REPUBLIC OF KENYA

MINISTRY OF HEALTH

PHARMACY AND POISONS BOARD

MODEL EXAMINATION QUESTION PAPER

STAGE TWO: PAPER II

TIME: 2.00 P.M. – 5.00 P.M. **DATE:** SEPTEMBER 2017

EXAM NUMBER: ……..

INSTRUCTIONS TO CANDIDATES

This examination consists of **THREE PARTS** as follows:

Part I:

This consists of **100 Multiple Choice Questions**. **Use the answer sheet** provided to indicate to indicate your answer choices. For each question, select **only one** most appropriate answer choice. Write your Exam Number clearly on the separate answer sheet provided using blue or black ink pen.

Part II:

This part consists of **15 Short Answer Questions**. Answer **all** the questions in the spaces provided.

Part III:

This consists of **3 Essay Questions**. Attempt **all**. Write **all** your answers on the sheets of paper provided. **Start each question on a separate sheet of paper and write your Exam Number on all the answer sheets.**

At the end of the examination, put all your answers sheets in the envelope provided. Write **your Exam Number** on the envelope. **DO NOT** write your name on the Answers Sheet, any page of this Examination Paper nor the envelope.

PART I:

This part consists of Multiple Choice Questions. Use the answer sheet provided to indicate your answer choices. For each question select the most appropriate answer.

1. Which of the following is covered under WHO Certification Scheme on quality of pharmaceutical products moving in international commerce?
   A. Finished pharmaceutical products
   B. Starting materials for use in dosage forms
   C. Information on safety and efficacy
   D. Finished pharmaceuticals administered to human

2. Which of the following statements is not true about an airlock?
   A. It is an open space between two rooms of different classes of cleanliness
   B. It is designed for use by personnel
   C. It is designed for use by equipment
   D. It controls air flow between two or more rooms

3. The demonstration that a specific process will consistently produce a product that meets predetermined specifications is referred to as
   A. design qualification
   B. performance qualification
   C. installation qualification
   D. operational qualification

4. The WHO concept of essential medicines comprises the following except
   A. ensuring drug quality
   B. continued development of better medicines
   C. having as many different brands of a pharmaceutical product in the market
   D. regularly updating medicines selection to reflect new therapeutic options

5. The following contribute to good clinical governance and pharmacy practice except
   A. practicing evidence based pharmaceutical care
   B. promptly prosecuting cases of negligence in a civil court
   C. carrying out periodical clinical audits
   D. storing patient information confidentially

6. The main reason continuous professional development (CPD) is enforced by professional regulators is to
   A. self-direct learning amongst professionals
   B. help professionals to plan their learning
   C. enable professionals to expand and fulfill their professional role
   D. assist professionals to think about their daily tasks

7. The following are the mandatory records to be kept by pharmacists except
   A. financial transactions
   B. records of medicine supply
   C. clinical governance records
   D. advice given and interventions made on prescribed medicine

8. Market authorization of a medicinal substance in Kenya is issued by
   A. Public Procurement Oversight Authority
   B. National Quality Control Board
   C. Kenya Bureau of Standards
   D. Pharmacy and Poisons Board

9. The following are functions of the head of pharmaceutical production unit except
   A. approve production instructions
   B. check maintenance of the department
   C. ensure training of production personnel
   D. evaluate and approve batch records for release

10. The following are categories of licences and/or permits issued to pharmacists by the Pharmacy and Poisons Board of Kenya, except
   A. annual trade licence
   B. wholesale dealer's licence
   C. annual practice licence
   D. premises registration

11. Type B adverse drug reaction refers to
   A. reactions that are due to exaggerated but expected pharmacology of the drug
   B. reactions that are predictable on the basis of a drug's known pharmacology
   C. reactions that are dose-dependent
   D. unpredictable reactions that are usually not observed during conventional pharmacological testing

12. The main purpose of *in vitro* studies is to
   A. establish the efficacy and toxicological profile in animals
   B. establish the efficacy and toxicological profile in humans
   C. establish the lead molecule
   D. detect adverse effects during marketing of drug

