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GUJARAT TECHNOLOGICAL UNIVERSITY M. Pharm. – SEMESTER – I • EXAMINATION – WINTER • 2015 Subject Code: 910202 Date: 02-01-2016 **Subject Name: Industrial Pharmacy Practice** Time: 10:30 am - 01:30 pm **Total Marks: 80 Instructions:** 1. Attempt any five questions. 2. Make suitable assumptions wherever necessary. 3. Figures to the right indicate full marks. **Q.1** (a) Discuss the importance of HVAC facilities for pharmaceutical industry 06 **(b)** Discuss the factors affecting the location of a pharmaceutical industry 05 Write a note on important essential utility services in a pharmaceutical factory? **(c)** 05 **Q.2** (a) Describe the departmental layout for manufacturing of effervescent tablets 06 Explain fluid bed processor with its application 05 **(b) (c)** Write a note on BMR during manufacturing of parenteral dosage forms 05 **Q.3** Describe various parameters to be validated for sterilization of parenteral (a) 06 dosage forms. Define the process validation? Give types of validation. 05 **(b)** Highlight the steps for validation of fluid bed dryer 05 (c) 0.4 Write a note on batch packaging record 06 (a) Define SOP. Enlist the objectives and format of SOP 05 **(b) (c)** Give SOP for Dissolution apparatus 05 **Q.5** (a) Describe the cleaning validation with its limits. 06 What is importance of documentation and records in GMP? 05 **(b)** (c) What is cGMP? Discuss briefly its significance 05 Discuss the objectives of production planning and materials control **Q.** 6 06 (a) Write in details on Material Control. 05 **(b)**

> What is pilot plant scale up? Give its importance. Describe the parameters to be considered during the scale up of tablet Coating.

Give techniques of inventory control.

(c)

(a)

Q.7

(b) (c) Discuss various types of batches in scale up process development 05

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