Exam Seat No:_____ Enrollment No:_____

C.U.SHAH UNIVERSITY

Wadhwan City

Subject Code : 5PS02QGP1 **Summer Examination-2014** **Date: 30/06/2014**

Subject Name: Quality Assurance ,GMP and Process Validation

Branch/Semester:- M.Pharm /II **Time:2:00 To 5:00**

Examination: Regular

Instructions:-

(1) Attempt all Questions of both sections in same answer book / Supplementary

(2) Use of Programmable calculator & any other electronic instrument is prohibited.

(3) Instructions written on main answer Book are strictly to be obeyed.

(4) Draw neat diagrams & figures (If necessary) at right places

(5) Assume suitable & Perfect data if needed

SECTION-I

Q.1

1. Explain the terms "internal audit". (2)
2. Why is Auditing Necessary. (2)
3. **Define** the terms "Design Qualification (DQ)" . (2)
4. Define the terms "calibration". (1)

Q.2

1. Write a note on water systems in the pharmaceutical industry. (5)
2. With a neat sketch, explain the qualitative and quantitative layout of liquid oral department. (5)
3. Describe the validation of tunnel sterilizer. (4)

OR

1. Describe the cGMP requirements for laboratory records and reports. (5)
2. Draw a layout for parenteral facility for freeze dried injectables. (5)
3. Write note on finished product testing (4)

Q.3

1. Describe the specific requirements for manufacture of parenterals as per revised Schedule M. (7)
2. Define process validation. Highlight the steps for validation of fluid bed dryer. (7)

OR

1. Explain the cGMP requirements for lighting, sanitation and hygiene. (7)
2. Write note on validation and qualification of HVAC. (7)

SECTION-II

Q.4

1. Explain the role of FDA in Validation. (2)
2. Enlist the methods for PAT Applications (2)
3. Define the terms "PRODUCT RECALLS" (2)
4. Define the terms "SITE MASTER FILE" (1)

Q.5

1. Discuss the qualities, national, international standard for clean rooms. (5)
2. Suggest a product layout for Lipsticks equipment requirement and newer advancement in this area with BMR copy. (5)
2. Validation of the steam sterilizer and importance of the D, Z, F value. (4)

OR

1. Explain the methods used for the validation of Computer. (5)
2. Discuss various equipments used in aerosol manufacturing. (5)
3. What is specific GMP requirement of liquid preparation? (4)

Q.6

1. Give qualitative and quantitative lay out, manufacturing steps with suitable equipments, important IPQC parameter, and packaging records and post marketing surveillance reports for sterile products. (7)

2. Enlist different equipments for manufacturing of eye-ointments, eye-lotions as per schedule-M. (7)

OR

1. Discuss the self inspection & Quality audit proposed by FDA regarding maintenance of pharma. Manufacuring. unit (7)
2. What is process analytical technology ? Explain the PAT tools. (7)

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