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GUJARAT TECHNOLOGICAL UNIVERSITY M. Pharm. - SEMESTER - II • EXAMINATION - SUMMER • 2015 Date: 14-05-2015 Subject Code: 1921501 **Subject Name: Modern Pharmaceutical Analysis** 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. 0.1 Write a note on Tryptic mapping technique. (a) 06 **(b)** Give a brief note on Isoelectric focusing technique. 05 Explain any one analytical method for analysis of product obtained through (c) 05 Genetic engineering. **Q.2** (a) Describe in detail properties associated with particulate level of 06 pharmaceuticals. Explain the effect of Impurities on drug stability. **(b)** 05 Discuss in detail bioburden analysis of parenteral dosage form. (c) 05 0.3 Enlist and discuss in detail ICH guidelines. 06 (a) Discuss in detail sterility testing of Parenteral dosage form. 05 **(b)** Explain various methods for analysis of cosmetic formulations. (c) 05 **Q.4** (a) Write a note on physicochemical Properties for analysis of solid oral dosage 06 Explain the role of Ion exchange chromatography in amino acid analysis. **(b)** 05 Describe in detail solid state analysis of pharmaceuticals at molecular level. 05 (c) **Q.5** What is Preformulation? Elaborate various analytical techniques used in (a) 06 preformulation study. Define crude drug. Enlist various test used for evaluation of herbal drugs. **(b)** 05 Explain any three in detail. Explain Compendial testing of formulated product with example. (c) 05 Explain the importance of preformulation study and describe various stages of **Q.** 6 06 (a) preformulation. Explain Compendial testing of active pharmaceutical ingredient with example. 05 **(b)** Explain IPQC test for solid oral dosage form. 05

- Q.7 Write a note on any two.
  - 1) USFDA
  - 2) Automated Analysis
  - 3) Quality control of radiopharmaceuticals

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