SCHEDULE Y

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Introduction

- Requirements and guideline for permission to import and or manufacture of new drug for sale or to undertake clinical trials.

- To frame guidelines for conduct of clinical reserch control and regulation for new drug.

- CDSCO and DTAB formulated GCP under schedule y in 2005.

Rule under Schedule-Y

- **Section122A -** Application for Permission to import new drug.
- **Section122B -** Application for approval to manufacture new drug.
- **Section122D -** Permission to import or manufacture fixed dose combination.

- **Section122DA -** Application for permission to conduct clinical trials for New Drug/ Investigational New Drug.
- **Section122DAA -** Definition of clinical trial.
- **Section122DB -** Suspension or cancellation of permission/approval.
- **Section122E -** Definition of new drug

Amendments in 2013 & 2014

- **Rule122DAB -** Compensation in case of injury or death during clinical trial.
- **Rule122DAC -** Condition of clinical trial permission and inspection.
- **Rule122DD -** Registration of ethic Committe Requirements and guidelines for registration of ethic committe.

Application for Permission

Application for permission to import or manufacture new drug shall be made in the form along with following data:

- Chemical and pharmaceutical information
- Animal pharmacology
- Animal toxicology

- Human/Clinical pharmacology (phase I)
- Therapeutic exploratory trials (phase II)
- Therapeutic confirmatory trials(phase III)
- Special studies
- Regulatory status in other countries
- Prescribing information

Clinical Trials

- **Approval of clinical trial -** Clinical trial on a new drug shall be initiated only after permission by licensing authorities and approval from ethical commette.
- **Responsibility of sponsor-** Submit status report to the licensing authority periodically.

  Implementing and maintaining quality assurance.

SAE(serious adverse event) should be reported to the licensing authority within 14 calendar days.

Responsibility of Investigator

- The investigator shall be responsible for the conduct of the trial according to the protocol.
- Ensure adequate medical care is provided to the subject.
- SAE(serious adverse event) and unexpected AE should be reported to the sponsor within 24 hrs.

Informed consent

- Freely given informed written consent.
- Provide information about the study verbally and in written.
- Non technically and understandale language.
- Legally acceptable representative.

Studies in special population

- **Geriatrics -** They should be included in phase III clinical trials.
- The disease is characteristically a disease of aging.
- Substantial number of geriatric paitents.
- Common in the elderly are likely to be encountered.
- When the new drug is likely to alter the geriatric patient response.

Paediatrics

- Being with older children before extending the trial to younger children and then infants.
- If the new drug is to for diseases predominantly or exclusively affecting paediatric paitents clinical trial data should be generated in the paediatric population except for initial safety and tolerability data.
- Written informed consent should be obtained from the parent/legal guardian.

Pregnant or Nursing women

- They should be included in clinical trials only when the drug is intended for use by pregnant/nursing women or fetus/nursing infants.
- Where the data generated from women who are not pregnant or nursing is not suitable.
- Where applicable excreation of the drug or its metabolites into human milk should be examined.

Post marketing surveillance

- Closely monitored new drugs clinical safety.
- Periodic Safety Update Reports(PSUR) to report all relevant new information.
- PSUR shall be submitted every 6month for the first 2 year.
- New studies specifically planned or conducted to examine a safety issue should be described in the PSURs.

Special studies Bioavailability/Bioequivalence study

- Conducted according to the guidance for BA and BE studies.
- Evaluation of the effect of food on absorption following oral administration.
- All bioavailability and bioequivalence studies should be conducted according to the guidelines for Bioavailability and Bioequivalence studies as prescribed.

Appendix

- Some hightlights of Schedule Y in terms of its appendices which provide the guidelines to conduct clinical trials are:
- APPENDIX I - Conduct clinical trials/import/manufacture of new drug.
- APPENDIX II - For grant of permission to import/ or manufacture a new drug.
- APPENDIX III - Structure contents and format for clinical study reports.

- APPENDIX IV - Animal pharmacology
- APPENDIX V - Informed consent
- APPENDIX VI - Fixed dose combination
- APPENDIX VII - Undertaking by the investigator
- APPENDIX VIII - Ethics Committee
- APPENDIX IX - Stability testing of New Drug

- APPENDIX X - Contents of protocol
- APPENDIX XI - Data elements for reporting SAE
- APPENDIX XII - Compensation in case of injury or death during clinical trial.