Declaration to be signed by Project Investigator (PI) and Head of the Institute

(To be enclosed with each Project Proposal that requires the use of large animals in Regulatory Testing)

The PI must submit the following information along with each project proposal which contains the protocol for undertaking studies using mammals of higher sentience, such as dogs, goats, pigs, cattle, monkeys etc.

INFORMATION REGARDING TOXICITY TESTS / PK STUDY CONDUCTED BY PI

I. Has the toxicity /PK Study test been conducted in rodent model?

√

Yes / No

II. If the answer is YES, kindly provide the following information:

1. What was the time period of the study?
2. What were the doses used?
3. Did any animal/s die during the study?
4. If yes, how many?
5. How many days after dosing did the animal/s die?

(Please provide information/reasons for each animal death)

III. If the answer is NO, kindly provide the following information:

1. Whether rat study needed? If so, why it has not been done so far?

   The rodent is not required in this case.

2. If rat study is not needed substantiate with appropriate reasons.

   Rodent study will not be conducted with the test items listed in proposal as

a) These are the depot formulation meant for the extended release for over a long period which is not possible to conduct in the rodent due to the small muscles mass. It may lead to the tissue injury and may complicate the study outcome.

b) The required blood volume for the sample analysis is more which cannot be obtained from rats. It would be unethical and unscientific to withdraw required large volume from rats. The required blood volumes can be obtained from dogs within the permitted level as prescribe in the guideline.

c) This drug is all ready rodent toxicity data available in public domain. As the molecular is all ready market in different formulation. Since the formulation of drug is novel and it is

marketed in US and European countries. The many Indians company trying to develop the long term depot /sustain release formulation to market in India.

d) As there is no terminal sacrifice and the dose to be given is tolerable dose, we humbly request to approve our proposal.

IV. Any additional information that you wish to provide? .....

[*You may use additional sheets if required*]

Declaration

I Satyajit Patil. (Name of PI), do solemnly declare that the information given by me is true and correct to the best of my knowledge and that nothing relevant to the toxicity test has been concealed. I understand that if any false or incorrect information has been provided by me, I will be held responsible for the same and liable for action taken by the CPCSEA.

19.12.2016
..... (Signature with date)

Satyajit Patil ..... (Name of PI)

I S. Ramamurthy... (Name of Head of the Institute), state that this institute has approved the project proposal to be conducted by the above named PI and that the information provided above is in accordance with the records produced before me by the PI.

19.12.16
..... (Signature of Head of Institute with date)

..... (Seal of Institute)