



IACUC Policy 400 : Use of Non-Pharmaceutical Grade Substances Policy

1. Definitions of Key Terms Specific to this Policy

A. A **pharmaceutical grade compound** is defined as any active or inactive drug, biologic or reagent, for which a chemical purity standard has been established by ThaiFDA. These standards are used by manufacturers to help ensure the products are of the appropriate chemical purity and quality, in the appropriate solution or compound, to ensure stability, safety, and efficacy. Pharmaceutical grade drugs are formulated to a standard compatible with the legal and ethical treatment of human or veterinary patients in a health care or practice setting by a pharmaceutical company or qualified compounding pharmacist.

B. **Non-pharmaceutical grade (NPG) agents** refer 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-pharmaceutical Grade Substances

To secure approval for the use of non-pharmaceutical grade substances, the PI must

A. Provide sound scientific justification for the use of the compound,

B. Verify that the compound is not available as a pharmaceutical grade product 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

C. Justify use of the NPG product 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 QC data sheets from the manufacturer, references to previous publications using the substance, and/or documentation of independent testing for purity or sterility.