

	Status of COVID-19 Medicines and Active Pharmaceutical Ingredients (APIs) 19 November 2025								
	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4	Aurobindo Pharma Ltd., India	Molnupiravir 200mg capsules	FPP prequalification	15-Nov-21	✓	✓	✓	Withdrawn by the applicant (was prequalified)	18-Dec-23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	MSN Lab, India	Molnupiravir 200mg capsules	FPP prequalification	15-Nov-21	✓	✓	✓	Under assessment	
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12	PT Kimia Farma	Molnupiravir 200mg capsules	FPP prequalification	15-Nov-21	✓	✓	✓	Withdrawn by the applicant	
13	Optimus Pharma, India	Molnupiravir 200mg capsules	FPP prequalification	15-Nov-21	✓				
14	Shanghai Desano, China	Molnupiravir 200mg capsules	FPP prequalification	15-Nov-21	✓	✓	✓	Prequalified	15-Jul-24
15	Shanghai Fosun, China	Molnupiravir 200mg capsules	FPP prequalification	15-Nov-21	✓	✓	✓	Prequalified	15-Jul-24
16	Stellapharm, Viet Nam	Molnupiravir 200mg capsules	FPP prequalification	15-Nov-21	✓	✓	✓	Withdrawn by the applicant	
17	Strides Pharma, India	Molnupiravir 200mg capsules	FPP prequalification	15-Nov-21	✓	✓	✓	Withdrawn by the applicant	
18	Sun Pharma	Molnupiravir 200mg capsules	FPP prequalification	15-Nov-21	✓	✓	✓	Withdrawn by the applicant	
19	Torrent Pharmaceuticals., India	Molnupiravir 200mg capsules	FPP prequalification	15-Nov-21	✓				
20	VKT Pharma, India	Molnupiravir 200mg capsules	FPP prequalification	15-Nov-21	✓	✓			
21	Celltrion, Republic of Korea	Nirmatrelvir 150mg + ritonavir 100mg co-packaged tablets	FPP prequalification	17-Dec-21	✓	✓	✓	Prequalified	10-Oct-23
22	Cipla, India	Nirmatrelvir 150mg + ritonavir 100mg co-packaged tablets	FPP prequalification	17-Dec-21	✓	✓	✓	Under assessment	

23	Pfizer, USA	Nirmatrelvir 150mg + ritonavir 100mg co-packaged tablets	FPP prequalification	17-Dec-21	✓	✓	✓	Prequalified	22-Apr-22
24	Shanghai Fosun, China	Nirmatrelvir 150mg + ritonavir 100mg co-packaged tablets	FPP prequalification	17-Dec-21	✓	✓	✓	Prequalified	04-Sep-24
25	Hetero Labs, India	Nirmatrelvir 150mg + ritonavir 100mg co-packaged tablets	FPP prequalification	17-Dec-21	✓	✓	✓	Prequalified	25-Dec-22
26	Macleods, India	Nirmatrelvir 150mg + ritonavir 100mg co-packaged tablets	FPP prequalification	17-Dec-21	✓	✓	✓	Withdrawn by the applicant	
27	Mylan, India	Nirmatrelvir 150mg + ritonavir 100mg co-packaged tablets	FPP prequalification	17-Dec-21	✓	✓	✓	Prequalified	19-Dec-24
28	Neolpharma, Puerto Rico	Nirmatrelvir 150mg + ritonavir 100mg co-packaged tablets	FPP prequalification	17-Dec-21	✓	✓	✓	Under assessment	
29	Shanghai Desano, India	Nirmatrelvir 150mg + ritonavir 100mg co-packaged tablets	FPP prequalification	17-Dec-21	✓	✓	✓	Prequalified	27-Sep-24
30	Strides Pharma, India	Nirmatrelvir 150mg + ritonavir 100mg co-packaged tablets	FPP prequalification	17-Dec-21	✓	✓			
31	Syngene Int Ltd	Nirmatrelvir 150mg + ritonavir 100mg co-packaged tablets	FPP prequalification	17-Dec-21	✓				
32	Yaopharma, China	Nirmatrelvir 150mg + ritonavir 100mg co-packaged tablets	FPP prequalification	17-Dec-21	✓				
33	Zhejiang Apelo Kangyu, China	Nirmatrelvir 150mg + ritonavir 100mg co-packaged tablets	FPP prequalification	17-Dec-21	✓	✓	✓	Prequalified	08-Nov-23
34	Zhejiang Huahai Pharm, China	Nirmatrelvir 150mg + ritonavir 100mg co-packaged tablets	FPP prequalification	17-Dec-21	✓	✓	✓	Prequalified	18-Dec-23
35	BF Biosciences Ltd, Pakistan	Remdesivir	FPP prequalification	17-Dec-21	✓				
36	Gilead, Ireland	Remdesivir	FPP prequalification	29-Mar-22	✓	✓	✓	Prequalified	25-Apr-22
37	Hetero Labs, India	Remdesivir	FPP prequalification	29-Mar-22	✓	✓	✓	Prequalified	14-May-25
38	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)
39	Hetero Labs, India	Tocilizumab inj for further dilution for IV infusion	BTP prequalification	19-May-21	✓				
40	GSK, UK	Sotrovimab solution for infusion	BTP prequalification	25-Nov-21	✓				
41	Tianjin Tianyao Pharmaceuticals Co., Ltd, PRC	Dexamethasone	API prequalification	10-Jul-20	✓	N/A	✓	Prequalified	27-Jan-21
42	Tianjin Tianyao Pharmaceuticals Co., Ltd, PRC	Dexamethasone sodium phosphate	API prequalification	10-Jul-20	✓	N/A	✓	Prequalified	27-Jan-21
43	Aurobindo Pharma Ltd., India	Molnupiravir	API prequalification	16-Nov-21	✓	N/A	✓	Under assessment	
44	Aurore Life Sciences, India	Molnupiravir	API prequalification	16-Nov-21	✓	N/A	✓	Prequalified	19-Sep-24
45	Biophore India Pharmaceuticals Pvt. Ltd	Molnupiravir	API prequalification	16-Nov-21		N/A	✓	Additional information requested	
46	Divi Laboratories Ltd	Molnupiravir	API prequalification	16-Nov-21	✓	N/A	✓	Prequalified	29-Sep-22
47	Dr Reddy's Laboratories Ltd, India	Molnupiravir	API prequalification	16-Nov-21	✓	N/A	✓	Additional information requested	
48	Emcure Pharmaceuticals, India	Molnupiravir	API prequalification	16-Nov-21	✓	N/A	✓	Withdrawn by the applicant (was prequalified)	21-Oct-22

49	Laurus Labs, India	Molnupiravir	API prequalification	16-Nov-21	✓	N/A	✓	Additional information requested	
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