REGULATORY INSPECTION MATRIX

Sr. No.	Name of Regulatory Authority	Scope of Inspection	Inspection Dates	Inspection Status
1.	United States Food and Drugs Administration (USFDA)	BA Review	13-Jul-2026 to 17-Jul-2026	EIR awaited (No form 483)
2.	Committee for Medical and Pharmaceutical Control, Kazakhstan	Compliance with the Eurasian Economic Union and GCP requirements	30-Jun-2026 to 03-Jul-2026	Report dated 08-Jul-2026 available. No observation
3.	United States Food and Drugs Administration (USFDA)	Clinical Review	04-May-2026 to 07-May-2026	EIR Dated: 02-Jun-2026 (No form 483)
4.	Central Drugs Standard Control Organization (CDSCO)	Renewal of facility license	25-Feb-2026 to 27-Feb-2026	Compliance verification done **Approval awaited**
5.	Central Drugs Standard Control Organization (CDSCO)	Facility name change approval	NA	Approval received on 04-Dec-2025
6.	National Pharmaceutical Regulatory Agency (NPRA)	Surveillance inspection	24-Jun-2024 to 28-Jun-2024	Approval received – 13-Jan-2025
7.	United States Food and Drugs Administration (USFDA)	Clinical Review	29-May-2024 to 04-Jun-2024	EIR Dated: 25-Feb-2025 (No form 483)
8.	United States Food and Drugs Administration (USFDA)	Bioanalytical Review	06-May-2024 to 10-May-2024	EIR Dated: 04-Feb-2025 No form 483
9.	WHO	Bioequivalence: Good Clinical Practice (GCP) Inspection	22-Jan-2024 to 26-Jan-2024	Approval received - 03-Apr-2024
10.	National Pharmaceutical Regulatory Agency (NPRA)	Extension of validity of Approval	NA	Extension of validity of NPRA compliance certificate 21-Nov-2023
11.	Central Drugs Standard Control Organization (CDSCO)	Approval of Additional number of beds (100 beds to 166 beds)	10-Apr-2023 to 11-Apr-2023	Approval received- 06-Jun-2023
12.	United States Food and Drugs Administration (USFDA)	Clinical Review	04-Jul-2022 to 08-Jul-2022	EIR Dated: 09-Jan-2023 (No form 483)

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13.	National Pharmaceutical Regulatory Agency (NPRA)	Extension of validity of Approval	NA	Extension of validity of NPRA compliance certificate 24-Nov-2022
14.	World Health Organization (WHO)	Bioequivalence: Good Clinical Practice (GCP) Inspection	24-May-2022 to 27-May-2022	Received approval on 07-Sep-2022
15.	United States Food and Drugs Administration (USFDA))	Remote Record Review	18- Apr-2022 to 21 - Apr-2022	Close out on 21-Apr-2022 (No observations)
16.	Medicines & Healthcare products Regulatory Agency (MHRA)	Bioequivalence Good Clinical Practice (GCP) Inspection	9 -Aug-2021 to 13-Aug-2021	Received Approval on 15-Nov-2021
17.	Central Drugs Standard Control Organization (CDSCO)	Facility Renewal	18 -Aug-2020 to 19 -Aug-2020	Received Approval on 09-Dec-2020
18.	National Pharmaceutical Regulatory Agency (NPRA)	Bioequivalence Centre Compliance Programme /Surveillance Inspection	23- Sep-2019 to 27-Sep-2019	Received Approval on 08 Feb -2020
19.	World Health Organization (WHO)	Bioequivalence Good Clinical Practice (GCP) Inspection	16 -Apr-2018 to 19-Apr-2018	Received Approval on 20-Jul-2018
20.	Central Drugs Standard Control Organization (CDSCO)	Facility Renewal	11-Oct-2017	Received Approval on 15-Nov-2017
21.	Medicines & Healthcare products Regulatory Agency (MHRA)	Bioequivalence Good Clinical Practice (GCP) Inspection	6 -Mar-2017 to 10-Mar-2017	Received Approval on 11-May-2017
22.	National Pharmaceutical Regulatory Agency (NPRA)	Bioequivalence Centre Compliance Programme	03-Oct-2016 to 7-Oct-2016	Received Approval on 08-Feb-2017
23.	Central Drugs Standard Control Organization (CDSCO)	Facility Renewal	29-Apr-2016	Received Approval on 05-Jul-2016
24.	Central Drugs Standard Control Organization (CDSCO)	Facility Approval	31-Oct-2012	Received Approval on 23-Jan-2013 Name Change: Received Amendment on 19-Feb-2013

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