སྨན་རིགས་ཆུན་བཀོད་དབང་འཛིན།

Drug Regulatory Authority
Royal Government of Bhutan
Thimphu, Bhutan; Post Box No. 1556

DRA/D2/21/GMP-Ex/2019-20/1107

30 September 2019

The Chairman
West Coast Pharmaceutical Works Limited
Meldi State, Gota, Ahmedabad
Gujarat: India

Subject: Status of cGMP compliance

Sir,

The Drug Regulatory Authority, Bhutan would like to extend our heartiest gratitude for rendering necessary cooperation during the inspection. Your firm has been inspected by the Drug Regulatory Authority, Bhutan on 26th August 2019 and from the observations made during the brief inspection, the Authority hereby concludes that your firm complies with current Good Manufacturing Practices (cGMP) requirements adopted from PIC/S GMP guide for medicinal products and WHO TR series no. 986, annex 2: WHO good manufacturing practices for pharmaceutical products.

Furthermore, the Authority hereby declare that your firm is placed under category " Satisfactory". Considering the categorization, your company will no longer be eligible to register products through expedited registration route. However, you may register the products through routine registration route provided all the deficiencies indicated in the GMP inspection report are addressed. And pertaining to production of β-lactam products, please submit us an undertaking confirming the termination of β-lactam production in the same building as generic production.

Thanking you.

Yours sincerely,

(Kinga Jamphel)
Drug Controller

Copy to:

1. Registration Division for kind information and necessary action.