

Status of COVID-19 Medicines and Active Pharmaceutical Ingredients (APIs)
25 September 2024

	Manufacturer/Applicant	Name of Medicine/API	Type of Application	Date of publication of the EOI	Advisory meetings/interactions*	Pre-submission meeting held	Dossier accepted for assessment	Status of Assessment	Date of prequalification
1	FarmaK JSC, Ukraine	Dexamethasone (sodium phosphate) 3.3mg/ml injection, 1ml ampoules	FPP prequalification	10-Jul-20	✓	✓	✓	Prequalified	05-Nov-20
2	Demo SA, Greece	Dexamethasone (sodium phosphate) 3.3mg/ml injection, 2ml ampoules	FPP prequalification	10-Jul-20	✓	✓	✓	Prequalified	29-Sep-21
3	Noridem Enterprises Ltd, Cyprus	Dexamethasone (sodium phosphate) 3.3mg/ml injection, 1ml ampoules	FPP prequalification	10-Jul-20	✓	✓	✓	Prequalified	17-Dec-21
4	Aurobindo Pharma Ltd., India	Molnupiravir 200mg capsules	FPP prequalification	15-Nov-21	✓	✓	✓	Prequalified	18-Dec-23
5	Cipla, India	Molnupiravir 200mg capsules	FPP prequalification	15-Nov-21	✓	✓	✓	Prequalified	18-Dec-23
6	Dr Reddy's, India	Molnupiravir 200mg capsules	FPP prequalification	15-Nov-21	✓	✓	✓	Prequalified	17-Apr-23
7	Emcure Pharmaceuticals, India	Molnupiravir 200mg capsules	FPP prequalification	15-Nov-21	✓	✓	✓	Prequalified	26-Dec-22
8	Hetero Labs, India	Molnupiravir 200mg capsules	FPP prequalification	15-Nov-21	✓	✓	✓	Prequalified	21-Sep-22
9	Laurus Labs, India	Molnupiravir 200mg capsules	FPP prequalification	15-Nov-21	✓				
10	Mylan, India	Molnupiravir 200mg capsules	FPP prequalification	15-Nov-21	✓	✓	✓	Prequalified	23-May-24
11	PT Kimia Farma	Molnupiravir 200mg capsules	FPP prequalification	15-Nov-21	✓	✓	✓	Withdrawn by the applicant	
12	Optimus Pharma, India	Molnupiravir 200mg capsules	FPP prequalification	15-Nov-21	✓				
13	Shanghai Desano, China	Molnupiravir 200mg capsules	FPP prequalification	15-Nov-21	✓	✓	✓	Prequalified	15-Jul-24
14	Shanghai Fosun, China	Molnupiravir 200mg capsules	FPP prequalification	15-Nov-21	✓	✓	✓	Prequalified	15-Jul-24
15	Stellapharm, Viet Nam	Molnupiravir 200mg capsules	FPP prequalification	15-Nov-21	✓	✓	✓	Withdrawn by the applicant	
16	Strides Pharma, India	Molnupiravir 200mg capsules	FPP prequalification	15-Nov-21	✓	✓	✓	Withdrawn by the applicant	
17	Sun Pharma	Molnupiravir 200mg capsules	FPP prequalification	15-Nov-21	✓	✓	✓	Withdrawn by the applicant	
18	Torrent Pharmaceuticals., India	Molnupiravir 200mg capsules	FPP prequalification	15-Nov-21	✓				
19	VKT Pharma, India	Molnupiravir 200mg capsules	FPP prequalification	15-Nov-21	✓	✓			
20	Celltrion, Republic of Korea	Nirmatrelvir 150mg + ritonavir 100mg co-packaged tablets	FPP prequalification	17-Dec-21	✓	✓	✓	Prequalified	10-Oct-23
21	Cipla, India	Nirmatrelvir 150mg + ritonavir 100mg co-packaged tablets	FPP prequalification	17-Dec-21	✓	✓	✓	Under assessment	
22	Pfizer, USA	Nirmatrelvir 150mg + ritonavir 100mg co-packaged tablets	FPP prequalification	17-Dec-21	✓	✓	✓	Prequalified	22-Apr-22
23	Shanghai Fosun, China	Nirmatrelvir 150mg + ritonavir 100mg co-packaged tablets	FPP prequalification	17-Dec-21	✓	✓	✓	Prequalified	04-Sep-24

