

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

Issue/Rev No: 1/0

Issue Date: 01/05/2023

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

Page 1 of 5

Registry updated 13/01/2024

				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

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

QF: Bio Inn.231.02 Issue/Rev No: 1/0

Issue Date: 01/05/2023 Rev Date: --/--/----
Registry updated 13/01/2024

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

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

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

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

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
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)

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

QF: Bio Inn.231.02 Issue/Rev No: 1/0

Issue Date: 01/05/2023 Rev Date: --/--/-----
Registry updated 13/01/2024

Page 5 of 5