CDSCO in clinical trials:

Central drug standard control organization guidelines in clinical trials:

1- Application for permission

2. Clinical trial.

3. Studies in special population

Guidelines of CDSCO:

I. Application for permission:

1. Chemical and Pharmaceutical information as prescribed in item 2 of Appendix I.

2. Animal pharmacology Data as prescribed in item 3 of Appendix I and Appendix IV.

3. Animal toxicology data as prescribed in item 4 of Appendix I and Appendix III.

4. Human clinical pharmacology data as prescribed in item 5, 6 and 7 of Appendix I and as

Stated below:

- Regulatory status in other countries as prescribed in item 9.2 of Appendix I, including information in respect of restrictions imposed, if any, on the use of the drug in other countries.
- The full prescribing information should be submitted as part of the new drug application for marketing as prescribed in item 10 of Appendix I. The prescribing information (package insert) shall comprise the following sections: generic name, composition, dosage form(s), indications, dose and method of administration; use in special populations (such as pregnant women, lactating women, pediatric patients, geriatric patients etc.); Contraindications; warning; precautions; drug interaction; undesirable effects; overdose; pharmacodynamic and pharmacokinetic properties.

II. Clinical Trial:

1. Approval for clinical trial:

- Clinical trial on a new drug shall be initiated only after the permission has been granted by the Licensing Authority under rule 21(b), and the approval obtained from the respective ethics committee(s).
- All trial investigator(s) should possess appropriate qualifications, training and experience and should have access to such investigational and treatment facilities as are relevant to the proposed trial protocol.
- Protocol amendments if become necessary before initiation or during the course of a clinical trial, all such amendments should be notified to the Licensing Authority in writing along with the approval by the ethics committee, which has granted the approval for the study.

2. Responsibilities of Sponsor:

- The clinical trial sponsor is responsible for implementing and maintaining quality assurance systems to ensure that the clinical trial is

conducted and data generated, documented and reported in compliance with the protocol and Good Clinical Practice (GCP) Guidelines.

- Sponsors are required to submit a status report on the clinical trial to the Licensing Authority at the prescribed periodicity

3. Responsibilities of the Investigator:

- The investigator is responsible for the conduct of the trial according to the protocol and the GCP guidelines.
- Standard operating procedures are required to be documented by the investigators for the tasks performed by them.

4. Informed Consent.

- In all trials, a freely given, informed, written consent is required to be obtained from each study subject. The investigator must provide information about the study verbally as well as

using a patient information sheet, in a language that is non-technical and understandable by the study subject.

- Where a subject is not able to give informed consent (e.g. an unconscious person or a minor or those suffering from severe mental illness or disability the same may be obtained from a legally acceptable representative.

5. Responsibilities of the Ethics committee:

- It is the responsibility of the ethics committee that reviews and accords its approval to a trial protocol to safeguard the rights, safety and well being of all trial subjects.

6. Human pharmacology (Phase I):

- The objective of studies in this Phase is the estimation of safety and tolerability with the initial administration of an investigational new drug into humans. Studies in this Phase of

development usually have non-therapeutic objectives and may be conducted in healthy volunteers subjects or certain types of patients.

- Studies conducted in Phase I, usually intended to involve one or a combination of the following objectives:

- Maximum tolerated dose
- Pharmacokinetics
- Pharmacodynamics

7. Therapeutic Exploratory Trials (Phase II):

- The primary objective of Phase II trials is to evaluate the effectiveness of a drug for a particular indication or indications in patients with the condition under study and to determine the common short-term side-effects and risks associated with the drug.
- An important goal for this Phase is to determine the dose(s) and regimen for phase III trials.

8. Therapeutic confirmatory trials (Phase III):

Phase III studies have primary objective of demonstration or confirmation of therapeutic benefit(s). Studies in Phase III are designed to confirm the preliminary evidence accumulated in Phase II that a drug is safe and effective for use in the intended indication and recipient population.

9. Post Marketing Trials (Phase IV):

- Post marketing trials are studies (other than routine surveillance) performed after drug approval and related to the approved indication(s)
- These trials may not be considered necessary at the time of new drug approval but may be required by the Licensing Authority for optimizing the drug's use.

III- Studies in special populations:

1. Geriatrics:

- Geriatric patients should be included in Phase

III clinical trials (and in Phase II trials, at the Sponsor's option) in meaningful numbers, if -
→ The disease intended to be treated is characteristically a disease of aging or;
→ when the new drug is likely to alter the geriatric patient's response (with regard to safety or efficacy) compared with that of the non-geriatric patient.

2. Pediatrics

The timing of pediatric studies in the new drug development program will depend on the medicinal product, the type of disease being treated, safety considerations, and the efficacy and safety of available treatments.
- If the new drug is intended to treat serious or life-threatening disease, occurring in both adults and pediatric patients, for which there are currently no or limited therapeutic options, pediatric population should be included in

the clinical trials.

3. Pregnant or Nursing Women:

Pregnant or nursing women should be included in clinical trials only when the drug is intended for use by pregnant/nursing women or fetuses/nursing infants and where the data generated from women who are not pregnant or nursing is not suitable.

□ The Central Drugs Standard Control Organisation is the national regulatory body for Indian pharmaceuticals and medical devices, and serves parallel function to the European Medicines Agency of the European Union, the PMDA of Japan and the FDA of united States.