



Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

06 December 2018

CERTIFICATION

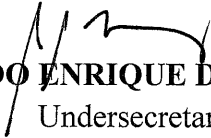
This is to certify the **one (1) year** provisional exemption from Executive Order No. 49 s. 1993 (*Directing the Mandatory Use of the Philippine National Drug Formulary (PNDF) Volume I as the Basis for Procurement of Drug Products by the Government*), effective upon receipt of this certificate, of the following medicine:

Medicine: Polymyxin B sulfate 500,000 units powder for solution for injection, 5mL vial

Indication: Treatment of infections of the blood stream caused by susceptible strains of *Pseudomonas Aeruginosa*. It may be indicated in serious infections caused by susceptible strains of the following organisms: *Haemophilus influenzae*; *Escherichia coli*; *Aerogenes*, specifically bacteremia; *Klebsiella pneumoniae*, specifically bacteremia.

The product shall only be utilized by the requesting party – the Eastern Visayas Regional Medical Center (EVRMC). Likewise, the concerned proponent shall provide the Formulary Executive Council (FEC), through the Pharmaceutical Division, the following documents at the end of exemption validity: (1) local efficacy and safety profile; (2) surveillance report on adverse effects; (3) registry of patients; and (4) impact study/outcomes of patients using the product.

For compliance and strict implementation.


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Health Regulation Team

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