

GCP Inspections Registry at EDA

SN	Study Code (Specified as per the submitted protocol)	Intervention(s) “Used IMPs & its type (Biological, Pharmaceutical, Innovative, Herbal, or medical device)	Study Phase (I, II, III, or IV)	Inspected site(s)/related entities	Country: -Inside Egypt -Outside Egypt	Inspection date	Regulatory decision: -Comply -Suspend -Terminate
1	CLEE011A3201C	Ribociclib (Pharmaceutical)	Phase II	Nasser Institute, Cairo	Inside Egypt	31/1/2022	Comply
2	GBT440-032	Voxelotor (Pharmaceutical)	Phase III	Ain Shams University CRC (MASRI), Cairo	Inside Egypt	1/2/2022	Comply
3	SPHINX22122020	EgyVax Vaccine (Biological)	Phase I	Al-Manial Specialized Hospital, Cairo	Inside Egypt	20/2/2022	Comply
4	01-sputnik light- 2021	Sputnik-Light: vector vaccine against the SARS-CoV-2 - induced coronavirus infection (Biological)	Phase III	Katameya Medical Center Cairo	Inside Egypt	6/3/2022	Comply
5	MN39159	Ocrelizumab (Biological)	Phase III	Ain Shams University CRC (MASRI), Cairo	Inside Egypt	22/3/2022	Comply
6	APD334-202	Etrasimod (Pharmaceutical)	Phase II/ III	Theodor Bilharz Research Institute, Cairo	Inside Egypt	23/3/ 2022	Comply
7	SPHINX22122020	EgyVax Vaccine (Biological)	Phase I	Al-Manial Specialized Hospital, Cairo	Inside Egypt	10/4/2022	Comply
8	GBT440-034	Voxelotor (Pharmaceutical)	Phase III	Cairo University, Abu El Rich Hospital, Cairo	Inside Egypt	13/4/2022	Comply
9	BO40336	Adjuvant Alectinib (Pharmaceutical)	Phase III	Cairo University, Kasr Al Eini, Center of Radiation Oncology	Inside Egypt	30/5/2022	Comply

Color	Green	Biological
Indicator	Blue	Pharmaceutical
	Orange	Medical Device
	Gray	Innovative
	Red	Herbal

QF: Bio Inn.231.02

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Rev Date: --/--/----

Page 1 of 5

Registry updated 3/01/2024

				and Nuclear Medicine, Cairo			
10	EMERALD-2	Durvalumab (Biological)	Phase III	National liver institute, Menoufia	Inside Egypt	7/6/2022	Comply
11	MK4482-013 MOVE-Ahead	Molnupiravir (Pharmaceutical)	Phase III	NHTMRI, Cairo	Inside Egypt	13/6/2022	Comply
12	EMERALD-2	Durvalumab (Biological)	Phase III	NHTMRI, Cairo	Inside Egypt	17/8/2022	Comply
13	SPHINX22122020	EgyVax Vaccine (Biological)	Phase I	Al-Manial Specialized Hospital and My lab, Cairo	Inside Egypt	24/8/2022 25/8/2022	Suspension Resumed
14	01-sputnik light- 2021	Sputnik-Light :vector vaccine against the SARS-CoV-2 - induced coronavirus infection (Biological)	Phase III	Katameya Medical Center, Cairo	Inside Egypt	29/8/2022	Comply
15	EMERALD-2	Durvalumab (Biological)	Phase III	Alexandria University, CRC, Alexandria	Inside Egypt	14/9/2022	Comply
16	GBT440-032	Voxelotor (Pharmaceutical)	Phase III	Alexandria University, CRC, Alexandria	Inside Egypt	15/9/2022	Suspension (21/9/2022) Resuming (29/9/2023)
17	F901318/0032	Olorofim (Pharmaceutical)	Phase IIb	Ain Shams University CRC (MASRI), Cairo	Inside Egypt	19/9/2022	Comply
18	MD-004	EZVent (Medical Device)	Pivotal/ Phase III	Critical Care Center, Kasr Al Einy, Cairo University Hospital, Cairo	Inside Egypt	13/10/2022	Comply
19	MK4482-002	Molnupiravir (Pharmaceutical)	Phase II/ III	Abbasya Fever Hospital, Cairo	Inside Egypt	19/10/2022	Comply

