C U SHAH UNIVERSITY

WADHWAN CITY

Summer Examination -2015

(Regular/Remedial Examination)

Subject Code: 5PS02QGP2 **Subject Name:** Quality Assurance, GMP & Process Validation

Date:

Course Name: M.PHARM **Marks:**-70

Semester-II **Time**:

Instructions:

1)
2) Use of Programmable calculator & any other electronic instrument 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-1

Q.1

1. Explain the terms "sterile area class 10,000". **(2)**
2. Explain the terms "Active Pharmaceutical Ingredient". **(2)**
3. Explain the terms "Salvaged drug products" . **(2)**
4. Explain the terms "Returned drug products". **(1)**

Q.2

1. Write the requirements of plant and equipments for the manufacture of ophthalmic preparations under revised schedule M**.** **(5)**
2. What is specific GMP requirement of liquid preparation? **(5)**
3. Discuss various equipments used in aerosol manufacturing. **(4)**

OR

1. Discuss product protection in context to role of HVAC in pharmaceutical Industry. **(5)**
2. Suggest a product layout for Lipsticks equipment requirement and newer advancement in this area with BMR copy. **(5)**
3. Discuss principle, construction and working of Triple roller mill. **(4)**

Q.3

1. Write a note on Master Formula record**.** **(5)**
2. Write a note on Batch Packing Record **(5)**
3. Define process validation. Highlight the steps for validation of tray dryer **(4)**

OR

1. Explain the cGMP requirements for lighting, sanitation and hygiene **(5)**
2. Describe the parameters to be considered during the scale up of Tablet Coating **(5)**
3. Discuss the Quality audit proposed by FDA . **(4)**

Section-II

Q.4

1. Explain the term "critical process parameters." **(2)**
2. Explain the terms "process validation" **(2)**
3. Explain the terms "Batch Packing Record" **(2)**

4. Explain the terms "cGMP" **(1)**

Q.5

1. Discuss the qualities, national, international standard for clean rooms. **(5)**
2. Write SOP for validation of an autoclave. **(5)**
3. What is the significance of SOP? Describe the contents of SOP. **(4)**

OR

1. Explain the methods used for the validation of Computer. **(5)**
2. Write SOP for validation of moist heat sterilizer. **(5)**
3. What are the objectives of production planning and material control? **(4)**

Q.6

1. Explain the elements of QbD **(5)**
2. What is process analytical technology ? **(5)**
3. Explain the PAT tools. **(4)**

OR

1. Explain the Steps in Development of Design Space **(5)**
2. Discuss process scale up with different types of batches. **(5)**
3. Write note on finished product testing **(4)**