13. Regarding a manufacturing licence, it
   A. is issued to foreign companies from which drugs are imported
   B. indicates that the company is GMP compliant
   C. usually specifies the kind of products to be manufactured
   D. gives marketing authorization for the products being manufactured

14. With respect to storage of pharmaceuticals, Kenya falls under climatic zone
    A. I – temperate
    B. II – subtropical
    C. III – hot, dry
    D. IVb – hot, humid

15. The study report that is not a requirement for an application for registration of a generic drug in Kenya is
    A. bioequivalence
    B. toxicology
    C. stability
    D. analytical

16. According to the Food Drug and Chemical substances Act, the following are offenses except
    A. selling uncooked food
    B. preparing food under poor sanitary conditions
    C. inaccurate labeling of a food product
    D. advertising food in a deceptive manner

17. The board established for the administration of the food, drugs and chemical substance Act is known as the
    A. Food, Drugs and Chemicals Board
    B. Pharmacy and Poisons Board
    C. Kenya Bureau of Standards
    D. Public Health (standards) Board

18. Employees working in a food plant must undergo medical assessment carried out by
    A. the public health analyst in the county
    B. a medical officer of health in a government medical institution
    C. any doctor registered with the medical practitioners and dentist board
    D. the county executive of health or his/her representative

19. The law permits the use of all the following as non-nutritive sweetening agents except
    A. ammonium saccharin
    B. stevia
    C. aspartame
    D. sodium saccharin

20. The Kenya Medical Supplies Authority was established by
    A. the Pharmacy and Poisons Board
    B. the Constitution of Kenya
    C. a presidential decree
    D. an Act of Parliament

21. A legal representative of a person with mental illness
    A. is appointed by the county executive of health
    B. shall charge not more than 5000 Kenya shillings for services offered
    C. has the right to attend and be heard in any hearing
    D. is not allowed access to the person's medical records

22. The following persons are represented in the Mental Health Board except
    A. psychiatrists
    B. clergy
    C. psychologists
    D. counselors

23. The World Health Organization is headed by
    A. Secretary General
    B. Director General
    C. Commissioner general
    D. Commander general

24. The sustainable development goals have health related targets for the following communicable diseases except
    A. HIV/AIDS
    B. malaria
    C. meningitis
    D. small pox

25. The Kenya Malaria Indicator Survey is to be conducted every
    A. 6 months
    B. 1 year
    C. 3 years
    D. 5 years

26. Who gives consent in a medical emergency case of a minor who has no parent or guardians?
    A. Police officer
    B. Legal officer
    C. Social worker
    D. Medical professional

27. The first international guideline pertaining to research involving human participants was the
    A. Declaration of Hiroshima
    B. Declaration of Helsinki
    C. Nuremberg Code
    D. WHO ethical guideline

28. Which principle of ethics is concerned with performing acts that help others?
    A. Non maleficence
    B. Responsibility
    C. Beneficence
    D. Fidelity

29. Which of the following is not an act of negligence in pharmacy practice
    A. failure to dispense correct medication
    B. failure to follow policy and procedure
    C. failure to correct prescription errors
    D. examination of a patient without consent

30. Morality is
    A. what's considered as correct within a society
    B. making the right decision where there's a choice to do wrong
    C. defining what is right and wrong for an individual or a community
    D. where individual has a conscious choice to make a right and ethical decision

31. After how many days does registration of a pharmacy premises become void after a change of ownership?
    A. 7 days
    B. 30 days
    C. 1 year
    D. 5 years

32. The following officers may order an authorized seller of poisons to produce his/her registration certificate or licence except
    A. medical officer
    B. police sergeant
    C. registrar
    D. pharmaceutical analyst

33. Which of the following poisons require to be specially labeled for transport?
    A. Phenol
    B. Nicotine
    C. Sodium hydroxide
    D. Insulin

34. The constitution of Kenya, confers the sovereign power to
    A. the President of Kenya
    B. the Supreme Court
    C. the Parliament and Senate
    D. the people of Kenya

35. The following are the national values and principles of governance as per the Constitution of Kenya except
    A. good governance
    B. planning
    C. sustainable development
    D. devolution of power

