

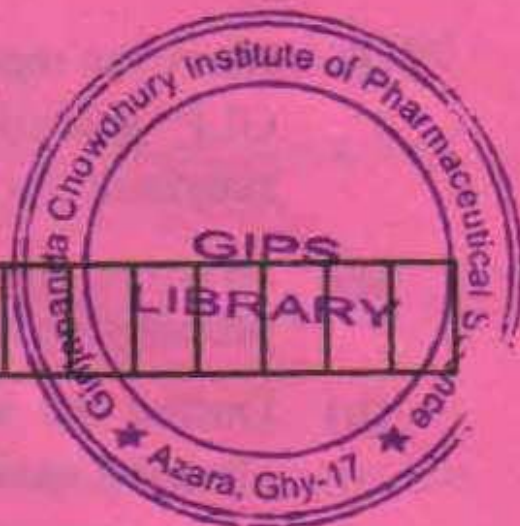
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2017



M. Pharm 2nd Semester End-Term Examination

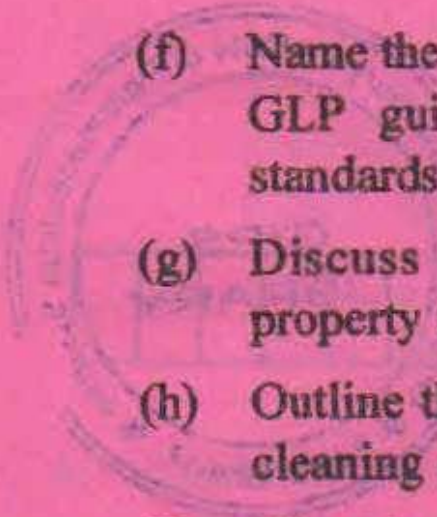
**ADVANCED INDUSTRIAL PHARMACY
AND REGULATORY AFFAIRS**

Full Marks-100 Pass Marks-35 Time-Three hours

The figures in the margin indicate full marks
for the questions.

1. Answer any *nine* questions : 2×9=18
 - (a) Write the meaning of Guidance documents "Code of Federal Regulations Title 211" ?
 - (b) What do you mean by copyrights and related rights ?
 - (c) Distinguish between prospective and retrospective validation.
 - (d) Write the meaning of "Acceptance criteria" as per cGMP regulations.
 - (e) What kind of trademark can be registered ?

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- (f) Name the regulatory agency that promulgates GLP guidelines. Mention two regulatory standards for good laboratory practice.
- (g) Discuss the importance of intellectual property rights.
- (h) Outline the innovations in techniques of air cleaning quality control system.
- (i) Give the criteria for selection of flavours in Pharmaceuticals.
- (j) Write two advantages and limitations of plastic as packaging materials.
- (k) Discuss the penalties for the violation of Patent.

2. Answer any *four* questions : 3×4=12

- (a) What is quality loop and spiral progress in quality ? 3
- (b) Outline the importance of IQ and PQ in a validation process. 3
- (c) Write the ideal qualities of skin care products. 3
- (d) Name some artificial sweeteners' used for diabetic patients. 3
- (e) How will you evaluate the stability of an aerosol preparation ? 3

3. Answer any *eight* questions : 8×5=40

- (a) How have copyright and related rights kept up with advances in technology ?
- (b) How does WIPO promote the protection of intellectual property ?
- (c) Mention the six FDA Quality Systems for pharmaceutical manufacturing process.
- (d) Write the importance of patents for pharmaceutical innovations.
- (e) Explain the relationship between Intellectual Property Rights and Foreign Direct Investment (FDI) inflows in developing countries.
- (f) Write the importance of Federal Good Laboratory Practice Standards ? What is the reinstatement procedure of a laboratory disqualified by FDA ?
- (g) How will you design a validation protocol of pharmaceutical extended release tablet dosage form ?
- (h) Give the criteria for selection of preservatives. Give suitable classification with examples.

- (i) Write the importance of FD&C colours in pharmaceutical preparations. Name four FD&C permitted colours.
- (j) Write in detail the regulatory standards for plastic as packaging materials.

4. Answer any *three* questions : $3 \times 10 = 30$

- (a) Outline the status and applications of cGMP regulations in various pharmaceutical manufacturing operations. Write the cGMP requirement for pharmaceutical equipment selection as specified in sub-part D.

$5 + 5 = 10$

- (b) Explain in detail on models of quality system management for industrial organization. Write the provisions of quality standards as laid down in ISO 13000 series.

$6 + 4 = 10$

- (c) Write the comparison of TRIPS and TRIMS. Write in brief the salient features of Indian Patent Act-1970.

$3 + 7 = 10$

- (d) Write in detail the guidelines and specifications for evaluation of pharmaceutical packaging materials. Write a short note on quality control of cosmetic products.

$7 + 3 = 10$