1.7.1.4 Pre-Clinical Studies

Is the term used to describe the tests conducted to a new drug or a new medical device using animal models, to see if it is really works and if it is safe to be tested on humans (Edward D. Zanders, 2011).

Goals of Pre-Clinical Testing of Drugs and Biological

• To identify the pharmacologic properties of a pharmaceutical molecule

• To establish a safe initial dose level of the first human exposure

• To understand the toxicological profile of a pharmaceutical molecule (Karen and Edward 2009).

Preclinical study Provide an imaginiation for the predicted clinical mechanism of action and efficacy, guide schedule and dose escalation schemes, provide information for selection of test species, aid in start dose selection, selection of investigations biomarkers, justify pharmaceutical combinations, understand pharmacodynamic properties (Karen and Edward 2009).

Preclinical safety testing should consider: selection of the relevant animal species, age, physiological state, the manner of delivery (including dose, route of administration, and treatment regimen) and stability of the test material under the conditions of use (Brennan *et al.*., 2004).

1.9. Method validation

Validation of an analytical method is the conformation by examination to assure that the performance characteristics of the method meet the requirements for the intended analytical application and is capable of giving reproducible and reliable result, when