

File No: BIO/CT/23/000008
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Biological Division)

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 grant permission to M/s Reliance Life Sciences, Center, R-282, TTC Area of MIDC, Thane -Belapur Road, Rabale, Navi Mumbai (India) – 400 701 Telephone No.: 022-40678770 FAX: 022-40678099, E-Mail: bobby.george@relbio.com to conduct clinical trial of the new drug or investigational new drug as per below mentioned clinical trial sites.

CT No.: CT- 07/2023

2. Details of new drug or investigational 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 trials 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 with automatically be granted to you.

Date:
Place: New Delhi

RAJEEV SINGH
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Annexure: Details of New Drug or Investigational New Drug:

Name of the new drug or investigational new drug:	RLS Protein Subunit Vaccine against SARS CoV 2 Virus	
Therapeutic class:	Vaccine	
Dosage form:	Liquid (Solution for injection) [10µg RBD+ 10µg Nucleocapsid protein]	
Composition:	Each dose of 0.5 ml contains:	
	Active ingredient	Quantity
	Receptor Binding Domain (RBD) of SARS CoV-2	10 mg
	Nucleocapsid protein of SARS Cov2 Virus	10 mg
	Aluminium Hydroxide Gel	0.5 mg
	Phosphorothioate Oligo oligonucleotide	0.2 mg
	2-Phenoxy ethanol	5 mg
Indication:	For administration as a single booster dose in subjects who have received two doses of COVID 19 vaccine about 6 months prior to this booster dose.	

Details of clinical trial sites-

S. No.	Name and Address of Clinical Trial Site	Ethics Committee details	Name of Principal Investigator
1	D Y Patil University School of Medicine and Hospital Plot NO. 2, Sector-5, Nerul, Navi Mumbai, Thane, Maharashtra-400706, India	Institutional Ethics Committee, D Y Patil Medical College and Research Centre [ECR/195/Inst/MH/2013/RR-19]	Dr. Deepak Kumar Langade
2	Grant Government Medical College & Sir J.J. Group of Hospitals, Byculla, Mumbai-400008, Maharashtra, India	Institutional Ethics Committee, GGMC, Mumbai [ECR/382/Inst/MH/2013/RR-19]	Dr. Akash Khobragade
3	Medipoint Hospitals Pvt. Ltd, 241/1, New D. P. Road, Aundh, Pune-411007, Maharashtra, India	Institutional Ethics Committee, Penta-Med Ethics Committee, Medipoint Hospitals Pvt. Ltd. [ECR/357/Inst/MH/2013/RR-20]	Dr. Vivek Sheloje
4	Bharati Vidyapeeth (Deemed to be University) Medical College and Hospital, Pune	Institutional Ethics Committee, Bharati Vidyapeeth Medical College and Hospital, Pune [ECR/313/Inst/MH/2013/RR-19]	Dr. Prachee Makashir
5	Orchid Speciality Hospital, L-Square, Porwal Road, Sr.No-282-3/3, Off, Dhanori JakatNaka, Lohgaon, Pune-411047, Maharashtra, India	Institutional Ethics Committee, Orchid Speciality Hospital, L-Square, Porwal Road. [ECR/1089/Inst/MH/2018/RR-21]	Dr. Ashish Goyal
6	Lokmanya Tilak Municipal	Institutional Ethics Committee,	Dr. Sudhir

