Approved Content Weightages for Drug Regulatory Authority Government of Pakistan Adv.No.01/2024

S.no	Title	Criteria and Subject Division	No of MCQ's
		As per the advertisement	100 MCQs
		Verbal Reasoning	10%
01-	Assistant Director (Technical Cadre) (Pharmaceutical Evaluation / Drugs Licensing / Quality Assurance / Health & OTC / Controlled Drugs / Pharmacy Services / Biological Drugs / Medical Devices) (RO-12)	As per the advertisement	100 MCQs
		 Guidelines: ICH (Quality & Safety) WHO (Production, Quality Control, Quality Assurance) 	20%

		As per the advertisement	100 MCQs
		Verbal Reasoning	10%
		Analytical Reasoning	10%
		 DRAP Act 2012, Drugs Act 1976: The Drugs Licensing, Registration & Advertising Rules, 1976 The Drugs (Federal Inspectors, Federal Drug Laboratory and Federal Government Analysis) Rules, 1976 Drugs (Specifications) Rules, 1978 The Ethical Marketing to Healthcare Professional Rules, 2021 	10%
		Subject Related:70%	
		Pharmaceutical Analytical Chemistry	
		• Fundamentals of bases, acids, solubility, polarity,	
		partition, and stereochemistry;	
		• Chemical analysis of pharmaceutical ingredient	
	Assistant Director (Technical Subject Specialist-Chemist) (RO-12)	• Chemical analysis of pharmaceutical preparations	
02-		Titration	
		• Introduction to spectroscopic methods	40%
		 UV-Vis spectrophotometry 	4070
		 IR Spectrophotometry 	
		Atomic Spectrometry	
		 Separation principle in liquid chromatography 	
		Gas Chromatography	
		Mass spectrometry	
		WHO Guidelines WHO TRS 1052 Annex 4, WHO Good Practices and	15%
		Pharmaceutical Quality Control Laboratories	1.3 70
		(11) USP Reference standards	
		• (621) Chromatography	
		• (711) Dissolution	
		• (905) Uniformity of dosage units	15%
		• (1224) Transfer of analytical procedures	
		• (1092) The Dissolution Procedure: Development	
		and Validation	
	Assistant Director (Technical Subject	As per the advertisement	100 MCQs
		Verbal Reasoning	10%
03-	Specialist-	Analytical Reasoning	10%
	Microbiologist)	• DRAP Act 2012, Drugs Act 1976	
	(RO-12)	• The Drugs Licensing, Registration & Advertising	10%
		Rules, 1976	

		 The Drugs (Federal Inspectors, Federal Drug Laboratory and Federal Government Analysis) Rules, 1976 Drugs (Specifications) Rules, 1978 The Ethical Marketing to Healthcare Professional Rules, 2021 Subject Related: 70% Pharmaceutical Microbiology Laboratory evaluation of antimicrobial agents Chemical disinfectants, antiseptics and preservatives 	40%
		 Sterilization procedures and sterility assurance Sterile pharmaceutical products The manufacturer and quality control of immunological products 	40%
		 WHO Guidelines WHO TRS 961 Annex 2, WHO practices for pharmaceutical microbiology laboratories WHO TRS 1052 Annex 4, WHO Good practices and pharmaceutical quality control laboratories. 	15%
		 (61) Microbiological examination of non-sterile products: microbial enumeration tests (62) Microbiological examination of Non-sterile products: tests for specified microorganisms. (71) Sterility tests (81) Antibiotics – microbial assays (85) Bacterial endotoxins test 	15%
		As per the advertisement	100 MCQs
		Verbal Reasoning	10%
	Assistant Director (Technical Cadre)(Subject Specialist-Bio-	Analytical Reasoning	10%
04-		 DRAP Act 2012, Drugs Act 1976 The Drugs (Federal Inspectors, Federal Drug Laboratory and Federal Government Analysis) Rules, 1976 The Ethical Marketing to Healthcare Professional Rules, 2021 	10%
	Medical Engineer)	Subject Related:70%	
	(RO-12)	 <u>Non-invasive instrumentation and measurement in</u> <u>medical diagnosis</u> Measurement of electrical Potentials and Magnetic Fields from the Body Surface Non-invasive measurement of blood pressure Ocular Tonometry 	40%

