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SEAT No. _____

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SARDAR PATEL UNIVERSITY

M.Sc. Pharmaceutical Chemistry, Fourth Semester Examination

Saturday, 23th March

2019

2:00 p.m. to 5:00 p.m.

Quality Assurance of Pharmaceuticals: PS04CPCH23

Total Marks : 70

Note : (i) All questions are to be attempted. (ii) Figures to the right indicate marks.

- Q.1** Choose the correct option for the following: 8x1
=08
- (i) QC department of Industry is a part of.....
(a) GMP (b) Validation (c) Management (d) All
- (ii) Identify the basic elements of a quality system.
(a) Quality Management, Purchasing and Document Control
(b) Quality Control, Quality Costs and Control Charts
(c) SPC, Inspection and Quality Assurance
(d) Quality Management, Quality Control and Quality Assurance
- (iii) Alcohols are used for
(a) Sterilization (b) Disinfectant (c) Decontamination (d) Anesthetics
- (iv) Autoclave is used for process .
(a) Sterilization (b) Freezing (c) Distillation (d) All
- (v) The goal of pilot plant is.....
(a) Transfer of product from lab to production.
(b) R & D of product
(c) Provide facility of raw material
(d) None
- (vi) A checklist of GMP items that should be part of scale-up new product introduction includes.....
(a) Equipment qualification
(b) Process validation
(c) Regular process review and revalidation
(d) All of the above
- (vii) SOP stands for
(a) Stationary Operating protocol
(b) Standard Operation protocol
(c) System Operational protocol
(d) a & C both
- (viii) Quality assurance incorporates
(a) GMP only
(b) GMP, Product design
(c) GMP, Product design & Development
(d) None

Q.2	Answer the following : (Attempt any seven)	7x2 =14
1	Explain the term quality control and quality assurance.	
2	What is meant by WFI?	
3	Enlist basic objective of quality control (QC).	
4	Write the main substance used for disinfectant in industry.	
5	Define basic concept of pilot plant design.	
6	Define decontamination and sterilization.	
7	What type of facilities needed for scale up of materials.	
8	List main function of quality assurance department	
9	Write the importance of "quality control" of product.	
Q.3	Answer the following :	
A	How the quality control department of Pharmaceutical Industry function?	03
B	Enlist the instrument used to control quality of pharmaceutical product and discuss major parameter affects the quality of finish product.	03
	OR	
B.	Write a note: Work culture of organization affects quality of product.	06
Q.4	Answer the following :	
A.	List out methods for water treatment in industry. Explain any two methods used in pharmaceutical industry	06
B.	Discuss about validation of different sterilization processes in pharmaceuticals.	06
	OR	
B.	Explain the utility of chlorination and Ozone disinfection process in pharmaceutical industry.	06
Q.5	Answer the following :	
A.	Discuss various parameter and basic equipment for the scale up of tablet formulation.	06
B.	Discuss basic requirement for pilot plant design.	06
	OR	
B.	Write a note on: Synthetic strategy for large scale synthesis.	06
Q.6	Answer the following:	
A.	Discuss basic concept of Quality Assurance.	06
B	How the raw materials quality can be control at industry.	06
	OR	
B	Explain in detail about packaging material for Pharmaceuticals.	06

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