	Medical College & General Hospital, Sion, Mumbai - 400022, Maharashtra, India	Lokmanya Tilak Municipal Medical College & General Hospital, Sion, Mumbai [ECR/266/Lokmanya/Inst/MH/2013/RR-19]	Pawar
7	IPGME&R and SSKM Hospital ,244, AJC Bose Road, Kolkata-700020	IPGME&R Resaerch Oversight Committee,IPGME&R and SSKM Hospital ,244, AJC Bose Road,Bhowanipore,Kolkata-700020 [ECR/35/Inst/WB/2013/RR-19]	Dr. Anupam Mandal
8	Dr. D.Y Patil Medical college and hospital and Research centre, Sant Tukaram Nagar Pimpri,Pune 411018	Ethics Committee Dr. D.Y Patil Vidyapeeth, Dr. D.Y Patil Medical college and hospital and Research centre, Sant Tukaram Nagar Pimpri,Pune 411018 [ECR361/Inst/MH/2013/RR-19]	Dr. Shrikant Tripathy
9	GMERS Medical College and civil Hospital Sola, Nr Gujrat Highcourt, S.G Highway, Sola Ahmedabad, 380061, Gujrat India	Institutional Ethics Committee, GMERS Medical College and Civil Hospital, Nr Gujrat Highcourt, S.G Highway, Sola [ECR/404/Inst/GJ/2013/RR-20]	Dr. Parul Bhatt
10	Belagavi Institute Of Medical Sciences ,Dr B R Ambedkar Rd, Sadashiv Nagar, Belagavi, Karnataka 590019	Institutional Ethics Committee BIMS, Belagavi Institute of medical science, B.R Ambedkar road Belgavi, 590001, Karnataka India [ECR/801/Inst/KA/2016/RR-20]	Dr. Sandeep Dandin
11	Sheth Vadilal Sarabhai General Hospital, Sheth Chinai Maternity Hospital Ellisbridge, Ahmedabad, Gujarat 380006	Sangini Hospital Ethics Committee, C/o Sangini Hospital 1st Floor, Santorini square, B/h Abhishree Complex, Opposite star bazar lane, Satellite Ahemedabad, 380015 [ECR/147/Inst/GJ/2013/RR-19]	Dr, Devang Rana
12	S.M.S. Medical College and Attached Hospitals .J.L.N. Marg, Jaipur Rajasthan -302004	Ethics Committee S.M.S. Medical College and Attached Hospitals J.L.N. Marg Jaipur Rajasthan - 302004 India [ECR/26/Inst/RJ/2013/RR-19]	Dr. Sunil Kumar mahavar
13	KEM Hospital Research Center Vadhu Budruk,Tal- Shirur, Dist Pune Maharashtra 412216	KEM Hospital research centre ethics Committee, sardar moodliar road, rasta peth, pune 41101 [ECR/272/Inst/MH/2013/RR-22]	Dr. Anand Kawade
14	Department of Medicine, King George's Medical University, Shah Mina Rd, Chowk, Lucknow, Uttar Pradesh 226003	Institutional ethics committee, research cell, administrative block, King george medical univercity, chowk, Lucknow 226003 [ECR/262/Inst/Up/2013/RR-19]	Dr. D Himanshu
15	Chopda Medicare & Research Center Pvt. Ltd: Magnum Heart	Magna-Care Ethics Committee, C/o Chopda medicare and	Dr. Swapnil Sakhala

