Policy Statement #17–08
Use of Non-Pharmaceutical Grade Substances
Faculty of Science, Mahidol University–Institutional Animal Care and Use Committee (MUSC–IACUC)

MUSC-IACUC requires that pharmaceutical grade substances (PGS) should be used in all cases in which they are available. Non-pharmaceutical grade substances (non-PGS) must not be used in animals for medical treatment or procedures related to veterinary care. However, non-PGS can be used as testing substances and the use requires scientific justification and approval by the IACUC. It is the responsibility of the principle investigator to provide adequate inventory and laboratory management procedures to ensure that any drug is properly prepared, identified, and stored.

1 Definitions of key terms specific to this policy

1.1 PGS is defined as any active or inactive drug and biologic agent, for which a chemical purity standard has been established by Thai food and drug administration (FDA). These standards are used by manufacturers to help ensure that the products are of the appropriate chemical purity and quality, in the appropriate solution or compound, for stability, safety, and efficacy. PGS is formulated to a standard compatible with the legal and ethical treatment of human or animal in health care or practice setting by a pharmaceutical company or qualified compounding pharmacist.

1.2 Non-PGS refers to chemical compounds that have not been formulated for production of medicine. Agents obtained from chemical supply companies and or prepared in a research laboratory are of reagent and not pharmaceutical grade.

2. Justification for use of non-PGS

To secure approval for the use of non-PGS, the PI must

2.1 Provide sound scientific justification for the use of the compound,

2.2 Verify that the compound is not available as a PGS in the required formulation or concentration (if available in higher concentrations than needed, identification of the diluent is necessary and dilution with a pharmaceutical grade diluent is generally required), and

2.3 Justify use of the non-PGS as an appropriate alternative. Required information for the latter includes description of the means to assure purity, sterility, and stability. In addition, information needed for review includes the site and route of administration, and potential side effects and adverse reactions. Other variables that investigators may wish to consider include information regarding the grade, acid–base balance, pyrogenicity, osmolality, compatibility of components, and pharmacokinetics of the NPG compound.

Investigators may refer to sources of information such as quality control data sheets from the manufacturer, references to previous publications using the substance, and/or documentation of independent testing for purity or sterility.