24	Hetero Labs, India	Nirmatrelvir 150mg + ritonavir 100mg co-packaged tablets	FPP prequalification	17-Dec-21	✓	✓	✓	Prequalified	25-Dec-22
25	Macleods, India	Nirmatrelvir 150mg + ritonavir 100mg co-packaged tablets	FPP prequalification	17-Dec-21	✓	✓	✓	Under assessment	
26	Mylan, India	Nirmatrelvir 150mg + ritonavir 100mg co-packaged tablets	FPP prequalification	17-Dec-21	✓	✓	✓	Under assessment	
27	Neolpharma, Puerto Rico	Nirmatrelvir 150mg + ritonavir 100mg co-packaged tablets	FPP prequalification	17-Dec-21	✓				
28	Shanghai Desano, India	Nirmatrelvir 150mg + ritonavir 100mg co-packaged tablets	FPP prequalification	17-Dec-21	✓	✓	✓	Under assessment	
29	Strides Pharma, India	Nirmatrelvir 150mg + ritonavir 100mg co-packaged tablets	FPP prequalification	17-Dec-21	✓	✓			
30	Syngene Int Ltd	Nirmatrelvir 150mg + ritonavir 100mg co-packaged tablets	FPP prequalification	17-Dec-21	✓				
31	Yaopharma, China	Nirmatrelvir 150mg + ritonavir 100mg co-packaged tablets	FPP prequalification	17-Dec-21	✓				
32	Zhejiang Apelo Kangyu, China	Nirmatrelvir 150mg + ritonavir 100mg co-packaged tablets	FPP prequalification	17-Dec-21	✓	✓	✓	Prequalified	08-Nov-23
33	Zhejiang Huahai Pharm, China	Nirmatrelvir 150mg + ritonavir 100mg co-packaged tablets	FPP prequalification	17-Dec-21	✓	✓	✓	Prequalified	18-Dec-23
34	BF Biosciences Ltd, Pakistan	Remdesivir	FPP prequalification	17-Dec-21	✓				
35	Gilead, Ireland	Remdesivir	FPP prequalification	29-Mar-22	✓	✓	✓	Prequalified	25-Apr-22
36	Hetero Labs, India	Remdesivir	FPP prequalification	29-Mar-22	✓	✓	✓	Additional information requested	
37	Roche Products Ltd, UK	Tocilizumab inj for further dilution for IV infusion (3 products)	BTP prequalification	19-May-21	✓	✓	✓	Prequalified	10-Feb-22 (3 products)
38	Hetero Labs, India	Tocilizumab inj for further dilution for IV infusion	BTP prequalification	19-May-21	✓				
39	GSK, UK	Sotrovimab solution for infusion	BTP prequalification	25-Nov-21	✓				
40	Tianjin Tianyao Pharmaceuticals Co., Ltd, PRC	Dexamethasone	API prequalification	10-Jul-20	✓	N/A	✓	Prequalified	27-Jan-21
41	Tianjin Tianyao Pharmaceuticals Co., Ltd, PRC	Dexamethasone sodium phosphate	API prequalification	10-Jul-20	✓	N/A	✓	Prequalified	27-Jan-21
42	Aurobindo Pharma Ltd., India	Molnupiravir	API prequalification	16-Nov-21	✓	N/A	✓	Under assessment	
43	Aurore Life Sciences, India	Molnupiravir	API prequalification	16-Nov-21	✓	N/A	✓	Prequalified	19-Sep-24
44	Biophore India Pharmaceuticals Pvt. Ltd	Molnupiravir	API prequalification	16-Nov-21		N/A	✓	Additional information requested	
45	Divi Laboratories Ltd	Molnupiravir	API prequalification	16-Nov-21	✓	N/A	✓	Prequalified	29-Sep-22
46	Dr Reddy's Laboratories Ltd, India	Molnupiravir	API prequalification	16-Nov-21	✓	N/A	✓	Additional information requested	
47	Emcure Pharmaceuticals, India	Molnupiravir	API prequalification	16-Nov-21	✓	N/A	✓	Prequalified	21-Oct-22
48	Laurus Labs, India	Molnupiravir	API prequalification	16-Nov-21	✓	N/A	✓	Additional information requested	

49	Mylan Laboratories Ltd	Molnupiravir	API prequalification	16-Nov-21				Additional information requested	
50	Optimus Drugs, India	Molnupiravir	API prequalification	16-Nov-21	✓	N/A	✓	Under assessment	
51	Shanghai Desano, China	Molnupiravir	API prequalification	16-Nov-21	✓	N/A	✓	Under assessment	
52	Arene Life Sciences Private Limited	Nirmatrelvir	API prequalification	14-Jan-22				Additional information requested	
53	Aurore Life Sciences Private Limited	Nirmatrelvir	API prequalification	14-Jan-22	✓	N/A	✓	Additional information requested	
54	Dongbang Future Tech & Life Co Ltd	Nirmatrelvir	API prequalification	14-Jan-22				Additional information requested	
55	Mylan Laboratories Limited	Nirmatrelvir	API prequalification	14-Jan-22				Additional information requested	
56	Shanghai Desano, China	Nirmatrelvir	API prequalification	14-Jan-22		N/A	✓	Under assessment	
57	Shanghai Fosun Pharmaceutical Industrial Development Co. Ltd.	Nirmatrelvir	API prequalification	14-Jan-22		N/A	✓	Additional information requested	
58	Zhejiang Apelo Kangyu Pharmaceutical Co., Ltd	Nirmatrelvir	API prequalification	14-Jan-22	✓	N/A	✓	Under assessment	
59	Zhejiang Huahai Pharmaceutical Co Ltd	Nirmatrelvir	API prequalification	14-Jan-22	✓	N/A	✓	Under assessment	
60	Zhejiang Jiuzhou Pharmaceutical Co, Ltd	Nirmatrelvir	API prequalification	14-Jan-22	✓	N/A	✓	Under assessment	
61	Zenji Pharmaceuticals	Remdesivir	API prequalification	15-Jan-22		N/A	✓	Additional information requested	
	* Ongoing advisory type interactions while the manufacturer continues to work on a possible submission. Includes clarification of requirements, review of data required to support a possible BCS based biowaiver or advice in terms of biosimilar development								