	Institute, 3/5, Patil Lane No.1, Laxmi Nagar, Near K.B.H. Vidyalaya, Canada Corner, Nashik - 4222005, Maharashtra India	research centre Pvt Lt; Magnum heart institute, Patil Lane no 1, Near K.B.H Vidyalaya, Canada Corner, Nashik-422005, Maharashtra [ECR/79/Inst/MH/2013/RR-19]	
16	Department of Anaesthesiology & Critical Care, MLB Medical College, Kanpur, Jhansi(U.P.)284128	Ethics Committee M.L.B Medical college, MLB Medical College and Associated Hospital, MLB college road Kanpur road, Jhansi, Uttar Pradesh- 284128 [ECR/1393/Inst/UP/2020]	Dr. Anshul Jain
17	Department of General Medicine, Rajendra Prasad Ward, King George Hospital, Maharanipeta, Vishakhapatnam-530002, Andhra Pradesh India	Institutional Ethics Committee, King George Hospital King George Hospital, Maharanipeta, Visakhapatnam-530002 Andhra Pradesh [ECR/197/Inst/KGH/2013/RR-20]	Dr. Kontham Rambabu
18	Department of Medicine, RCSM Govt. Medical college & CPR hospital, Dasara Chowk, Bhausingji road, Town Hall Kolhapur-416012, Maharashtra, India.	Rajarshree Chhatrapati Shahu Maharaj Govt. Medical College and Chhatrapati Pramila Raje Hospital, Kolhapur Institutional ethics Committee 2 (RCSMGMCI EC2)., Dasara Chowk, Bhausingji road, town hall, Kolhapur-416012 Maharashtra India [ECR/703/Inst/MH/2015/RR-20]	Dr. Vijaykumar Barge
19	Oyster & Pearl Hospital (Phadnis Clinic Pvt Ltd) 1671 - 75, Ganeshkhind Road, Shivajinagar Pune, 411005, Maharashtra, India	O & P institutional committee, Oyster & Pearl Hospital (Phadnis Clinic Pvt Ltd) 1671 - 75, Ganeshkhind Road Shivajinagar Pune, 411005, Maharashtra, India [ECR/71/Inst/EC/2013/RR-19]	Dr. Aniket Joshi
20	Department of Medicine, Shree Siddhivinayak Maternity & Nursing home, Unity Campus, Opp. KTHM College, Gangapur Road, Nasik 422002, Maharashtra India	Shree Siddhivinayak Hospital Ethics Committee, C/O Shree Siddhivinayak Maternity & Nursing home, Unity Campus, Opp. KTHM College, Gangapur Road, Nasik 422002, Maharashtra India [ECR/1247/Inst/MH/2019]	Dr. Sandesh Patil

In addition to point 3, the permission is subject to following condition(s):

- I. The Phase II clinical trial should be conducted as per title "Prospective, multi-center, randomized, open label, active control, phase 2 clinical study to evaluate immunogenicity, safety and tolerability of single heterologous booster dose of RelCoVax® (Protein Subunit Vaccine of Reliance Life Sciences against SARS-CoV-2 Virus) with Corbevax® (Protein Subunit Vaccine of Biological E Ltd. against SARS-CoV-2 Virus) vide Protocol no.: RLS/VAC/2023/01, Version 3.0, Dated: 30-Jun-2023.
- II. Firm is requested to submit the copy of contract entered by the sponsor with the investigator/institutions with regard to financial support, amount of fees, honorarium, payments

in kind etc. to be paid to the investigator. In case no contract has yet been entered with any Investigator / Institution, plan for financial support, fees, honorarium, and payments in kind etc. to be paid to the investigator.

- Date: _____
Place: New Delhi

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post@centraldrugs.org, postalCode=600034, st=AMIL NADU,
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FORM CT-11

(See rules 53, 54, 55, 56, 57 and 58)

PERMISSION TO MANUFACTURE NEW DRUG OR INVESTIGATIONAL NEW DRUG FOR CLINICAL TRIAL, BIOAVAILABILITY OR BIOEQUIVALENCE STUDY OR FOR EXAMINATION, TEST AND ANALYSIS**Licence Number: CT11/BIO/23/000103**

The Central Licencing Authority hereby grant permission to M/s Reliance Life Sciences, Center, R-282, TTC Area of MIDC, Thane -Belapur Road, Rabale, Navi Mumbai (India) – 400 701 Telephone No.: 022-40678770 FAX: 022-40678099 to manufacture the new drug or investigational new drug **“RLS Protein Subunit Vaccine against SARS-CoV-2 Virus 10 µg (RelCoVax®)”** for conduct of clinical trial or bioavailability or bioequivalence study as per Protocol no.: RLS/VAC/2023/01, Version 3.0, Dated: 30-Jun-2023 in the below mentioned clinical trial sites or bioavailability and bioequivalence study centre [As per Annexure] or for examination, test and analysis.

