CLINICAL RESEARCH CHAPTERWISE QUESTION BANK

Chapter No	Topics	Questions	Marks
Drug Development Process			
1	Introduction	With schematic representation, discuss integrated drug development process.	5
1.1	Pharmacological approach	Define therapeutic index	2
		Short note on Helsinki declaration	2
		What is LD50? and ED50	2
		What is Human Equivalent Dose (HED)? How to convert animal dose to HED?	2
		Explain the different pharmacological action studies in the drug development process	5
		explain pre-clinical trials	5
		write a note ADME profiling	5
		Define Proof of Concept	2
		define maximum tolerated dose	2
		Write a note on lead selection and optimization drug development process.	5
1.2	Toxicological approach	Importance of chronic toxicity	2
		Explain the toxicological approach to drug development process	5
		mutagenecity and carcinogenicity	2
		Sub acute toxicity	2
1.3	IND Application	Discuss in detail the IND application	10
		What is IND? Enlist the different criteria for IND application	5
1.4	Drug characterization	Discuss various drug characterization techniques in drug development process	5
1.5	Dosage form	biopharmaceutical classification of drugs	2
		name the critical Pharmacokinetic parameter in drug development	2
		drug bioavailability	2
		Fixed dose combinations	2
		Explain the importance of dosage form design in pre-clinical and clinical stages	5
Clinical Development of Drug			
2.1	Introduction to Clinical trials	Requirements to conduct clinical trials as per schedule Y	10
		What is clinical trail	2
		define single blind method	2

		explain inclusion and exclusion criteria in selection of clinical trial subjects	5
		define double blind method	2
		name different types of clinical trials	2
		investigation product/drug	2
		What is Belmont report?	2
		Nuremberg trials	2
		Explain the role of BPOs in conducting clinical research in India	5
		what is 'The Orange Book'	2
		Note on Non-inferiority clinical study	2
		define bias	2
		Regulations for orphan drugs	2
		Regulations for Counterfeit drugs	2
		drug labeling requirement in clinical studies	2
		What is scurvy trail?	2
2.2	Various phases of clinical trial	Discuss in detail the various phases of clinical trial	10
		note on randomized clinical trial	2
		Briefly explain phase 1 and phase 2 clinical trials	5
		write short note on clinical trial design	5
		define phase Zero	2
		objectives of phase 1/2/3/4	5
		methods of randomization	5
		Note on open labeled clinical trails	2
		Methods of sample size calculations in clinical trials	2
		difference between phase 2a and phase 2b	5
		what are the objectives of phase 2 studies	2
		Use of Placebo in clinical trials	2
		principles of trial subject sampling	2
2.3	Methods of post marketing surveillance	Discuss about the different methods of post marketing surveillance	10
		write a note on case control studies	5
		difference between retrospective and prospective study	5
		observational studies	5
		write a note on meta analysis	5
		note on cohort studies	2
		differentiate ADR and ADE	2
		retrospective study	2
		cross sectional study	2
		Epidemiological study	2
		Define false positive result with an example	2

2.4	Abbreviated New Drug Application submission	explain briefly about ANDA submission	10
		Explain in detail NDA submission	10
		write a note on ANDA	5
		basic methodology and study designs of BA/BE studies	5
		limitations of post marketing surveillance	2
2.5	Good Clinical Practice – ICH, GCP, Central drug standard control organization (CDSCO) guidelines	discuss the principles of ICH-GCP guidelines	10
		explain clinical trial protocol as per ICH-GCP guidelines	10
		Explain Clinical trials and monitoring. Discuss different types of monitoring visits in detail	10
		What do you mean by expedited reporting in clinical trial? Discuss the safety reporting as per schedule Y	10
		discuss the recent amendments in schedule Y with special reference to ethics committee	10
		what the note on ICH-GCP guidelines	5
		essential documents in conducting clinical trials	5
		Discuss in detail about CDSCO guidelines	5
		Role of ICMR in clinical research	2
		list the guidelines and acts that govern the conduct of clinical trials in India	2
		selection and withdrawal of subjects in clinical trail	2
		multicentre trails	2
		Write a short note on new amendments to Schedule Y.	5
		what are medical devices and classify with suitable examples	5
		preparative termination of clinical trail	2
		statistical design in clinical trails	5
		unblinding	2
		drug master file	2
		subject identification code	2
		write a note on Clinical Study Reports	5
		Note on CIOMS	2
		Premature Termination or Suspension of a Study	5
		ICH E6	2
		contract research	2
		clinical trial registries	2
		clinical trial insurance	2
		comparative studies	2
		coding of investigation products	2
		importance of confidentiality statement in IB	2
		Phases of Vaccine Trials	2