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Page 2 of 5

20	M16-067	Risankizumab (Biological)	Phase IIb/ III	AIR force hospital, Cairo	Inside Egypt	25/10/2022	Comply
21	CLSYN.1702	Colchicine and Spironolactone (Pharmaceutical)	Phase III/ IV	Fayoum General Hospital, Fayoum	Inside Egypt	8/11/2022	Comply
22	MK4482-013 MOVE-Ahead	Molnupiravir (Pharmaceutical)	Phase III	Imbaba Fever Hospital	Inside Egypt	16/11/2022	Comply
23	CLSYN.1702	Colchicine and Spironolactone (Pharmaceutical)	Phase III/ IV	Suez Canal University Hospital, Suez Canal	Inside Egypt	6/12/2022	Comply
24	CAIN457A2310	Secukinumab (Biological)	Phase III	Ain Shams University CRC (MASRI), Cairo	Inside Egypt	17/1/2023	Comply
25	SPHINX22122020	EgyVax Vaccine (Biological)	Phase I	Al-Manial Specialized Hospital, Cairo	Inside Egypt	1/2/2023	Comply
26	Cl_Tr_17122019 MIRACLE-ALA	Thiotacid (Pharmaceutical)	Phase IV	Alexandria University Hospital, Alexandria	Inside Egypt	2/3/2023	Comply
27	ENRICH-AF	Edoxaban (Pharmaceutical)	Phase IV	Zagazig University Hospital, Zagazig	Inside Egypt	30/3/2023	Comply
28	APD334-202	Etrasimod (Pharmaceutical)	Phase II/ III	Ain Shams University CRC (MASRI), Cairo	Inside Egypt	21/5/2023	Comply
29	CLEE011A3201C	Ribociclib (Pharmaceutical)	Phase II	Baheya Foundation for Early Detection & Treatment of Breast Cancer, Cairo	Inside Egypt	24/5/2023	Comply
30	M16-066	Risankizumab (Biological)	Phase III	National Liver Institute Menoufia University, Menoufia	Inside Egypt	30/5/2023	Comply
31	Cl_Tr_17122019	Thiotacid (pharmaceutical)	Phase IV	Mansoura University, Intrinsic Specialized Hospital, Mansoura.	Inside Egypt	7/6/2023	Comply

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32	COAV101B12301	Zolgensma (Onasemnogene abeparvovec) (Innovative)	Phase III	Ain Shams Specialized Hospital, Cairo	Inside Egypt	20/6/2023	Comply
33	GBT2104-131	Inclacumab (Biological)	Phase III	Clinical Research Center, Faculty of Medicine, Cairo University & Abo El Rish Hospital	Inside Egypt	19/7/2023	Comply
34	GO42784 LidERA	Giredestrant (Pharmaceutical)	Phase III	Dar El Salam Cancer Hospital, Cairo.	Inside Egypt	30/7/2023	Comply
35	MP-ADA1-01	Adessia (Biological)	Phase I	CRS Berlin GmbH, Germany	Outside Egypt	31/7/2023	Comply
36	MP-ADA1-01	Adessia (Biological)	Phase I	CRS Mannheim GmbH, Germany	Outside Egypt	3/8/2023	Comply
37	MP-ADA1-01	Bonosome (Biological)	Phase I	CRS Mannheim GmbH, Germany	Outside Egypt	4/8/2023	Comply
38	CIPRO-001	Cipro Diazole ® Tablets (Ciprofolxacin/Metronidazole) (Innovative)	Phase III	Menoufia University Hospital, Menoufia.	Inside Egypt	16/8/2023	Suspension (12/9/2022)
39	CEGA230B2404	Triclabendazole (EGATEN) (Pharmaceutical)	Phase IV	Al Mounira Children Hospital, Cairo University, Cairo.	Inside Egypt	28/8/2023	Comply
40	EZVent (MD-004)	EZVent ventilator system (Medical device)	Pivotal confirmatory phase (III)	Critical Care Unit, Kasr Al Eini Hospital, Cairo University, Cairo.	Inside Egypt	4/9/2023	Comply
41	URSO - 003	Ursoplus® capsules/ Ursofalk® capsules (Innovative)	Phase IV	Helwan University, Hospital, Cairo.	Inside Egypt	14/9/2023	Comply

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42	ENRICH-AF	Edoxaban (Pharmaceutical)	Phase IV	Fayoum General Hospital, Fayoum.	Inside Egypt	30/9/2023	Comply
43	M16-000	Risankizumab (Biological)	Phase III	Alexandria University Hospital, CRC, Alexandria.	Inside Egypt	2/10/2023	Comply
44	MN39159	Ocrelizumab (Biological)	Phase IIIb	Alexandria University Hospital, CRC, Alexandria.	Inside Egypt	3/10/2023	Comply
45	GBT440-034	Voxelotor (Pharmaceutical)	Phase III	Zagazig University Hospital, Zagazig.	Inside Egypt	5/11/2023	Comply
46	M14-430	Upadacitinib (ABT-494) (Pharmaceutical)	Phase III	National Liver Institute-Menoufia University, Menoufia.	Inside Egypt	6/12/2023 7/12/2023	Comply
47	COAV101B12301	Zolgensma (Onasemnogene abeparvovec) (Innovative)	Phase III	Ain Shams Specialized Hospital, Cairo.	Inside Egypt	13/12/2023	Comply
48	CERE-CAP	Cerebrolysin (Biological)	Phase III	Neurology and psychiatry department, Ain Shams University Hospital	Inside Egypt	26/12/2023	Terminate (15/1/2024)
49	GBT440-032	Voxelotor (Pharmaceutical)	Phase III	Al Mounira Children Hospital, Cairo University, Cairo.	Inside Egypt	28/12/2023	Comply
50	MD-004	EZVent (Medical Device)	Pivotal/ Phase III	Critical Care Center, Kasr Al Eini, Cairo University Hospital, Cairo.	Inside Egypt	2/1/2024	Suspension (1/1/2024) Resuming (13/1/2024)

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