36. The rights and fundamental freedoms in the Bill of Rights,
    A. belong to each individual and are granted by the state
    B. exclude other rights not in the Bill of Rights
    C. are not subject to any limitations contemplated in the constitution
    D. apply to all laws and binds all state organs

37. Which of the following does not constitute manufacture of a narcotic drug?
    A. Extemporaneous preparation of morphine solution in a hospital
    B. Refining of morphine raw material in laboratory
    C. Making of codeine linctus in the pharmacy for own use
    D. Grinding of cannabis leaves to fine powder for own use

38. Which of the following persons is not a member of the board that issues licences for export, import and manufacture of narcotic drugs?
    A. Chief pharmacist
    B. Commissioner of police or the representative
    C. Registrar, Pharmacy and Poisons Board
    D. Director of medical services

39. The following are scheduled psychotropic substances except
    A. cathinone
    B. phentermine
    C. fentanyl
    D. methaqualone

40. The rehabilitation fund for persons addicted to narcotic drugs is funded by
    A. court fines imposed on traffickers
    B. money earned from seized properties
    C. multinational drug companies
    D. sale of seized narcotic substances

41. Opium is obtained from
    A. Cannabis sativa
    B. Catha edulis
    C. Nicotiana tobacum
    D. *Papaver somniferum*

42. According to Public Health Act, the minister may declare all the following as formidable epidemic diseases except
    A. schistosomiasis
    B. sleeping sickness
    C. yellow fever
    D. HIV/AIDS

43. Publication of an advertisement or statement intended to provide sale of medicine for the cure of the following conditions is prohibited except
    A. kidney failure
    B. syphilis
    C. fatigue
    D. impotence

44. According to Public Health Act, the person is responsible for inspection, sampling and examination of vaccines intended for use in human is
    A. Director of Veterinary Services
    B. Government Chemist
    C. Minister of Health
    D. Director of Medical Services

45. The best study tool to use in auditing clinical outcomes is
    A. checklist
    B. questionnaire
    C. dummy tables
    D. audio-visual recording

46. Descriptive analysis of study data involves of the following except
    A. regression
    B. median
    C. mean
    D. percentage

47. Why is piloting of a data collection tool crucial in a study?
    A. It makes study affordable
    B. Ensures suitability and comprehension of tool
    C. Assists in recruiting study participants
    D. It reduces duration of study period

48. Discrete or count data may be presented as
    A. histogram
    B. bar chart
    C. frequency polygon
    D. line graph

49. The following are measures of central tendency except
    A. mode
    B. standard deviation
    C. median
    D. mean

50. Which of the following is the most appropriate indicator of the adequacy of a pharmaceutical budget?
    A. Percentage of drugs procured by tender
    B. Pharmaceutical budget per capita
    C. Policy on procurement
    D. Average time out of stock

51. Which of the following is not a source of funding for public procurement of pharmaceuticals?
    A. Donor
    B. Taxes
    C. User fees
    D. Private health insurance

52. A prime vendor system for drug supply
    A. is an autonomous drug supply agency
    B. involves a central ware house
    C. involves tendering for storage and distribution services
    D. is fully private

53. In the pharmaceutical procurement cycle
    A. qualification is done before drug selection
    B. reconciliation is done to achieve a balance between the desired quantities and available funds
    C. does not entail specification of drug supply terms
    D. does not rely on past consumption data

54. Which of the following is not a hidden cost in medicines supply?
    A. Incomplete supply
    B. Expiry of procured medicines
    C. Late deliveries
    D. Stipulated financial penalties for delayed payments

55. The county governments can collectively minimize the cost of procuring drugs and pharmaceutical expenditure by
    A. group purchasing
    B. single source procurement
    C. product quality assurance
    D. supplier monitoring

56. County X procures drugs by reviewing records continually and placing orders whenever stock levels fall before the reorder quantity. This method of procurement is called
    A. perpetual purchasing
    B. trade terms
    C. lead-time compliance
    D. back order procurement

57. Which of the following is not a correct method for quantifying drug needs for a health facility?
    A. Consumption data
    B. Local epidemiological disease patterns
    C. Bed capacity of health facility
    D. Number of skilled personnel

