

AZ Medicines Control Authority of Zimbabwe

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18th October, 2024

REF: B/279/4/225/2024

P.O. Box 10559

Harare

Zimbabwe

West Coast Pharmaceutical Works Limited

Nr. Bhagwati Glass Factory, Opp.Jogni Mata Temple, Denis Chem Lab Vadavswami Side Road, Ambavpura-Vadavswami Road, Village: Vadavswami, Taluka: Kalol, Dist. Gandhigar-382740, Gujarat. (India)

ATTENTION: Head Quality

Dear Sir/Madam

RE: INSPECTION OF A MANUFACTURING PREMISES – WEST COAST PHARMACEUTICAL WORKS LIMITED, NR. BHAGWATI GLASS FACTORY, OPP.JOGNI MATA TEMPLE, DENIS CHEM LAB VADAVSWAMI SIDE ROAD, AMBAVPURA-VADAVSWAMI ROAD, VILLAGE: VADAVSWAMI, TALUKA: KALOL, DIST. GANDHIGAR-382740, GUJARAT. (INDIA)

We refer to the inspection of the above-mentioned premises, to verify compliance with current Good Manufacturing Practices (cGMP) conducted from the 6th to 10th of June, 2024.

The summary of the inspection report was tabled at the 592nd meeting of the Registration Committee held on the 9th of October, 2024. Based on the areas inspected, the people met, and the documents reviewed, and considering the findings of the inspection, the manufacturer, West Coast Pharmaceutical Works Limited situated at Nr. Bhagwati Glass Factory, Opp.Jogni Mata Temple, Denis Chem Lab Vadavswami Side Road, Ambavpura-Vadavswami Road, Village: Vadavswami, Taluka: Kalol, Dist. Gandhigar-382740, Gujarat. (India) was found to be operating at an acceptable level of compliance with cGMP guidelines for the manufacture of the dosage forms listed in the table below:

Block	Dosage Form	Compliance Status
General Block	General Oral Solid Dosage Form	Compliant
	General Liquid Dosage Form	Compliant
	External Creams, Gels, Ointments, Lotions and Powders	Compliant
Hormonal Block	General Oral Solid Dosage Form	Compliant
	External Creams, Ointments and Gels	Compliant

Based on the inspection, approval was given to West Coast Pharmaceutical Works Limited situated at Nr. Bhagwati Glass Factory, Opp.Jogni Mata Temple, Denis Chem Lab Vadavswami Side Road, Ambavpura-Vadavswami Road, Village: Vadavswami, Taluka: Kalol, Dist. Gandhigar-382740, Gujarat. (India) to manufacture products for the Zimbabwean market.

Please be advised that the facility will be due for another inspection one and a half (1.5) years from the date of last inspection in line with MCAZ risk scheduling process. You will be expected to make the necessary arrangements and communicate with our offices for the routine inspection of your facility before the due date.

Yours faithfully,

MEDICINES CONTROL AUTHORITY OF ZIMBABWE

C. Samatanga (Mrs.)

Head Licensing and Enforcement For: DIRECTOR-GENERAL

for Directo

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