		 Non-invasive tests using ultrasound (excluding imaging) Innovations in non-invasive instrumentation and measurements 	
		 Medical Instrumentation: Application and Design Clinical laboratory instrumentation Chemical biosensors Therapeutic and prosthetic devices Measurement of flow and volume of blood Blood pressure and sound Bio-potential amplifiers 	10%
		WHO TRS 1019 Annex 3, Good manufacturing practise: guidelines on validation	10%
		Medical Devices Rules 2017	10%
		As per the advertisement	100 MCQs
		Verbal Reasoning	10%
		Analytical Reasoning	10%
	Assistant Director (Technical Subject Specialist- Biotechnologist) (RO-12)	 DRAP Act 2012, Drugs Act 1976 The Drugs Licensing, Registration & Advertising Rules, 1976 The Bio Study Rules, 2017 The Ethical Marketing to Healthcare Professional Rules, 2021 The Pharmacovigilance Rules, 2022 	10%
		Subject Related:70%	
05-		Cell Biology/ Molecular Biology (CELL BIOLOGY Introduction to cell theory including historical perspective; chemical constituents of the cell and their function, cell organelles including ribosomes, endoplasmic reticulum, lysosome, golgi apparatus, mitochondria, peroxisome, vacuole, chloroplast, structure and their functions, composition and structure of cell membranes; membrane receptors and transport mechanisms; nucleus; structure and function of chromosomes; cell cycle, mitosis and meiosis; cell movement, structure and function of cytoskeleton, centriole, cilia and flagella)	10%
		Organic Chemistry (Introduction to Organic Chemistry, Chemical Bonding and Properties of Organic Molecules, Classes and Nomenclature of Organic Compounds, Functional Group Chemistry)	10%
		Fundamentals of Genetics (Mendelian Genetics, principle of segregation, monohybrid crosses, dominance,	10%

in g ty p c. c c e p b d	ecessiveness, codominance, semidominance, principle of ndependent assortment, dihybrid and trihybrid ratios, gene interaction, epistasis, multiple alleles, ABO blood ype alleles in humans, Rh factor alleles in humans, probability in Mendetion inheritance, structure of thromosomes and Genes, function of DNA and RNA, classes of RNA, DNA as storage of Genetic information, experimental evidence that DNA is genetic material; ohysical and chemical structure of DNA, Difference between Prokaryotic and Eukaryotic Genetic material, sex letermination and differentiation, sex-linked traits, sex unomalies, linkage and crossing over)	
M O P D D O O I I D D D D D D D D D D D D D D	Molecular Biology (Overview of Molecular Biology, Macromolecules, chemical structures of the major classes of Macromolecules: Proteins, Nucleic Acids, Polysaccharides, Nucleic Acids, DNA Helix, Form of DNA Helix, Factor that determine structure of DNA, properties of Genetic Material (storage and Transmission of Genetic information by DNA). Transmission of nformation from parent to progeny, chemical stability of DNA, Ability of DNA to change, DNA Replication, Enzymology of DNA Replication. Events in the Replication Fork, Initiation of synthesis of Leading and agging strands, Okazaki fragments, importance of $3 \diamond 5$ and $5 \diamond 3$ Exonuclease activities of DNA polymerase, Rolling circular Replication, Loop Rolling circular Replication, Difference between Prokaryotic and Eukaryotic Replication)	10%
a (e tu re (j p e si o c c p	Biochemistry (Introduction to metabolism and basic aspects of bioenergetics and biochemical thermodynamics endergonic and exergonic reactions); phosphoryl group ransfer and ATP production; metabolism, oxidation- eduction; carbohydrate metabolism and regulation glycolysis, glycogenolysis; gluconeogenesis; pentose ohosphate pathway); citric acid cycle (reactions, energetics and control), electron transport chain, oxidative ohosphorylation, shuttle mechanisms (glycerolphosphate hunt), lipid metabolism (energy yield from fatty acid oxidation, ketone bodies, acyl glycerol, compound lipids, cholesterol); Calvin Cycle; metabolism of nitrogenous compounds (amino acid synthesis, catabolism, purine and oyrimidine synthesis); nucleic acid metabolism and control; urea cycle.)	10%
	mmunology (Overview of the body defense nechanisms, the immune system, elements of innate and	10%