S. No.	Name of the new drug or investigational new drug to be manufactured.	Class of new drug or investigational new drug	Quantity to be manufactured														
1.	RLS Protein Subunit Vaccine against SARS-CoV-2 Virus 10 µg (RelCoVax®) <table><tr><td colspan="2">Each dose of 0.5 ml contains:</td></tr><tr><td>Active ingredient</td><td>Quantity</td></tr><tr><td>Receptor Binding Domain (RBD) of SARS CoV 2</td><td>10 mg</td></tr><tr><td>Nucleocapsid protein of SARS Cov2 Virus</td><td>10 mg</td></tr><tr><td>Aluminium Hydroxide Gel</td><td>0.5 mg</td></tr><tr><td>Phosphorothioate Oligo oligonucleotide</td><td>0.2 mg</td></tr><tr><td>2-Phenoxy ethanol</td><td>5 mg</td></tr></table>	Each dose of 0.5 ml contains:		Active ingredient	Quantity	Receptor Binding Domain (RBD) of SARS CoV 2	10 mg	Nucleocapsid protein of SARS Cov2 Virus	10 mg	Aluminium Hydroxide Gel	0.5 mg	Phosphorothioate Oligo oligonucleotide	0.2 mg	2-Phenoxy ethanol	5 mg	Vaccine	8000 vials
Each dose of 0.5 ml contains:																	
Active ingredient	Quantity																
Receptor Binding Domain (RBD) of SARS CoV 2	10 mg																
Nucleocapsid protein of SARS Cov2 Virus	10 mg																
Aluminium Hydroxide Gel	0.5 mg																
Phosphorothioate Oligo oligonucleotide	0.2 mg																
2-Phenoxy ethanol	5 mg																

- This licence is subject to the conditions specified in the Chapter VIII of New Drugs and Clinical Trials Rules, 2019 under the Drugs and Cosmetics Act, 1940.
- This licence shall, unless previously suspended or revoked, be in force for a period of three years from the date of its issuance.
- Details of manufacturer and manufacturing site under this licence.

S. No.	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).
1.	M/s Reliance Life Sciences, Center, R-282 TTC Area Of MIDC, Thane -Belapur	For RBD Drug substance: M/s Reliance Life Sciences Private Limited,

Road, Rabale Navi Mumbai (India) – 400701 Telephone No.: 022-40678770 FAX: 022-40678099	Dhirubhai Ambani Life Sciences Center, Plot No. R-282, Plant # 2, first Floor, DS Suite-Mammalian, TTC Area of MIDC, Thane - Belapur Road, Rabale, Navi Mumbai – 400701, India. For Nucleocapsid Drug substance: M/s Reliance Life Sciences Private Limited, Dhirubhai Ambani Life Sciences Center, Plot No. R-282, Plant # 2, first Floor, DS Suite-Microbial, TTC Area of MIDC, Thane - Belapur Road, Rabale, Navi Mumbai – 400701, India. Drug Product formulation: M/s Reliance Life Sciences Private Limited, Dhirubhai Ambani Life Sciences Center, Plot No. R-282, Plant # 2, Ground Floor, DP Suite, TTC Area of MIDC, Thane - Belapur Road, Rabale, Navi Mumbai – 400701, India
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Place: New Delhi
Date:

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Note: The permission is “For Clinical Trial Purpose and not for commercial use”.

Annexure:

Details of clinical trial sites:

S. No.	Name and Address of Clinical Trial Site	Ethics Committee details	Name of Principal Investigator
1	D Y Patil University School of Medicine and Hospital Plot NO. 2, Sector-5, Nerul, Navi Mumbai, Thane, Maharashtra-400706, India	Institutional Ethics Committee, D Y Patil Medical College and Research Centre [ECR/195/Inst/MH/2013/RR-19]	Dr. Deepak Kumar Langade
2	Grant Government Medical College & Sir J.J. Group of Hospitals, Byculla, Mumbai-400008. Maharashtra, India	Institutional Ethics Committee , GGMC, Mumbai [ECR/382/Inst/MH/2013/RR-19]	Dr. Akash Khobragade
3	Medipoint Hospitals Pvt. Ltd, 241/1, New D. P. Road, Aundh, Pune-411007, Maharashtra, India	Institutional Ethics Committee, Penta-Med Ethics Committee, Medipoint Hospitals Pvt. Ltd. [ECR/357/Inst/MH/2013/RR-20]	Dr. Vivek Sheloje
4	Bharati Vidyapeeth (Deemed to be University) Medical College	Institutional Ethics Committee, Bharati Vidyapeeth Medical	Dr. Prachee Makashir

