



## ZAMBIA MEDICINES REGULATORY AUTHORITY

*Regulating Medicines for Public and Animal Health Protection*

**All correspondence should be addressed to the Director General**

**Reference No: ZAMRA-25/GMP/O/0003**

West-Coast Pharmaceutical Works Ltd

F.p. No. 17 & 16t1, Meldi Estate, b/s Meldi Mata Temple, Nr. Gota Railway crossing 'AT & POST Gota  
Gujarat, India

Dear Sir/Madam

**RE: Good Manufacturing Practice Inspection Outcome - West-coast Pharmaceutical Works Ltd., Nr. Bhagwati Glass Factory, Opp.Jogni Mata Temple, Denis Chem Lab, Ambavpura - Vadavswami Road, Vil in India**

We refer to the inspection conducted at your manufacturing site to ascertain compliance to set standards of current Good Manufacturing Practices (cGMP).

Based on the areas inspected, the staff met and the documents reviewed, and considering the findings of the inspection, including the deficiencies listed in the Inspection Report and CAPAs reviewed, **West-coast Pharmaceutical Works Ltd., Nr. Bhagwati Glass Factory, Opp.Jogni Mata Temple, Denis Chem Lab, Ambavpura - Vadavswami Road, Vil** was found to be operating at acceptable levels of compliance with current Good Manufacturing Practice 1 (cGMP) guidelines and is hereby given clearance for a maximum period of **24** from the date of inspection. The scope of the GMP clearance covers state, **Product Line(s) Hormonal Tablets-Design, Development, Manufacture, Servicing and distribution, External Preparations (Creams, Ointments and Gels)-Design, Development, Manufacture, Servicing and distribution**, etc. You are advised to notify the Authority of any changes that may affect the GMP status of your manufacturing site. Further, the Authority may decide to conduct an inspection at any point before the above stated clearance period elapses.

You will be required to apply for a renewal of the GMP clearance at least state period here in 24 months before the due date of the next routine inspection.

Accompanying this letter is a copy of the inspection report for the inspection conducted at your facility on the above stated dates. For any questions or clarifications regarding this matter, you may contact the Authority at [pharmacy@zamra.co.zm](mailto:pharmacy@zamra.co.zm) and [gmp@zamra.co.zm](mailto:gmp@zamra.co.zm).

This clearance letter remains valid until:08-04-2027

SIGNATURE