58. In inventory management, the key role of safety stock levels is to
    A. prevent stock-outs
    B. specify the maximum quantities that should be procured
    C. reduce the lead times
    D. minimize expiry of drugs

59. Which of the following indicators is not used to monitor the performance of a supplier?
    A. Lead times
    B. Compliance with pricing terms
    C. Product complaints received
    D. ABC analysis of warehouse

60. County X wishes to procure vaccines from an international supplier. Which of the following is not a mandatory clause in the contract specifications for vaccines?
    A. Shipment must be by air
    B. Provision of temperature charts required during shipment
    C. Contingency plans for power outages
    D. Vaccine waste disposal plan

61. Which of the following in not a component of the drug distribution cycle?
    A. Dispensing
    B. Storage
    C. Delivery
    D. Manufacturing

62. In a push supply system
    A. Each facility determines the types and quantities of drugs it requires
    B. The requisition system is independent
    C. The central supplies office plans the medicines allocations to the facilities
    D. The lower-level facilities are competent in drug procurement.

63. A warehouse received 1000 litres of surgical spirit. It should be stored
    A. on pallets in the warehouse
    B. on shelves for liquid formulations
    C. in a secure room for controlled drugs
    D. in a special separate building for flammables

64. Which of the following is an in-process control procedure?
    A. Definition of a finished product
    B. Validation of analytical method
    C. Performing stability studies
    D. Qualification of manufacturing equipment

65. What parameter is tested if a sample is spiked with a known amount of impurities?
    A. Linearity
    B. Precision
    C. Accuracy
    D. Reproducibility

66. The following are Good Laboratory Practice Personnel requirements except
    A. taking personal sanitation
    B. wearing protective clothing
    C. qualification in personnel management
    D. withdrawing from the lab in the event of an infection with influenza

67. Which the following is not a Quality Control activity?
    A. Testing of API's
    B. Stability testing
    C. Sampling
    D. Product design

68. A substance whose characteristics are assigned and/or calibrated by comparison with a primary reference substance is called
    A. primary reference
    B. reference standard
    C. secondary reference
    D. comparator

69. In Quality Management System, the following are part of a quality manual, except
    A. quality policy statement
    B. key annual performance indicators
    C. policy for dealing with complaints
    D. policy for performing management reviews

70. The following are elements of an effective Standard Operation Procedure except
    A. scope
    B. responsibility
    C. procedure
    D. equipment design

71. Which of the following is usually used to sample powdered materials in the quarantine area of production?
    A. Sampling scoop
    B. Sampling spoon
    C. Sampling thief
    D. Spatula

72. The following are the major causes of errors in a quality control laboratory except
    A. mistakes in following the method of analysis
    B. mistakes in in-process controls
    C. use of incorrect standards
    D. miscalculations

73. The following is the preliminary stage of production planning
    A. capacity planning
    B. material requirements planning
    C. scheduling
    D. product development and design

74. Checklist for job safety analysis (JSA), consists of
    A. work area, material, machine, tools
    B. men, machine, material, tools
    C. men, machine, work area, tools
    D. men, work area, material, tools

75. Which of the following colors is used to signifying radiation hazard?
    A. Red
    B. Orange
    C. Green
    D. Purple

76. The following definition “Materials fabricated, compounded, blended, or derived by chemical reaction that is produced for, and used in the preparation of the drug product” is known as
    A. intermediate product
    B. in-process materials
    C. out-process materials
    D. active ingredients

77. The procedure used to prove that the various production procedures, equipment and materials will produce accurate results is known as
    A. GMP
    B. quality control
    C. quality assurance
    D. validation

78. Good Manufacturing Practice (GMP), a general guide intended to provide guidance for manufacturing active principle ingredients (APIs), covers the following aspects, except
    A. all manufacturing operations
    B. human drug products
    C. aspects of protection of the environment
    D. APIs manufactured by cell culture

79. The master production instructions should include the following except
    A. expected yield ranges at appropriate phases of processing
    B. any sampling performed
    C. identity of major equipment used in the production
    D. actual results recorded for critical process parameters