	and Hospital, Pune	College and Hospital, Pune [ECR/313/Inst/MH/2013/RR-19]	
5	Orchid Speciality Hospital, L-Square, Porwal Road, Sr.No-282-3/3, Off,Dhanori JakatNaka, Lohgaon, Pune- 411047, Maharashtra,India	Institutional Ethics Committee, Orchid Speciality Hospital, L- Square, Porwal Road. [ECR/1089/Inst/MH/2018/RR-21]	Dr. Ashish Goyal
6	Lokmanya Tilak Municipal Medical College & General Hospital, Sion, Mumbai - 400022, Maharashtra, India	Institutional Ethics Committee, Lokmanya Tilak Municipal Medical College & General Hospital, Sion, Mumbai [ECR/266/Lokmanya/Inst/MH/2013 /RR-19]	Dr. Sudhir Pawar
7	IPGME&R and SSKM Hospital ,244, AJC Bose Road, Kolkata- 700020	IPGME&R Resaerch Oversight Committee,IPGME&R and SSKM Hospital ,244, AJC Bose Road,Bhowanipore,Kolkata- 700020 [ECR/35/Inst/WB/2013/RR-19]	Dr. Anupam Mandal
8	Dr. D.Y Patil Medical college and hospital and Research centre, Sant Tukaram Nagar Pimpri,Pune 411018	Ethics Committee Dr. D.Y Patil Vidyapeeth, Dr. D.Y Patil Medical college and hospital and Research centre, Sant Tukaram Nagar Pimpri,Pune 411018 [ECR361/Inst/MH/2013/RR-19]	Dr. Shrikant Tripathy
9	GMERS Medical College and civil Hospital Sola, Nr Gujrat Highcourt, S.G Highway, Sola Ahmedabad, 380061, Gujrat India	Institutional Ethics Committee, GMERS Medical College and Civil Hospital, Nr Gujrat Highcourt, S.G Highway, Sola [ECR/404/Inst/GJ/2013/RR-20]	Dr. Parul Bhatt
10	Belagavi Institute Of Medical Sciences ,Dr B R Ambedkar Rd, Sadashiv Nagar, Belagavi, Karnataka 590019	Institutional Ethics Committee BIMS, Belagavi Institute of medical science, B.R Ambedkar road Belgavi, 590001, Karnataka India [ECR/801/Inst/KA/2016/RR-20]	Dr. Sandeep Dandin
11	Sheth Vadilal Sarabhai General Hospital, Sheth Chinai Maternity Hospital Ellisbridge, Ahmedabad, Gujarat 380006	Sangini Hospital Ethics Committee, C/o Sangini Hospital 1st Floor, Santorini square, B/h Abhishree Complex, Opposite star bazar lane, Satellite Ahemedabad, 380015 [ECR/147/Inst/GJ/2013/RR-19]	Dr, Devang Rana
12	S.M.S. Medical College and Attached Hospitals .J.L.N. Marg, Jaipur Rajasthan -302004	Ethics Committee S.M.S. Medical College and Attached Hospitals J.L.N. Marg Jaipur Rajasthan - 302004 India [ECR/26/Inst/RJ/2013/RR-19]	Dr. Sunil Kumar mahavar
13	KEM Hospital Research Center Vadhu Budruk,Tal- Shirur, Dist Pune Maharashtra 412216	KEM Hospital research centre ethics Committee, sardar moodliar road, rasta peth, pune 41101	Dr. Anand Kawade