		acquired immunity, antibody structure and function, antigenantibody interactions, cells of the immune system, monoclonal antibodies, Genetics of antibody structure and diversity, Activation and function of T and B cells and their receptors, Major histocompatibility complex, Complement system, Hypersensitivity, cytokines, Autoimmunity, resistance and immunity to infectious diseases, cell- mediated effector response, leukocyte migration and inflammation, vaccines, diseases of the immune system - autoimmunity, transplantation immunology)	
		Recombinant DNA Technology (Introduction and History of Recombinant DNA technology, An overview of cloning steps; Preparation of insert, restriction endonucleases, restriction mapping, vectors and their types, cloning vectors, cloning strategies, site-directed mutagenesis, sequencing strategies, transformations, regeneration through tissue culture techniques, expression of recombinant proteins and their purification by affinity chromatography; Polymerase Chain reaction, analysis of nucleic acids by gel electrophoresis, analysis of proteins by native and SDS-PAGE; 2-D gels; generation of antibodies and their uses; Southern, Western, Northern blotting. Application of recombinant DNA Technology (agriculture, health, industry, environment and basic research).	10%
		As per the advertisement	100 MCQs
		Verbal Reasoning	10%
		Analytical Reasoning	10%
	Assistant Director	Subject Related:80%	
06	(Management	Programming (Php/.Net)	30%
06-	Information Systems Division)	Databases (Mysql, SQL)	20%
	(RO-12)	Website Designing & Development (HTML, CSS, JAVA	15%
		Scripting, CMS)	
		Information Security (Database Security, Application	15%
		Software Security)	100 MCO~
	Assistant Director (Budget & Accounts/ Costing & Pricing) (RO-12)	As per the advertisement Verbal Reasoning	100 MCQs 10%
		Analytical Reasoning	10%
07-			10%
		 DRAP Act, 2012 DRAP Accounting Procedure & Financial Rules, 2015 	
		• DRAP Employees Service Regulations, 2015 (as amended till date)	

		 Public Procurement Rules, 2004 Procurement of Consultancy Services Regulations, 2010 	05%
		 Pension Rules of Federal Government General Provident Fund (Federal Services) Rules 	05%
		 TA/DA Rules of Federal Government Fundamental Rules and Supplementary Rules (FR & SR) (Volume I & II) of Federal Government 	05%
		 General Financial Rules (GFR) of Federal Government (Volume I & II) Treasury Rules of Federal Government (Volume I & II) 	05%
		 Income Tax Ordinance, 2001 Income Tax Rules, 2002 	05%
		 The Sales Tax Act, 1990 Sales Tax Rules, 2006 The Islamabad Capital Territory (Tax on Services) Ordinance, 2001 	05%
		Subject Related:40%	
		Financial AccountingFinancial Management	10%
		 Managerial Accounting Cost Accounting 	10%
		International Financial Reporting Standards (IFRS)	10%
		 Auditing International Standards on Auditing (ISAs) 	10%
		As per the advertisement	100 MCQs
		Verbal Reasoning	10%
		Analytical Reasoning	10%
08-	Assistant Director (Legal Affairs	 Drugs Act 1976 & DRAP Act, 2012 The Drugs (Licensing, Registering & Advertising) Rules, 1976 	20%
00-	Division) (RO-12)	• The Drugs (Import & Export) Rules, 1976	
		 The Drug Research Rules, 1978 The Appellate Board Rules, 1976 The Drugs (Labelling & Packing) Rules, 1986 	

 The Drugs (Federal Drugs Inspectors, Federal Drug Laboratory & Federal Government Analysts) Rules, 1976 Medical Devices Rules, 2017 Alternative Medicines & health Products (Enlistment) Rules, 2014 Drug Pricing Policy, 2018 DRAP Employees Service Regulations, 2015 DRAP Accounting Procedure & Financial Rules, 2015 Civil Servants Act, 1973 	10%
Constitution of Pakistan 1973	05%
Criminal Procedure Code 1898	05%
Pakistan Penal Code Act,1860	05%
Code of Civil Procedure and Limitation Act, 1908	05%
Qanun-e-Shahadat Order 1984	05%
Transfer of Property Act & Specific Relief Act	05%
Intellectual Property Law i.e Trade Mark Ordinance, 2001 and Patent Ordinance, 2000	05%
Control of Narcotics & Substance Act, 1997, Control of Narcotics & Substance Rules, 2001 & UN Conventions on controlled Substances	05%
Import & Export Policy Orders, 2022	05%
Income Tax Ordinance, 2001 and Sales Tax Act, 1990	05%