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17th February 2025

Responsible Pharmacist/Person: Mrs. Radhika Patel - Managing Director

Site Name: West Coast Pharmaceutical Works Limited Site Address: Nr. Bhagwati Glass Factory, Opp, Jogni Mata Temple Dennis Chem Lab, Vadaswami Side Road Chattral-Vadaswami Road, Tal. Kalol Dist. Gandhinagar, Gujarat-382740 **INDIA**

Tel: +91 7567569841

Email: radhika@westcoastin.com

Dear Mrs. R. Patel,

RE: ZAZIBONA RESOLUTION IN TERMS OF THE INSPECTION CONDUCTED AT WEST COAST PHARMACEUTICAL WORKS LIMITED, NR. BHAGWATI GLASS FACTORY, OPP, JOGNI MATA TEMPLE DENNIS CHEM LAB, VADASWAMI SIDE ROAD, CHATTRAL-VADASWAMI ROAD, TAL. KALOL DIST. GANDHINAGAR, GUJARAT-382740 INDIA.

The inspection report and your subsequent responses for the inspection of West Coast Pharmaceutical Works Limited, Nr. Bhagwati Glass Factory, Opp, Jogni Mata Temple, Dennis Chem Lab, Vadaswami Side Road, Chattral-Vadaswami Road, Tal. Kalol, Dist. Gandhinagar, Gujarat-382740 India conducted by the ZAZIBONA Inspection team represented by Beatrice Kabaso - Lead (ZAMRA) and Ms. Martha Mwatseteza - Co Inspector (MCAZ), 17th and 19th to 22nd November, 2024 to verify compliance with current Good Manufacturing Practices (cGMP) refers.

It is confirmed that the inspection covered the following areas only:

- a) General Oral Solid Dosage Forms and Oral powders
- b) Liquid preparations
- c) External preparation

SADC MRF States: Angola, Botswana, Comoros Islands, Democratic Republic of Congo, Lesotho, Madagascar, Malawi, Mauritius, Mozambique, Namibia, Seychelles, Swaziland, South Africa, Tanzania, Zambia, and Zimbabwe



At the conclusion of the inspection the following resolutions were made:

1. **GMP Status**

Based on the areas inspected, the people met, and the documents reviewed; and considering the findings and the deficiencies listed in the inspection report, and the company's responses, the manufacturer, West Coast Pharmaceutical Works Limited, Nr. Bhagwati Glass Factory, Opp, Jogni Mata Temple, Dennis Chem Lab, Vadaswami Side Road, Chattral-Vadaswami Road, Tal. Kalol, Dist. Gandhinagar, Gujarat-382740India, was found operating at an acceptable level of compliance with the WHO principles and guidelines for Good Manufacturing Practice of pharmaceutical products.

2. Validity

The resolution reflects the status of the manufacturer at the time of inspection. A reinspection of the facility will be conducted two (02) years from the date of this letter, at which time, commitments made in the company's responses will be verified.

This letter does not constitute a GMP certificate or licence. ZAZIBONA Member States may however choose to issue a GMP certificate/licence based on the inspection conducted and the resolutions made. The authenticity of this letter can be verified with the issuing authority or the ZAZIBONA coordinating agency, MCAZ on gmp@mcaz.co.zw.

Yours faithfully

MEDICINES CONTROL AUTHORITY OF ZIMBABWE

RICHARD T. RUKWATA (MR.)

DIRECTOR-GENERAL



SADC MRF States: Angola, Botswana, Comoros Islands, Democratic Republic of Congo, Lesotho, Madagascar, Malawi, Mauritius, Mozambique, Namibia, Seychelles, Swaziland, South Africa, Tanzania, Zambia, and Zimbabwe