

GMP Guidelines for Veterinary Products

To all manufacturers of veterinary products and to whom it may concern

Under the Control of Drugs and Cosmetics Regulations (Amendment) 2006, compliance with Good Manufacturing Practice (GMP) is required as one of the conditions to be considered in the evaluation of applications for a Manufacturing License.

As of 1st January 2002, the National Pharmaceutical Control Bureau, Ministry of Health Malaysia, was accepted as the 26th member of Pharmaceutical Inspection Co-operation Scheme (PIC/S). This is an international co-operation between authorities in country members which provide together an active and constructive co-operation in the field of Good Manufacturing Practice (GMP) and related areas towards promoting quality inspection of pharmaceutical factories / manufacturers.

In order to ensure the maintaining of high standards of quality assurance in the development, manufacture and control of medicinal products the following PIC/S Guide to Good Manufacturing Practice (GMP) for Medicinal Products and its Annexes has been adopted. The standards set out herein apply to medicines and similar products intended for human use but however, it is recommended that the same kind of attention be given to the manufacture of veterinary products.

For the purpose of GMP compliance for veterinary products, these documents are intended to serve as references for information on good manufacturing practice in Malaysia as required by PIC/S.

1) PIC/S GMP Guide (Part 1 : Basic Requirements for Medicinal Products)

2) PIC/S GMP Guide (Annexes) – Annex 4 and Annex 5

These documents can be freely downloaded through the PIC/S website (www.picscheme.org) under the section 'Publications'.