

SUPPLEMENTARY
MASTER OF PHARMACY (M. PHARM.) (CBCS-2019 COURSE)
M.Pharm. Sem-II PHARMACEUTICAL QUALITY ASSURANCE :SUMMER- 2022
SUBJECT : PHARMACEUTICAL VALIDATION

Day : Friday

Time : 10:00 AM-01:00 PM

Date : 16-09-2022

S-20778-2022

Max. Marks : 75

N.B.

- 1) **Q.No.1** and **Q.No.5** are **COMPULSORY**. Out of the remaining questions attempt **ANY TWO** questions from each section.
 - 2) Answer to both the section should be written in **SEPARATE** answer books.
 - 3) Figures to the **RIGHT** indicate **FULL** marks.
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SECTION – I

- Q.1** Discuss Calibration with example of any one pharmaceutical equipment. **[08]**
- Q.2** Discuss Qualification of Pharmaceutical equipment in detail. **[15]**
- Q.3** Discuss Validation of HVAC System. **[15]**
- Q.4** Write notes on **ANY TWO** of the following: **[15]**
- a) Qualification of HPLC
 - b) Validation Master Plan
 - c) URS

SECTION – II

- Q.5** Discuss Cleaning method development for Cleaning Validation. **[07]**
- Q.6** What is a Patent? Discuss various types of patent abuse including ever greening **[15]**
- Q.7** Discuss Media Fill Validation in detail. **[15]**
- Q.8** Write notes on **ANY TWO** of the following: **[15]**
- a) Computer System Validation
 - b) Copyrights and Trademarks
 - c) Qualification of Disintegration Test Apparatus

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