EUROPEAN DIRECTORATE FOR THE QUALITY OF MEDICINES & HEALTHCARE





Certification of Substances Department

ATTESTATION OF INSPECTION

MANGALAM DRUGS & ORGANICS LTD. Unit-2, Plot No. 1203, G.I.D.C. India-396 195 Vapi, Gujarat SPOR ORG ID: 100012477 SPOR LOC ID: 100061587 MANGALAM DRUGS & ORGANICS LTD. Rupam Building, 3rd Floor 239, P. D'mello Road, Near G.P.O. India-400 001 Mumbai, Maharashtra SPOR ORG ID: 100012477 SPOR LOC ID: 100021137 References of CEP dossier Inspection dates MANGALAM DRUGS & ORGANICS LTD. Rupam Building, 3rd Floor 239, P. D'mello Road, Near G.P.O. India-400 001 Mumbai, Maharashtra SPOR ORG ID: 100012477 SPOR LOC ID: 100021137 The inspection focused on the compliance with	
Inspected site India-396 195 Vapi, Gujarat SPOR ORG ID: 100012477 SPOR LOC ID: 100061587 MANGALAM DRUGS & ORGANICS LTD. Rupam Building, 3rd Floor 239, P. D'mello Road, Near G.P.O. India-400 001 Mumbai, Maharashtra SPOR ORG ID: 100012477 SPOR LOC ID: 100021137 References of CEP dossier Inspection dates October 2024 to 11 October 2024	
SPOR ORG ID: 100012477 SPOR LOC ID: 100061587 MANGALAM DRUGS & ORGANICS LTD. Rupam Building, 3rd Floor 239, P. D'mello Road, Near G.P.O. India-400 001 Mumbai, Maharashtra SPOR ORG ID: 100012477 SPOR LOC ID: 100021137 References of CEP 2019-063 / Furosemide Inspection dates 9 October 2024 to 11 October 2024	
SPOR LOC ID: 100061587 MANGALAM DRUGS & ORGANICS LTD. Rupam Building, 3rd Floor 239, P. D'mello Road, Near G.P.O. India-400 001 Mumbai, Maharashtra SPOR ORG ID: 100012477 SPOR LOC ID: 100021137 References of CEP dossier CEP 2019-063 / Furosemide Inspection dates 9 October 2024 to 11 October 2024	
Holder of the Certificate of Suitability MANGALAM DRUGS & ORGANICS LTD. Rupam Building, 3rd Floor 239, P. D'mello Road, Near G.P.O. India-400 001 Mumbai, Maharashtra SPOR ORG ID: 100012477 SPOR LOC ID: 100021137 References of CEP 2019-063 / Furosemide Inspection dates 9 October 2024 to 11 October 2024	
Holder of the Certificate of Suitability Rupam Building, 3rd Floor 239, P. D'mello Road, Near G.P.O. India-400 001 Mumbai, Maharashtra SPOR ORG ID: 100012477 SPOR LOC ID: 100021137 References of CEP 2019-063 / Furosemide Inspection dates 9 October 2024 to 11 October 2024	
Holder of the Certificate of Suitability 239, P. D'mello Road, Near G.P.O. India-400 001 Mumbai, Maharashtra SPOR ORG ID: 100012477 SPOR LOC ID: 100021137 References of CEP dossier CEP 2019-063 / Furosemide Inspection dates 9 October 2024 to 11 October 2024	
Certificate of Suitability 239, P. D'mello Road, Near G.P.O. India-400 001 Mumbai, Maharashtra SPOR ORG ID: 100012477 SPOR LOC ID: 100021137 References of CEP dossier Inspection dates 239, P. D'mello Road, Near G.P.O. India-400 001 Mumbai, Maharashtra SPOR ORG ID: 100012477 SPOR LOC ID: 100021137 CEP 2019-063 / Furosemide 9 October 2024 to 11 October 2024	
Suitability India-400 001 Mumbai, Maharashtra SPOR ORG ID: 100012477 SPOR LOC ID: 100021137 References of CEP dossier CEP 2019-063 / Furosemide Inspection dates 9 October 2024 to 11 October 2024	
SPOR ORG ID: 100012477 SPOR LOC ID: 100021137 References of CEP dossier CEP 2019-063 / Furosemide Inspection dates 9 October 2024 to 11 October 2024	
References of CEP 2019-063 / Furosemide Inspection dates 9 October 2024 to 11 October 2024	
CEP 2019-063 / Furosemide Inspection dates 9 October 2024 to 11 October 2024	
Inspection dates 9 October 2024 to 11 October 2024	
The inspection focused on the compliance with	
Scope of the inspection Scope of the inspection focused on the above-mentioned application focused in the above-mentioned application focused in the above-mentioned application focused on the inspection focused on the compliance with information provided in the above-mentioned application focused on the	or a f a ood lles
Conclusion The company operates in accordance with the applicat submitted and the requirements of Resolution AP-CSP (07). This attestation is valid only in conjunction with a valid vers of a CEP for the dossier mentioned above.	1.

EDQM Inspection Reference number: INSP 2024-053-P01

On behalf of the Director of EDQM