Function
	1	Mepolizumab	(IH)	144.000 mg	Active
	2	Sucrose	(Ph. Eur.)	197.500 – 256.800 mg	Inactive
	3	Sodium Phosphate Dibasic Heptahydrate	(USP)	8.820 – 11.470 mg	Inactive
	4	Polysorbate 80	(Ph. Eur.)	0.820 – 1.070 mg	Inactive
	5	Hydrochloric Acid	(Ph. Eur.)	q.s. (for pH adjustment)	Inactive
	6	Water for Injection	(Ph. Eur.)	q.s. (to approx. 1.920 mL)	Inactive
Indications:	As an add-on treatment for severe refractory eosinophilic asthma in adult patients.				

Details of clinical trial sites:

S. No.	Name and Address of Clinical Trial Site	Ethics Committee Details	Name of Principal Investigator
1	Fortis Hospital, 730, Anandapur, EM Bypass Road, Kolkata- West Bengal-700107.	Fortis Hospital Ethics Committee, Fortis Hospital, 730 Anandapur, EM Bypass Road, Kolkata- 700107, West Bengal. EC Reg. No. ECR/240/Inst/WB/2013/RR-16	Dr. Raja Dhar
2	Sri Muthukumaran Medical College Hospital and Research Institute, Chikkarayapuram, Mangadu, Chennai- 600069.	Institutional Ethics Committee, Sri Muthukumaran Medical College Hospital & Research Institute, Chikkarayapuram, Mangadu, Chennai- 600069 EC Reg No. ECR/718/Inst/TN/2015/RR-18	Dr. S. Balamurugan
3	Fortis Hospital, Sector 62, Phase VIII, Mohali-160062, Punjab.	IEC Fortis Hospital, Fortis Hospital, Sector 62, Phase VIII, Mohali-160062, Punjab EC Reg No. ECR/28/Inst/PB/2013/RR-19	Dr. Amit Kumar Mandal
4	King George's Medical University, (Erstwhile Chhatrapati Shahuji Maharaj Medical University), Lucknow, Uttar Pradesh, INDIA – 226003.	Institutional Ethics Committee, Research Cell, King George's Medical University, (Erstwhile Chhatrapati Shahuji Maharaj Medical University), Chowk, Lucknow, Uttar Pradesh, INDIA – 226003. EC Reg No. ECR/262/Inst/UP/2013/RR-16	Dr Surya Kant

5	SMS Hospital, Jawahar Lal Nehru Marg, Ashok Nagar, Jaipur, Rajasthan 302004.	Ethics Committee of SMS Medical College and attached hospital, SMS Hospital, Jawahar Lal Nehru Marg, Ashok Nagar, Jaipur, Rajasthan 302004. EC Reg. No.: ECR/26/Inst/RJ2013/RR-19	Dr. Narendra Khippal
6	Ganesh Shankar Vidyarthi Memorial Medical College, Department of Pulmonology Swaroop Nagar, Near Rawtpur Crossing, Kanpur - 208005.	Ethics Committee, GSVM Medical College, Department of Pulmonology, Swaroop Nagar, Near Rawtpur Crossing, Kanpur - 208005. EC Reg. No. ECR/680/Inst/UP/2014/RR-17	Dr. Anand Kumar
7	Maharaja Agrasen Hospital, Near Metro Station Jain Muni Guru Ramkrishan Marg, Block C, Shivaji Park, West Punjabi Bagh, Delhi, 110026.	Institutional Ethics Committee, Maharaja Agrasen Hospital Near Metro Station Jain Muni Guru Ramkrishan Marg Block C, Shivaji Park, West Punjabi Bagh, Delhi, 110026. EC Reg. No. ECR/745/Inst/DL/2015/RR-18	Dr. Bharat Gopal
8	Fortis Ft. Lt. Rajan Dhall Hospital, Aruna Asaf Ali Marg, Pocket 1, Sector B, Vasant Kunj, New Delhi, Delhi 110070.	Ethics Committee for Research, Fortis Ft. Lt. Rajan Dhall Hospital, Aruna Asaf Ali Marg, Pocket 1, Sector B, Vasant Kunj, New Delhi, Delhi 110070. EC Reg. No. ECR/57/Inst/DL/2013/RR-19	Dr. Vivek Nangia
9	St. Johns National Academy of Health Sciences, Sarjapur Main Rd, Beside Bank Of Baroda, John Nagar, Koramangala, Bengaluru, Karnataka 560034.	Institutional Ethics Committee, St.Johns National Academy of Health Sciences, Sarjapur Main Rd, Beside Bank Of Baroda, John Nagar, Koramangala, Bengaluru, Karnataka 560034. EC Reg. No. ECR/238/Inst/KA/2013/RR-19	Dr. Uma Maheswari Krishnaswamy
10	KIMS Hospital, Department of Pulmonary Medicine, B-Block, OPD Building, Ground Floor, K.R Road, V.V. Puram, Bangalore-560004, Karnataka.	KIMS Institutional Ethics Committee, KIMS Hospital, Department of Pulmonary Medicine, B-Block, OPD Building, Ground Floor, K.R Road, V.V. Puram, Bangalore-560004, Karnataka. EC Reg. No. ECR/216/Inst/KAR/2013/RR-19	Dr. Huliraj N
11	SDS TRC & Rajiv Gandhi Institute Of Chest Diseases, Someshwar nagar 1st Main Road, Dharmaram College Post, 1st Block, Hombegowda Nagar, Bengaluru, Karnataka 560029.	BMCRI, SDS TRC & Rajiv Gandhi Institute Of Chest Diseases, Someshwar nagar 1st Main Road, Dharmaram College Post, 1st Block, Hombegowda Nagar, Bengaluru, Karnataka 560029. EC Reg. No. ECR/302/Inst/KA/2013/RR-16	Dr. Nagaraja Chikkavenkatappa
12	Apollo Gleneagles Hospital, 58, Canal Circular Road, Kadapara, Phool Bagan, Kankurgachi, Kolkata, West Bengal 700054.	Institutional Ethics Committee, Apollo Gleneagles Hospital, 58, Canal Circular Road, Kadapara, Phool Bagan, Kankurgachi, Kolkata, West Bengal 700054. EC Reg. No.: ECR/373/Inst/WB/2013/RR-16	Dr. Sushmita Roychowdhury