80. Which of the following must be included in the cleaning procedure of a pharmaceutical manufacturing equipment?
    A. The name of the intermediate or API being manufactured
    B. Ranges of process parameters to be used
    C. Mechanism for ensuring complete elimination of detergent residues
    D. Actual results recorded for critical process parameters

81. Which of the following particulars for raw materials is the most critical for inclusion in the records?
    A. Identity and quantity of each shipment
    B. Name of supplier
    C. Supplier control number
    D. The date of receipt

82. What is the standard number of rotations per minute used for friability test?
    A. 10 rotations
    B. 25 rotations
    C. 50 rotations
    D. 100 rotations

83. The term used to describe the breaking of tablets at the edges during manufacturing and handling is
    A. cracking
    B. capping
    C. mottling
    D. chipping

84. The assignment of shelf life to a home infusion after formulation is mainly based on
    A. chemical nature of drug
    B. infusion volume
    C. rate of infusion
    D. drug stability

85. The following are ingredients in calamine lotion B.P. except
    A. light kaolin
    B. zinc carbonate
    C. bentonite
    D. zinc oxide

86. Which of the following suspending agents is a natural polysaccharide used in external preparations?
    A. Methylcellulose
    B. Gelatin
    C. Tragacanth
    D. Polyvinylalcohol

87. Which of the following can be used as a preservative in pharmaceutical solutions for oral use?
    A. Chloroform water BP
    B. Low sucrose concentration
    C. Peppermint
    D. Chlorocresol

88. The amount of drug present in 50ml of 3.2% w/v preparation expressed as grams is
    A. 1.6
    B. 16
    C. 0.16
    D. 160

89. The label on a bottle of ampicillin syrup indicates that 92 ml of water should be added to make 100ml of syrup. How much water should be added to make 130ml of syrup?
    A. 99ml
    B. 122ml
    C. 124ml
    D. 108ml

90. The selection of a packaging for a pharmaceutical product is dependent on the following factors except
    A. contribution to delivering a drug to site of action at right temperature
    B. dosage form
    C. method of administering the medication
    D. required shelf life

91. The following are advantages of plastics for packaging except they
    A. are flexible and not easily broken
    B. can be neatly sealed
    C. are inert to most medicinal products
    D. are easily moulded into various shapes

92. Alcoholic, oily solutions or emulsions designed to be rubbed into the skin are
    A. tinctures
    B. ointments
    C. lotions
    D. liniments

93. The ability within a given range for a test method to obtain results that is directly proportional to the concentration of analyte in the sample, best describes its
    A. selectivity
    B. linearity
    C. robustness
    D. precision

94. The following are in-process control tests for hard gelatin capsule dosage forms except
    A. moisture content
    B. disintegration
    C. sterility
    D. content of active principle

95. GMP is designed to minimize the following risks during production except
    A. unexpected contamination
    B. wrong labeling
    C. high cost of production
    D. lapse of regulatory licensure

96. The following are requirements applicable to personnel who have to move several times between self-contained facilities and the regular production facilities, except
    A. movement is subject to procedures to prevent gross contamination
    B. need to reduce number of sampling visits
    C. showering and change of clothes is necessary
    D. may involve decontamination procedures

97. Training records of all personnel in a manufacturing facility must be kept detailing
    A. possible salary changes
    B. standard operating procedures
    C. external job applicable training
    D. curriculum covered

98. A retention sample is one
    A. representing the batch of the finished product
    B. undergoing stability testing
    C. taken for the purpose of future analysis
    D. representing the manufacturing conditions in a specific facility

99. The following products are regulated as biologicals except
    A. human stem cells
    B. tissue based products
    C. vaccines
    D. cell based products

100. In designing a clean room, all the following requirements must be met except

A. safety
B. authorised personnel
C. environmental aspects
D. GMP considerations

PART II:

This part consists of Short Answer Questions. Answer ALL the questions in the spaces provided.

