| Name:<br><br>Enrolment No: |  |
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**UNIVERSITY OF PETROLEUM AND ENERGY STUDIES**
**End Semester Examination May 2023**

**Course: Quality Assurance** — **Semester: VI**
**Program: B. Pharm** — **Duration: 03 Hours**
**Course Code: BP606T** — **Max. Marks: 75**
**Instructions: No additional material like graph paper, log table, *etc* is allowed for this examination.**

**SECTION A**
**(20 Q x 1 M = 20 Marks)**

| S. No. | Attempt all questions from section A. | Marks | COs |
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| **Q 1** | Key element of ISO quality system *i.e.* ISO 9001 is<br>a) Quality policy<br>b) Quality documentation<br>c) Quality audit<br>d) Quality review | **1** | **CO1** |
| **Q 2** | NABL head office is located at<br>a) Chennai<br>b) Mumbai<br>c) Delhi<br>d) Chandigarh | **1** | **CO1** |
| **Q 3** | In the hierarchy of quality documentation system the top most element is<br>a) Quality manual<br>b) Quality policy<br>c) Quality procedures<br>d) Work instructions | **1** | **CO1** |
| **Q 4** | Treated soda lime glass is<br>a) Type 1<br>b) Type 2<br>c) Type 3<br>a) Type 4 | **1** | **CO1** |
| **Q 5** | The permissible number of particles (≥ 5 µm size) in Class 2 as per the BS 5295 clean room standards is<br>a) 20000<br>b) 200000<br>c) 2000<br>d) 20 | **1** | **CO2** |
| **Q 6** | Which of the following department holds responsibility for quality monitoring and audits?<br>a) Regulatory affair<br>b) Quality control<br>c) Quality assurance<br>d) Production | **1** | **CO2** |
| **Q 7** | The correct sequence for handling complaint is<br>a) Receiving complaint, Investigation, corrective actions, feedback to customer, Trend analysis by QC<br>b) Investigation, Receiving complaint, corrective actions, Trend analysis by QC, feedback to customer | **1** | **CO2** |

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| | c) Receiving complaint, Trend analysis by QC, Investigation, feedback to customer, corrective actions<br>d) Receiving complaint, feedback to customer, Trend analysis by QC, corrective actions, Investigation | | |
| **Q 8** | Airlock doors should be equipped with systems that<br>a) Allow simultaneous opening of both doors<br>b) Prevent simultaneous opening of both doors<br>d) Both are necessary<br>b) It is not specific | **1** | **CO2** |
| **Q 9** | As per the ISO, below formula is used to calculate maximum permitted concentration (particles/ $m^3$ of air) of air born particles in a clean room<br>a) $Cn = 10N \times [0.1/D]^{2.08}$<br>b) $Cn = 0.1N \times [ISO9/D]^{2.08}$<br>c) $Cn = 0.1N \times [D/ISO9]^{2.08}$<br>d) $Cn = 10N \times [D/0.1]^{2.08}$ | **1** | **CO3** |
| **Q 10** | GMP ensures which of the following<br>a) Quality<br>b) Safety<br>c) Efficacy<br>d) All of the above | **1** | **CO3** |
| **Q 11** | Complaints arising because of not keeping products under appropriate conditions of temperature, humidity and light so that the identity, strength, quality and purity of the drug product are affected are called as<br>a) Non confirmed complain<br>b) Tamper suspicion<br>c) Confirmed complaint<br>d) None | **1** | **CO3** |
| **Q 12** | Reference standard for preparing batch manufacturing record by a manufacturing unit is<br>a) Quality audit<br>b) Master Formula records<br>c) Standard Operating Procedure<br>d) All of the above | **1** | **CO3** |
| **Q 13** | Clean rooms are classified according to the<br>a) Airchecks/ hour<br>b) Material being processed<br>e) Number & size of particles permitted per volume of air<br>c) All of above | **1** | **CO3** |
| **Q 14** | Between Manufacturing area and support areas difference of pressures required must be atleast<br>a) 15 pascal<br>b) 25 pascal<br>f) 50 pascal<br>d) 100 pascal | **1** | **CO3** |
| **Q 15** | As per Q series, climate zone III has temperature and humidity<br>a) 21°C ± 2°C, 45% ± 5% RH<br>b) 25°C ± 2°C, 60% ± 5% RH<br>c) 30°C ± 2°C, 35% ± 5% RH | **1** | **CO3** |

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| | d) 30°C ± 2°C, 75% ± 5% RH | | |
| **Q 16** | Process control is carried out<br>a) During production<br>b) After production<br>c) Before product<br>d) All of the above | **1** | **CO3** |
| **Q 17** | During validation, at least _____ batches should be tested, and at least _____ tests should be carried out for each sample.<br>a) 6, 3<br>b) 3, 2<br>c) 3, 3<br>d) 1, 1 | **1** | **CO4** |
| **Q 18** | Which one is key element of TQM is<br>a) Continuous improvement<br>b) Focus on customer<br>c) Employee involvement<br>d) All of the above | **1** | **CO4** |
| **Q 19** | Which of the following statement(s) is/are true about quality assurance?<br>(i) QA is a set of activities for ensuring quality in the process by which products are developed<br>(ii) QA is corrective tool and product oriented<br>a) Statement (i) is correct<br>b) Statement (ii) is correct<br>c) Both statement (i) and (ii) are correct<br>d) None of these | **1** | **CO4** |
| **Q 20** | Type A complaints does not include:<br>a) Purity and safety<br>b) Potency<br>c) Product stability<br>d) Extraneous contamination, mix ups *etc*. | **1** | **CO4** |
| **SECTION B (20 Marks)**<br>**(2 Q x 10 M = 20 Marks)** | | | |
| | **Attempt any two questions from section B.** | **Marks** | |
| **Q 1** | Enlist four categories of ICH topics. Describe the testing frequency and storage conditions for the stability testing of drug product that are stored under room temperature, in refrigerator, and in freezer. | **2+8** | **CO1** |
| **Q 2** | What are general considerations followed for equipment selection? Enlist various factors affecting equipment selection. Describe Brown-Gibson model for equipment selection. | **2+2+6** | **CO4** |
| **Q 3** | Define validation. Draw Ishikawa Diagram (Fish Bone Diagram). Write in detail about cleaning validation. | **2+2+6** | **CO2** |
| **SECTION-C (35 Marks)**<br>**(7 Q x 5 M = 35 Marks)** | | | |
| | **Attempt any seven questions from section C.** | **Marks** | |
| **Q 1** | Enlist various sources of contamination in a sterile formulation area. What are various approaches used to prevent contamination in an aseptic area? | **2+3** | **CO4** |

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| **Q 2** | What is Total Quality Management? Explain various elements of Total Quality Management. | **1+4** | **CO1** |
| **Q 3** | Enlist any two unfortunate events that leads to the development of GLP regulations. Write a note on Industrial Bio Test laboratory case. | **2+3** | **CO5** |
| **Q 4** | Describe the process of handling of complaints and their evaluation in pharmaceutical industries. | **5** | **CO2** |
| **Q 5** | Classification and explain various packaging defects. | **5** | **CO3** |
| **Q 6** | Explain quality audit in pharmaceutical manufacturing industries. | **5** | **CO3** |
| **Q 7** | Describe the protocol for conduct of a non-clinical laboratory study. | **5** | **CO5** |
| **Q 8** | Explain materials management approach in a pharmaceutical manufacturing facility. | **5** | **CO5** |
| **Q 9** | What are the possible grounds for disqualification of testing facilities? What are the consequences of noncompliance of GLP regulations? | **2+3** | **CO5** |