		[ECR/272/Inst/MH/2013/RR-22]	
14	Department of Medicine, King George's Medical University, Shah Mina Rd, Chowk, Lucknow, Uttar Pradesh 226003	Institutional ethics committee, research cell, administrative block, King George medical university, chowk, Lucknow 226003 [ECR/262/Inst/Up/2013/RR-19]	Dr. D Himanshu
15	Chopda Medicare & Research Center Pvt. Ltd: Magnum Heart Institute, 3/5, Patil Lane No.1, Laxmi Nagar, Near K.B.H. Vidyalaya, Canada Corner, Nashik - 4222005, Maharashtra India	Magna-Care Ethics Committee, C/o Chopda Medicare and research centre Pvt Ltd; Magnum heart institute, Patil Lane no 1, Near K.B.H Vidyalaya, Canada Corner, Nashik-422005, Maharashtra [ECR/79/Inst/MH/2013/RR-19]	Dr. Swapnil Sakhala
16	Department of Anaesthesiology & Critical Care, MLB Medical College, Kanpur, Jhansi(U.P.)284128	Ethics Committee M.L.B Medical college, MLB Medical College and Associated Hospital, MLB college road Kanpur road, Jhansi, Uttar Pradesh- 284128 [ECR/1393/Inst/UP/2020]	Dr. Anshul Jain
17	Department of General Medicine, Rajendra Prasad Ward, King George Hospital, Maharanipeta, Vishakhapatnam-530002, Andhra Pradesh India	Institutional Ethics Committee, King George Hospital King George Hospital, Maharanipeta, Visakhapatnam-530002 Andhra Pradesh [ECR/197/Inst/KGH/2013/RR-20]	Dr. Kontham Rambabu
18	Department of Medicine, RCSM Govt. Medical college & CPR hospital, Dasara Chowk, Bhausingji road, Town Hall Kolhapur-416012, Maharashtra, India.	Rajarshree Chhatrapati Shahu Maharaj Govt. Medical College and Chhatrapati Pramila Raje Hospital, Kolhapur Institutional ethics Committee 2 (RCSMGMCI EC2), Dasara Chowk, Bhausingji road, town hall, Kolhapur-416012 Maharashtra India [ECR/703/Inst/MH/2015/RR-20]	Dr. Vijaykumar Barge
19	Oyster & Pearl Hospital (Phadnis Clinic Pvt Ltd) 1671 - 75, Ganeshkhind Road, Shivajinagar Pune, 411005, Maharashtra, India	O & P institutional committee, Oyster & Pearl Hospital (Phadnis Clinic Pvt Ltd) 1671 -75, Ganeshkhind Road Shivajinagar Pune, 411005, Maharashtra, India [ECR/71/Inst/EC/2013/RR-19]	Dr. Aniket Joshi
20	Department of Medicine, Shree Siddhivinayak Maternity & Nursing home, Unity Campus, Opp. KTHM College, Gangapur Road, Nasik 422002, Maharashtra India	Shree Siddhivinayak Hospital Ethics Committee, C/O Shree Siddhivinayak Maternity & Nursing home, Unity Campus, Opp. KTHM College, Gangapur Road, Nasik 422002, Maharashtra India [ECR/1247/Inst/MH/2019]	Dr. Sandesh Patil



**PERMISSION TO MANUFACTURE UNAPPROVED ACTIVE PHARMACEUTICAL
INGREDIENT FOR THE DEVELOPEMNT OF FORMULATION FOR TEST OR ANALYSIS OR
CLINICAL TRIAL OR BIOAVAILABILITY OR BIOEQUIVALENCE STUDY**

