BIRLA INSTITUTE OF TECHNOLOGY, MESRA, RANCHI
(END SEMESTER EXAMINATION)

CLASS: M. Pharm. **SEMESTER: 2nd**
BRANCH: PHARMACY **SESSION: SP 2022**
SUBJECT: Pharmaceutical Manufacturing Technology (MQA 204T)
TIME: 3.00 Hours **FULL MARK: 75**

INSTRUCTIONS:
1. The missing data, if any, may be assumed suitably.
2. Before attempting the question paper, be sure that you have got the correct question paper.
3. Tables/Data hand book/Graph paper etc. to be supplied to the candidates in the examination hall.

1a. i. Differentiate between Lubricant, Glidants with proper examples for each [2]
ii. Discuss the steps in direct compression for tablet preparation and also mention the limitations of this method [3]
iii. Explain the terms: Capping & Lamination [1+1=2]

1b. Discuss elaborately the different stages of granulation [8]

2a. Discuss the different film defects along with the remedies. What is meant by Coating efficiency? [6+1=7]

2b. i. Discuss the drug Plastic interactions [3]
ii. Write the composition of Colourless white flint soda lime glass [1]
iii. Differentiate between thermoplastic and thermosetting materials [2]
iv. Discuss the addition and condensation polymerization process [2]

3a. i. Discuss the methods for determination of Gel strength and Viscosity of gelatin used for Soft gelatin capsule preparation. Also mention the official range for these parameters for gelatin used for capsule preparation. [2+2=4]
ii. Calculate the Base adsorption of a drug where the weight of the solid drug is 20 gm and weight of the liquid base is 50ml, where the specific gravity of the liquid base is 1.263 at RT. [3]

3b. Explain the preparation and evaluation of the following with proper diagram wherever necessary: [4+4=8]
i. Soft gelatin capsule
ii. Hard gelatin capsule shells

4a. What do you mean by Production control? Discuss the production control in detail. [7]

4b. Discuss the significance of production planning in detail. [8]

5a. What is QbD Approach? Discuss critical elements of QbD by generating a QbD case design. [7]

5b. Explain in detail "PAT as a driver for improving quality and reducing cost" referring to QbD. [8]

6a. Explain in detail about Risk assessment approach in QbD in relation with ICH guidelines. [7]

6b. Discuss the principles, process and equipment of lyophilisation technology. [8]

7a. Draw a flowchart for manufacturing of sterile ophthalmic ointments and discuss area planning and environment control for manufacturing facility. [7]

7b. Discuss in detail (any two only): [4+4=8]
i. CIP
ii. SIP
iii. FFS

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