
POLICY ON USE OF PHARMACEUTICAL-GRADE SUBSTANCES ON ANIMALS

Investigators are expected to use **pharmaceutical-grade** chemical substances or compounds whenever they are available, even in acute procedures. Non-pharmaceutical grade chemical substances or compounds should only be used in regulated animals after specific review and approval by the IACUC for reasons such as scientific necessity or non-availability of an acceptable veterinary or human pharmaceutical-grade product. Cost savings alone is not an adequate justification for using non-pharmaceutical-grade compounds in regulated animals.

The rationale for the use of **pharmaceutical-grade** substances or compounds is that they have undergone tests on **sterility, pyrogenicity, stability, pharmacokinetics, and quality control**, hence safe for human and animal use. These may not have been addressed for non-pharmaceutical-grade chemical substances or compounds and may result to a number of related animal welfare and scientific issues including safety, efficacy, and the inadvertent introduction of research-complicating variables.

The use of non-pharmaceutical-grade chemical substances or compounds in experimental animals under certain circumstances will only be acceptable based on (1) scientific necessity (e.g., study of novel compounds synthesized, or extracted and purified in the laboratories of the investigators), (2) commercial non-availability of an acceptable veterinary or human pharmaceutical-grade compound, and (3) specific review and approval by the IACUC.

Cost savings alone does not adequately justify the use of non-pharmaceutical-grade substances or compounds in animals.

When used with the approval of IACUC, non-pharmaceutical grade substances or compounds, including those prepared by investigators, must be filter-sterilised using a 0.22 µm filter prior to administration.