

## Check-Sheet Preclinical Pharmacology

- A. Chemical Identity, Purity, Strength Quality      YES    NO
1. Is the route of synthesis shown?
  2. Is structure known?
  3. Is complete, practical elemental analysis in agreement with structure?
  4. Has IR, Chromatographic, homogeneity, UV, elemental analysis, and physical description been completed by independent investigators?
  5. Has trace metal determination been done?
  6. Are methods available for quality control- (chromatography, spectrophotometric IR, UV etc.)
  7. Has the compound been tested for stability over a reasonable period?
  8. Have storage conditions been controlled and documented?
  9. Has dosage formulation and preparation been adequately documented?
  10. Is product in the USP or N.F, if not
  11. Does product meet USP, N.F. and PHS standards?
  12. Has a suitable analytical method been developed?
- B. Acute and Subacute Toxicity
1. Has LD50 been done on 3 species, one a non-rodent?
  2. Has route of administration which will be used clinically been included in toxicity study?
  3. Do LD50 values agree within reason ( $\pm 100$ )?
  4. Has 90 day or longer sub-acute toxicity in two species, one a non-rodent, at three dose levels been completed.

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C. Investigator

YES NO

1. Has investigator supplied statement required by AR40-7?
2. Has investigator had adequate experience in clinical pharmacology?
3. Has investigator had experience in treatment of disease or condition involved in the experiment?
4. Have statements on co-investigators been submitted?
5. Are facilities adequate for close observation of subjects?
6. Has thought been given and facilities supplied for emergency treatment of untoward reactions?
7. Is clinical observation form attached?
8. Is clinical observation form adequate?
9. Is subject consent form attached?
10. Has an adequate plan for maintenance of records and reports been made?

D. Experimental:

1. Have references to use of material in man or experimental animals been furnished?
2. Has an adequate search of the literature been made?
3. Is the proposal for a Phase I study? (Drug toleration in a few subjects)
4. Is the proposal for a Phase II study? (Trial up to 6 months in limited number of subjects)
5. Is the proposal for a Phase III study? (Large scale testing)

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YES NO

6. Does the toxicity data submitted support the study? (Phase I, II, III)
7. Are enough subjects included to answer the experimental questions?
8. Are proper controls and end-points included?
9. Is selected initial dose no more than 1/600 of the lowest LD50?
10. Is selected initial dose no more than 1/60 of the maximum tolerated dose in the most sensitive species in the sub-acute toxicity study?

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1303-01 Human Volunteer Research Plans