Code: 17S11101

M.Pharm I Semester Regular Examinations February 2018

GOOD REGULATORY PRACTICES

(Pharmaceutical Regulatory Affairs)

(For students admitted in 2017 only)

Time: 3 hours Max. Marks: 60

Answer all the questions

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1 Give a detailed account on principles of GMP including various articles.

OR

2 Give an account on:
(a) USFDA guidance on medical devices.
(b) GMP guidelines for packing of pharmaceuticals.

3 What is the significance of GLP regulations? Give an account on 21 CFR Part 58 guidelines for GLP.

OR

4 Write about the following:
(a) Goals of laboratory quality audit.
(b) QCI standards relevant to GLP.
(c) Future of GLP regulations.

5 Write a detailed account on general checklist of 21 CFR Part 11.

OR

6 Write a short note on:
(a) GALP requirements.
(b) SOPs of GALP.

7 Explain about the GDP regulations for the following:
(a) Personnel and documentation.
(b) Premises and equipment.

OR

8 What is GDP? What are the principles of GDP? Explain about the requirements of GDP. Add a note on Good Storage Practices (GSP).

9 Write the significance of process validation. What are the various types of process validation? Explain in detail about prospective validation.

OR

10 Write an account on the following:
(a) Total Quality Management.
(b) Quality by design.

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