Total No. of printed pages = 4

PY 134204

Roll No. of candidate

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 ?

[Turn over

(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 : 3×10=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