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PY 134204

Roll No. of candidate

2016

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 *ten* questions : 3×10=30

(a) Define prospective and retrospective validation.

(b) What is cGMP ? Write the meaning of 'representative sample' as per cGMP regulations.

(c) Name the regulatory agency that promulgates GLP guidelines. Mention two regulatory standards for Good Laboratory Practice.

(d) Discuss the importance of intellectual property rights.

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(e) Define clean room specifications as per cGMP. Name two techniques of air cleaning quality control system.

(f) What is Trademark ? Give some examples.

(g) Give the criteria for selection of colours in pharmaceuticals.

(h) What do you mean by copyright and trade secret ?

(i) Write two advantages and limitations of plastic as packaging materials.

(j) Write three validation guidelines parameters for tablet coating process.

(k) Name some artificial sweetners used for diabetic patients.

(l) What are patentable inventions ?

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

(a) Mention the six FDA quality systems for pharmaceutical manufacturing process.

(b) What are the different types of patent applications ?

(c) What happens if a workplace does not comply with federal good laboratory practice standards ? What is the reinstatement procedure of a laboratory disqualified by FDA ?

(d) What are important points included in a validation protocol of pharmaceutical solid dosage forms ?

(e) Discuss the offences and penalties of patent infringement.

(f) Give the criteria for selection of preservative. Give suitable classification with example.

(g) Name four FD&C permitted colours. Write the importance of FD&C colours in pharmaceutical preparations.

(h) What are patentable items? Write a note on consequences of patent infringement.

(i) Write in detail on formulation and manufacturing of lipsticks.

(j) Differentiate between cold cream and vanishing cream.

(k) Discuss the salient features of TRIPS.

3. Answer any *three* questions : 3×10=30

(a) Write the basic facility requirements of aseptic processing area as per cGMP. Write at least four standard procedure guidelines of cGMP for organization and personnel requirement as specified in subpart B. 5+5=10

(b) What are quality loop and quality spiral progress in quality ? Write a note on steps involved in quality management approaches in an industrial organization. 4+6=10

(c) What is the concept behind GATT ? Elaborate the ISO 9000 and 13000 families under quality management system. 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