13	Government Medical College and super speciality hospital, Near Tukdoji Square, Nagpur-440009.	Institutional Ethics Committee, GMC, Nagpur, Government Medical College, Near Hanuman Nagar, Nagpur- 440009. EC Reg. No. ECR/43/Inst/MH/2013/RR-19	Dr. Sushant Meshram
14	P. D. Hinduja National Hospital & Medical Research Centre, SVS Rd, Mahim West, Shivaji Park, Mumbai, Maharashtra 400016.	Institutional Ethics Committee, P. D. Hinduja National Hospital & Medical Research Centre, SVS Rd, Mahim West, Shivaji Park, Mumbai, Maharashtra 400016 EC Reg. No. ECR/61/Inst/MH/2013	Dr. Zarir Udwadia
15	Grant government Medical College and Sir JJ Group of Hospitals, Byculla, Mumbai-400080, Maharashtra.	Institutional Ethics Committee, Grant government Medical College and Sir JJ Group of Hospitals, Byculla, Mumbai-400080, Maharashtra ECR/382/Inst/MH/2013/RR-19	Dr. Preeti Meshram
16	Get Well Hospital & Research Institute, plot no. 20/1, Dr. Khare Marg, Dhantoli,-440012 Nagpur Maharashtra.	Getwell Institutional Ethics Committee, Get Well Hospital & Research Institute, plot no. 20/1, Dr. Khare Marg, Dhantoli,-440012 Nagpur Maharashtra. EC Reg. No.: ECR/109/Inst/MAHA/2013/RR16	Dr. Rajesh Swarnakar
17	Jaydeep hospital, Near St Xavier's Loyola school, Opp. Kamnath Mahadev, Near Darpan Six Road, Naranpur, Ahmedabad - 380013, Gujarat.	Kaizen Ethics Committee Kaizen at 132 Feet Ring Road Helmet Circle memnagar Ahmedabad-380052 Gujarat India EC Reg. No. ECR/447/Inst/GJ/2013/RR-19	Dr. Deepali Kamdar
18	Siddhi Hospital, P-67, MIDC, Satpur, Behind PF Office, Trimbak Road, Nashik-422 007.	Siddhi Hospital Institutional Ethics Committee, Siddhi Hospital, P-67, MIDC, Satpur, Behind PF Office, Trimbak Road, Nashik-422 007 EC Reg. No.: ECR/739/Inst/MH/2015/RR-18	Dr. Abhinandan B. Mutha
19	Jehangir Hospital, 32, Sasoon Road Opposite Railway Station, Central Excise Colony, Sangamvadi, Pune 411001, Maharashtra, India.	Ethics Committee, Jehangir Clinical Development Cente Pvt. Ltd, Jehangir Hospital, 32, Sasoon Road Opposite Railway Station, Central Excise Colony, Sangamvadi, Pune - 411001, Maharashtra, India. EC Reg. No. ECR/352/Inst/MH/2013/RR-19	Dr. Ashish Goyal
20	SMS Hospital, Jawahar Lal Nehru Marg, Ashok Nagar, Jaipur, Rajasthan 302004.	Ethics Committee of SMS Medical College and attached hospital, SMS Hospital, Jawahar Lal Nehru Marg, Ashok Nagar, Jaipur, Rajasthan-302004. EC Reg. No. ECR/26/Inst/RJ2013/RR-19	Dr. Ajit Singh