Manipal College of Pharmaceutical Sciences
MAHE, Manipal

BPharm Semester VI ----- END Semester Examination –July/August 2021

Sub: PQA PQA-BP606T

Date: 04.08.2021 Duration: 2 hr. (2.30-4.30 pm) (MST) Max. Marks: 50

Instruction: Answer ALL

I Multiple Choice Questions (MCQs) 20 Q × 1 mark = 20 marks		**EVALUATOR NAME**	**CO**	**Typology**
1	Maximum number of viable microbes in B grade WHO air classification system for manufacture of sterile products are a) **5** b) 10 c) 100 d) 500	SGV	2	Understanding (2)
2	Quality of seal test is done for a) Vial b) **ampule** c) bottle d) syringe	SGV	3	Understanding (2)
3	Accelerated stability studies conditions for Drug substance intended for storage in a refrigerator _____ a. 35°C ± 2°C/60% ± 5% b. 25°C ± 2°C/65% ± 5% c. 45°C ± 2°C/60% ± 5% **d. 25°C ± 2°C/60% ± 5%**	BSM	1	Understanding (2)
4	**Northern Europe, Canada, Russia comes under_____** **a. Climatic zone I** b. Climatic zone II c. Climatic zone III d. Climatic zone IV	BSM	1	Understanding (2)
5	When electrode is not in use , it should be stored in a. Distilled/deionized water b. Any buffer solution (< 4 or >7) **c. Solution of 4 M KCl** d. Solution of pH:1.5 HCl	ARN	3	Understanding (2)
6	For the Over the Counter (OTC) products where there is _____ expiry date, the file must be maintained for at least _____after the product's distribution. a. 2 years, 3 years **b. No, 3 years** c. 2 years, 1 year d. No, 1 year	ARN	3	Understanding (2)
7	One of the following indicator is used in Powdered glass test a) Phenolphthalein b) Ferroin c) **Methyl red** d) Methyl orange	SGV	3	Application (3)
8	The licensee should keep an inventory of all raw materials as per Schedule .....to the Drug & Cosmetic Rules, 1945 a) **U** b) N c) M d) A	SGV	1	Application (3)

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9	_____ is not covered under Deming's 14 points a. On job training b. Leadership c. Management d. **Quality circle**	BSM	1	Application (3)
10	The main objective of ISO 9000 is _____ **a.** Profit making **b. Customer Satisfaction** c. Skill enhancement d. To avoid Environmental issues	BSM	1	Application (3)
11	One of the following is the report on quality assessment of the production batch, which ensures that release product meets the desired quality standards. a. Records **b. Certificate of analysis** c. Test methods & report d. Specification	ARN	2	Application (3)
12	According to the segregation of solid bio-medical waste, in which colour coded container anatomical waste is collected: a. White b. Black **c. Yellow** d. Red	ARN	3	Application (3)
13	.....number of glass containers to be examined with capacity of the container is 6-30 ml in hydrolytic resistance test. a) at least 20 b) at least 10 c) **at least 5** d) at least 3	SGV	3	Analysis (4)
14	Bubble air locks are found in a) **Parenteral manufacturing area** b) Oral liquid manufacturing area c) Solid dosage manufacturing area d) Semisolid dosage manufacturing area	SGV	1	Analysis (4)
15	Deviations from current SOP related to the study should be documented and must be approved by _____ a. Analyst b. Team leader c. Sponsorer **d. Study director**	BSM	2	Analysis (4)

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16	All precision instruments should be_____ before used for routine analysis a. Checked b. Maintained **c. Calibrated** d. Authenticated	BSM	2	Analysis (4)
17	During a validation run, the _____must be kept same as that intended for regular industrial scale production. a. Batch number **b. Batch size** c. Lot number d. Lot name	ARN	3	Analysis (4)
18	What is zero value in the context of calibration? a. The difference between the upper and lower range b. The capability of the instrument c. The region within which a quantity is measured d. **The lower end of the calibration range**	ARN	2	Analysis (4)
19	The authorized person responsible for approving a batch release should certify that principles of GMP as laid down in the guidelines published by ……have been followed. a) FDA b) MHRA c) **WHO** d) CDRA	SGV	2	Evaluation (5)
20	One of the following cannot be categorized as QbD elements a. Quality Target Product Profile (QTPP). b. Critical Quality Attributes (CQA). **c. Standard operating procedure** d. Design Space.	BSM	2	Evaluation (5)
	Short Answer Questions 6 Q × 5 M = 30 MARKS			
1	Explain the principle and procedure for arsenic test for glass containers (5 marks) **Key:** **Principle-2 marks** **Procedure with acceptance criteria: a 3 marks**	SGV	3	Application (3)
2	Write the role of quality control head in producing the safe and efficacious medicines. (5 marks) **Key:** **5-6 points in explaining the role of QC head-5 marks**	SGV	2	Analysis (4)

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3	Discuss in detail about ISO 9000 certification process and its importance to pharmaceutical industries in the present scenario (5 marks) **Key:** **Process of certification: 3 M** **Importance: 2 M**	BSM	1	Application (3)
4	Explain the functional elements of non-clinical laboratory study protocol (5 marks) **Key:** **Functional elements with explanation: 5 M**	BSM	2	Analysis (4)
5	Duloxetine 30 mg Tablet and 60 mg tablet was introduced into the market by Alberta Pharma Inc. in the year 2018. 15 & 20 batches for these tablets strengths were marketed in the year 2019 & 2020. Based on this statement answer the following questions: a. Who is responsible for the preparation of quality review for this product? (1 mark) **Key: Responsible person : 1 mark** b. How many batches shall be taken for quality review of this product in the year 2021? (1 mark) **Key: Exact number of batch : 1 mark** c. Explain the steps involved in preparation of annual product quality review. (3 mark) **Key: 4 major steps / Step by step preparation of APQR/ with flow chart 3 marks**	ARN	3	Application (3)
6	a. Write the differences between prospective and concurrent validation. (2 marks) **Key: 4 differences between prospective and concurrent validation (2 marks)** b. Write the content of prospective validation protocol. (3 marks) **Key: 12 points as contents of prospective validation protocol.**	ARN	3	Remembering (1)