

Status of COVID-19 Medicines and Active Pharmaceutical Ingredients (APIs)
23 May 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	Fosun, China	Molnupiravir 200mg capsules	FPP prequalification	15-Nov-21	✓	✓	✓	Dossier cleared. Inspection issues	
9	Hetero Labs, India	Molnupiravir 200mg capsules	FPP prequalification	15-Nov-21	✓	✓	✓	Prequalified	21-Sep-22
10	Laurus Labs, India	Molnupiravir 200mg capsules	FPP prequalification	15-Nov-21	✓				
11	Mylan, India	Molnupiravir 200mg capsules	FPP prequalification	15-Nov-21	✓	✓	✓	Prequalified	23-May-24
12	PT Kimia Farma	Molnupiravir 200mg capsules	FPP prequalification	15-Nov-21	✓	✓	✓	Under assessment	
13	Optimus Pharma, India	Molnupiravir 200mg capsules	FPP prequalification	15-Nov-21	✓				
14	Shanghai Desano, China	Molnupiravir 200mg capsules	FPP prequalification	15-Nov-21	✓	✓	✓	Under assessment	
15	Stellapharm, Viet Nam	Molnupiravir 200mg capsules	FPP prequalification	15-Nov-21	✓	✓	✓	Withdrawn by the applicant	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	✓	✓	✓	Dossier cleared. Inspection issues	
17	Sun Pharma	Molnupiravir 200mg capsules	FPP prequalification	15-Nov-21	✓	✓	✓	Withdrawn by the applicant	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	Fosun Pharma	Nirmatrelvir 150mg + ritonavir 100mg co-packaged tablets	FPP prequalification	17-Dec-21	✓	✓	✓	Under assessment	
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	Shanghai Desano, India	Nirmatrelvir 150mg + ritonavir 100mg co-packaged tablets	FPP prequalification	17-Dec-21	✓	✓	✓	Under assessment	
28	Strides Pharma, India	Nirmatrelvir 150mg + ritonavir 100mg co-packaged tablets	FPP prequalification	17-Dec-21	✓	✓			
29	Syngene Int Ltd	Nirmatrelvir 150mg + ritonavir 100mg co-packaged tablets	FPP prequalification	17-Dec-21	✓				
30	Yaopharma, China	Nirmatrelvir 150mg + ritonavir 100mg co-packaged tablets	FPP prequalification	17-Dec-21	✓				
31	Zhejiang Apelo Kangyu, China	Nirmatrelvir 150mg + ritonavir 100mg co-packaged tablets	FPP prequalification	17-Dec-21	✓	✓	✓	Prequalified	08-Nov-23
32	Zhejiang Huahai Pharm, China	Nirmatrelvir 150mg + ritonavir 100mg co-packaged tablets	FPP prequalification	17-Dec-21	✓	✓	✓	Prequalified	18-Dec-23
33	BF Biosciences Ltd, Pakistan	Remdesivir	FPP prequalification	17-Dec-21	✓				
34	Gilead, Ireland	Remdesivir	FPP prequalification	29-Mar-22	✓	✓	✓	Prequalified	25-Apr-22
35	Hetero Labs, India	Remdesivir	FPP prequalification	29-Mar-22	✓	✓	✓	Additional information requested	
36	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)
37	Hetero Labs, India	Tocilizumab inj for further dilution for IV infusion	BTP prequalification	19-May-21	✓				
38	GSK, UK	Sotrovimab solution for infusion	BTP prequalification	25-Nov-21	✓				
39	Tianjin Tianyao Pharmaceuticals Co., Ltd, PRC	Dexamethasone	API prequalification	10-Jul-20	✓	N/A	✓	Prequalified	27-Jan-21
40	Tianjin Tianyao Pharmaceuticals Co., Ltd, PRC	Dexamethasone sodium phosphate	API prequalification	10-Jul-20	✓	N/A	✓	Prequalified	27-Jan-21
41	Aurobindo Pharma Ltd., India	Molnupiravir	API prequalification	16-Nov-21	✓	N/A	✓	Under assessment	
42	Aurore Life Sciences, India	Molnupiravir	API prequalification	16-Nov-21	✓	N/A	✓	Under assessment	
43	Biophore India Pharmaceuticals Pvt. Ltd	Molnupiravir	API prequalification	16-Nov-21		N/A	✓	Under assessment	
44	Divi Laboratories Ltd	Molnupiravir	API prequalification	16-Nov-21	✓	N/A	✓	Prequalified	29-Sep-22
45	Dr Reddy's Laboratories Ltd, India	Molnupiravir	API prequalification	16-Nov-21	✓	N/A	✓	Additional information requested	
46	Emcure Pharmaceuticals, India	Molnupiravir	API prequalification	16-Nov-21	✓	N/A	✓	Prequalified	21-Oct-22
47	Laurus Labs, India	Molnupiravir	API prequalification	16-Nov-21	✓	N/A	✓	Additional information requested	

48	Mylan Laboratories Ltd	Molnupiravir	API prequalification	16-Nov-21				Additional information requested	
49	Optimus Drugs, India	Molnupiravir	API prequalification	16-Nov-21	✓	N/A	✓	Under assessment	
50	Shanghai Desano, China	Molnupiravir	API prequalification	16-Nov-21	✓	N/A	✓	Under assessment	
51	Arene Life Sciences Private Limited	Nirmatrelvir	API prequalification	14-Jan-22				Additional information requested	
52	Aurore Life Sciences Private Limited	Nirmatrelvir	API prequalification	14-Jan-22	✓	N/A	✓	Additional information requested	
53	Dongbang Future Tech & Life Co Ltd	Nirmatrelvir	API prequalification	14-Jan-22				Additional information requested	
54	Mylan Laboratories Limited	Nirmatrelvir	API prequalification	14-Jan-22				Additional information requested	
55	Shanghai Desano, China	Nirmatrelvir	API prequalification	14-Jan-22		N/A	✓	Under assessment	
56	Shanghai Fosun Pharmaceutical Industrial Development Co. Ltd.	Nirmatrelvir	API prequalification	14-Jan-22		N/A	✓	Additional information requested	
57	Zhejiang Apelo Kangyu Pharmaceutical Co., Ltd	Nirmatrelvir	API prequalification	14-Jan-22	✓	N/A	✓	Under assessment	
58	Zhejiang Huahai Pharmaceutical Co Ltd	Nirmatrelvir	API prequalification	14-Jan-22	✓	N/A	✓	Under assessment	
59	Zhejiang Jiuzhou Pharmaceutical Co, Ltd	Nirmatrelvir	API prequalification	14-Jan-22	✓	N/A	✓	Under assessment	
60	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								