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JBS-102-T

Seat No. _____

M. Pharm. (Sem. I) (W.E.F. 2017) Examination

January - 2020

MRA - 102T : Documentation & Regulatory Writing

Time : **3** Hours] [Total Marks : **75**

Instructions : (1) Attempt all the questions.

(2) Make Suitable assumptions where required.

1 Answer the following : **20**

(a) Enumerate regulatory agencies for Brazil, Australia and Canada.

(b) What is Prior Approval Statement?

(c) Classify various types of Audits.

(d) What is ISO 13485?

(e) What is NeeS? Give its objectives.

(f) Give full forms of ACTD and ESG in dossier preparation.

(g) What is CBE - 30.

(h) Discuss importance of Drug Master File.

(i) What is Product Development Report?

(j) What is Establishment Inspection Report?

2 Answer any **two** of the following : **20**

(a) Discuss in detail overview and modules of eCTD.

(b) Write in detail about SUPAC IR guideline to Industry for Solid Oral Dosage Forms with respect to site change.

(c) What is Audit? Describe in detail preparation and conduction of audit and auditing strategies.

3 Answer any **seven** of the following : **35**

(a) Write a note on drug master file.

(b) Discuss warning letters with example.

(c) Give objectives of Drug master file (DMF). Compare European and US Drug master file preparation.

(d) Discuss in detail submission process in SUGAM system of CDSCO.

(e) What do you mean by CAPA? Explain purpose of CAPA.

(f) Describe in detail ISO risk management standard.

(g) Discuss in detail about preparation for pre-approval inspections of FDA.

(h) What is product recall? Explain recall procedure for drug product.

(i) Explain certificate of analysis (CoA) with example.