1. a) List any three circumstances in which handling a narcotic drug is not considered trafficking (3 Marks)

   b) State any two circumstances that can lead to forfeiture of narcotic drugs from a person (2 Marks)

2. a) List any three methods used for counting of tablets and capsules (3 Marks)

   b) Why should caution be taken when counting penicillins? (2 Mark)

3. For each of the following commonly used materials, give their (synonyms) (5 Marks)
   a) Cocoa butter
   b) Whitfield's ointment
   c) Lanolin
   d) Paraffin wax
   e) Polyethylene glycol 2000

4. a) State the any three basic principles of radiation protection 3 Marks)

   b) State any two major uses of radiopharmaceuticals (2 Marks)

5. List any five components of a total parenteral nutrition (TPN) formulation (5 Marks)

6. The erythrocyte sedimentation rates (ESRs) of 7 men are 7, 5, 3, 4, 6, 4, 5.
   a) Calculate mean (1 Mark)

   b) State median value (1 Mark)

   c) State the modal rate (1 Mark)

   d) Calculate the range of rates (1 Mark)

   e) Calculate standard deviation (1 Mark)

7. List any five equipment or devices that are mandatory in a facility for maintenance of cold chain storage conditions. (5 Marks)

8. Dr. Karanja is the pharmacist in charge of the county warehouse. He is required to develop a system to guide the order of storage of tablets, injectable preparations and capsules in warehouse so as to facilitate inventory taking and location of drug. Briefly describe any five methods for physically organizing drugs in a warehouse. (5 Marks)

9. List the any five goals of a good inventory control system in a health facility. (5 Marks)

10. List at any five different costs that are incurred when procuring drugs. (5 Marks)

11. A county pharmacist was concerned that on tendering for goods, he was receiving sub-standard products. List any five ways in which he can improve the drug procurement process to ensure he receives quality goods. (5 Marks)

12. List any five notifiable infectious diseases as per the Public Health Act. (5 Marks)

13. What is the difference between calibration and validation? (5 Marks)

14. Define the term "Clinical Trial Protocol" (5 Marks)

15. List any five situations in which the law permits the disclosure of confidential information relating to a patient illness. (5 Marks)

PART III:

This part consists of 3 Essay Questions. Attempt ALL.

1. a)
   i) State the main objectives of sampling in experimental studies (2 Marks)

   ii) State the main characteristics of a representative sample (2 Marks)

   iii) State the sampling technique in use of published table of random numbers (1 Mark)

   b) State the requirements of the Pharmacy & Poisons Board for the assessment of safety during a clinical trial (5 Marks)

   c) Briefly
   i) Outline the procedure for analysis of seized narcotic drugs according to Narcotic Drugs and Psychotropic Substances Control Act. (5 Marks)

   ii) Outline the details required of a drug before being issued a certificate of registration in Kenya. (10 Marks)

2. a) Outline the technique and precautions taken when preparing cytotoxic preparations for a patient (10 Marks)

   b) i) Briefly describe the principle of "Quality Assurance" in pharmaceutical manufacturing (3 Marks)

   ii) State at least eight (8) ways in which a Quality Assurance System will influence pharmaceutical production and quality therein (12 Marks)

3. Dr. Mutua is in charge of procuring drugs for Biohealth Hospital. The average monthly consumption of Amoxicillin capsules is 16 containers per month. The procurement period is 12 months. Most of the suppliers have a lead time of 3 months. The bin cards show the hospital currently has 10 containers of amoxicillin. The pipeline stock is 100 containers of amoxicillin. In computing the average monthly consumption, seasonal stock was not considered.
   a) Define the following terms (5 Marks)
      i) Lead Time
      ii) Procurement period
      iii) Pipeline stock
      iv) Bin cards
      v) Seasonal stock

b) Compute the following (5 Marks)

i) The safety stock level

ii) Quantity to order if stock at hand and pipeline stock are not considered

iii) Quantity to order if stock at hand and pipeline stock are considered

c) The hospital management is concerned that there might be high inventory holding costs.

i) Define Inventory Holding Costs (1 Mark)

ii) List the components of inventory holding costs. (4 Marks)

d) The store has a lot of pharmaceutical waste. List the methods that can be used to dispose of the waste. (5 Marks)

e) When receiving goods from a supplier, what types of discrepancies should one check for? (5 Marks)