		Non-Therapeutic Study	2
		Validation of clinical study	2
		Selection and recruitment of Study Subjects	5
		Clinical Trials with Surgical Procedures / Medical devices.	5
2.6	Challenges in the implementation of guidelines	comment on the challenges in the implementation of ethical guidelines	5
2.7	Ethical guidelines in Clinical Research	write a note on clinical data management in clinical trials	10
		research involving children	2
		Inclusion of pregnant women and nursing mothers in CT?	2
		vulnerable subject	2
		define Ethics	2
		Ethical issues involved in Genetic Screening	2
		explain clinical trials for vaccines	5
		pregnant women as research participant	5
		Explain the ethical guidelines for clinical research	5
		write a note on compensation for clinical Trial subjects as per ethical guidelines	5
		Conflict of interest in clinical trials	5
2.8	Composition, responsibilities, procedures of IRB / IEC	members of ICH	2
		explain composition and responsibilities of IRB	5
		Discuss in detail about institutional review board	5
2.9	Overview of regulatory environment in USA, Europe and India	write on European Clinical Directive	2
		function of dcgi	2
		Note on 21CFR Part 312	2
		Note on Marketing Authorization Holder (MAH)	2
		note on centralized marketing and decentralized marketing	2
		Note on Clinical Trial Document (CTD	2
		MHRA	2
		EMEA	2
		USFDA	2
		what are different regulator system in USA, europe and India	5
		give an overview of regulatory environment in India	5
		expand forms of the following MHRA, CRO, CRF, MAH, EMEA, CTA, GLP, CFR	5
		write a note on regulations for OFF-Label Use	5
		Write a note on pharmaceutical regulations in regard to clinical trials in European union	10

		Write a note on Centralized procedure and Decentralized Mutual Recognition Procedure in European union	10
		write a note on Accelerated Approval	5
		write a note on Accelerated Approval, Fast Track, and Priority Review	10
		write a note on Fast Track, and Priority Review	5
2.10	Role and responsibilities of clinical trial personnel as per ICH GCP a. Sponsor b. Investigators c. Clinical research associate d. Auditors e. Contract research coordinators f. Regulatory authority	write a note on CRA	5
		Explain in detail the role and responsibilities of a)investigator b) clinical research associate c) Regulatory authority as per ICH-GCP	10
		explain about clinical trials audit and inspection with special emphasis on national regulatory authorities	10
		Expand the following: IND, DCGI, PvPI, BPO	2
		role of CRC	2
		Role of auditor In clinical data	2
		What is an Investigators brochure and explain its content?	5
		role and responsibilities of auditors	5
		explain the role of investigators I clinical trials	5
		criterias for selection of an investigator/s	2
		Role and responsibilities of sponsor in clinical trials	5
2.11	Designing of clinical study documents (protocol, CRF, ICF, PIC with assignment)	Explain in detail the process of designing study protocol in clinical trials. Add a note on importance of CRF	10
		explain designing of CRF with a suitable example	5
		define protocol	2
2.12	Informed consent Process	Discuss about designing of inform consent form for clinical study?	5
		explain confidentiality and impartial witness	2
		Explain in detail the informed consent process	5
		difference between consent and assent forms	2
		explain Waiver of consent	2
2.13	Data management and its components	write a note on QA and QC	5
		Discuss data management and its component	5
		write the application of computers in clinical data management	5
		write a note on clinical data archive	5
		What is ANOVA?	2

		Role of DSMB in safety monitoring	2
		Components of documentation form	2
		Discuss Electronic Data Processing	5
2.14	Safety monitoring in clinical trials	Explain the monitoring visits in initiation, conduction and closing of clinical trial	10
		List global ADR reporting Forms?	2
		Define unexpected ADR	2
		Minimum criteria to report ADR	2
		List various criterias to classify a serious ADR	2
		write about safety monitoring in clinical trails	5
		Explain the purpose of the clinical trial monitoring and the responsibilities of monitors in clinical monitoring	5
		PVPI	2
		PSUR	2
		SUSAR	2
		write a note on Active Surveillance in ADR reporting	5
		Role of Eudravigilance in safety monitoring	5
		Role of Uppsala monitoring centre (UMC) in safety Monitoring	2
		Explain spontaneous reporting of ADR with suitable examples. What are the merits and demerits of spontaneous reporting	10