Licence Number: CT15/BIO/23/000016

The Central Licencing Authority hereby grant permission to M/s Reliance Life Sciences Pvt Ltd Dhirubhai Ambani Life Sciences Center, R-282 TTC Area Of MIDC, Thane -Belapur Road, Rabale Navi Mumbai (India) – 400701, Telephone No.: 022-40678770 FAX: 022-40678099, E-Mail : bobby.george@relbio.com to manufacture the unapproved active pharmaceutical ingredient specified below to manufacture its formulation ~~for test or analysis or for conduct of clinical trial or bioavailability or bioequivalence study.~~

S. No.	Name of the unapproved active pharmaceutical ingredient (API) to be manufactured.	Quantity to be manufactured
1.	SARS-CoV 2 Receptor Binding Domain (RBD	90 grams
2	SARS-CoV 2 Nucleocapsid (NC)	30 grams

5. Details of Manufacturer, Manufacturing site of active pharmaceutical ingredient.

S. No.	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).
1.	M/s Reliance Life Sciences Pvt. Ltd., Dhirubhai Ambani Life Sciences Center (DALC), R-282 TTC area of MIDC, Thane -Belapur Road, Rabale, Navi Mumbai, Maharashtra (India) - 400701 Telephone No.: 02235338000 FAX: 02235338099	For RBD Drug substance: M/s Reliance Life Sciences Private Limited, Dhirubhai Ambani Life Sciences Center, Plot No. R-282, Plant # 2, first Floor, DS Suite-Mammalian, TTC Area of MIDC, Thane - Belapur Road, Rabale, Navi Mumbai – 400701, India. For Nucleocapsid Drug substance: M/s Reliance Life Sciences Private Limited, Dhirubhai Ambani Life Sciences Center, Plot No. R-282, Plant # 2, first Floor, DS Suite-Microbial, TTC Area of MIDC, Thane - Belapur Road, Rabale, Navi Mumbai – 400701, India. Telephone No.: 02235338000 FAX: 02235338099

3. Details of Manufacturer, Manufacturing site of formulation manufacturer to be supplied.

S. No.	Name and address of formulator (Full address with telephone, fax and e-mail address of the manufacturer).	Name and address of site where the manufactured unapproved active pharmaceutical ingredient to be used (full address with telephone, fax and e-mail address of the manufacturing site).
1.	M/s Reliance Life Sciences Pvt. Ltd., Dhirubhai Ambani Life Sciences Center (DALC), R-282 TTC area of	M/s Reliance Life Sciences Private Limited, Dhirubhai Ambani Life Sciences Center, Plot No. R-282, Plant # 2, Ground Floor, DP Suite,

MIDC, Thane -Belapur Road, Rabale, Navi Mumbai, Maharashtra (India) - 400701 Telephone No.: 02235338000 FAX: 02235338099	TTC Area of MIDC, Thane - Belapur Road, Rabale, Navi Mumbai – 400701, India
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4. This permission is subject to the conditions specified in the Chapter VIII of New Drugs and Clinical Trials Rules, 2019 under the Drugs and Cosmetics Act, 1940.
5. This permission shall, unless previously suspended or revoked, be in force for a period of three years from the date of its issuance.

Place: New Delhi

Date:

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Annexure:**Details of record of unapproved active pharmaceutical ingredient manufactured:**

S. No.	Date of manufacture	License number	Name of the unapproved active ingredient	Quantity manufactured	Manufactured for
1.	NA	NA	NA	NA	NA

Details of reconciliation of unapproved active pharmaceutical ingredient manufactured:

Date	Name of the unapproved active pharmaceutical ingredient	License number	Quantity manufactured	Quantity supplied	Quantity remained	Supplied to	Quantity-left over or remain unused or got damaged or expired or found of sub-standard quality	Action taken
NA	Receptor Binding Domain of SARS cov- 2	NA	NA	NA	NA	NA	NA	NA
NA	SARS-CoV 2 Nucleocapsid (NC)	NA	NA	NA	NA	NA	NA	NA

Note: The permission is “for Clinical Trial purpose and not for Commercial use”