Yashoda Shikshan Prasarak Mandal's
YASHODA TECHNICAL CAMPUS, SATARA
Faculty of Pharmacy (B Pharmacy) ACADEMIC PLANNING

Name of Department: Pharmaceutics **Class: T. Y. B. Pharm(SemVI)**
Subject: Quality Assurance **Academic Year: 2024- 25**
Total no. of Lectures: 45 **Name of the faculty: Mrs.S.M.Pawar**
Validated By: **Reference Code:**

Code	Author/ Editor	Title
A.	Kushik Maitra and Sedhan K Ghosh	A guide to Total Quality Management
B.	Marcel Deckker Series	Good laboratory Practices

L. No.	Main Topic	Subtopic & Contents Planned	Date	Reference
1	Quality Assurance and Quality Management concepts	Definition and concept of Quality control, Quality assurance and GMP		Internet A, B
2	Total Quality Management (TQM):	Definition, elements, philosophies		A, B
3	ICH Guidelines	purpose, participants, process of harmonization, ,		A, B
4		Brief overview of QSEM, with special emphasis on Q-series guidelines		A, B
5		ICH stability testing guidelines		A, B
6	Quality by design (QbD):	Definition, overview,		Internet A, B
7		elements of QbD program		A, B
8		tools ISO 9000 & ISO14000: Overview		Internet A, B
9		Benefits, Elements, steps for registration NABL accreditation		Internet A, B
10		Principles and procedures		A, B
11	Organization and personnel	Personnel responsibilities		Internet A, B
12		training, hygiene and personal records.		A, B
13	Premises	Design, construction and plant layout		Internet A, B
14		maintenance, sanitation, environmental control,.		A, B
15		utilities and maintenance of sterile areas,		Internet A, B

16		control of contamination .		A, B
17	Equipments and raw materials	Equipment selection,		A, B
18		purchase specifications		Internet A, B
19		, maintenance		A, B
20		purchase specifications and maintenance of stores for raw materials.		A, B
21	Quality Control	Quality control test for containers		Internet A, B
22		Quality control test for rubber closures		A, B
23		Quality control test for secondary packing		A, B
24	Good Laboratory Practices	General Provisions		A, B
25		Organization and Personnel, Facilities,		A, B
26		Equipment, Testing Facilities Operation		Internet A, B
27		Test and Control Articles		Internet A, B
28		Protocol for Conduct of a Nonclinical Laboratory Study		A, B
29		Records and Reports		A, B
30		Disqualification of Testing Facilities		A, B
31	Complaints	Complaints and evaluation of complaints .		Internet A, B
32		Handling of return good		A, B
33		recalling and waste disposal.		A, B
34	Document maintenance in pharmaceutical industry	Batch Formula Record, Master Formula Record		A, B
35		SOP, Quality audit		A, B
36		Quality Review and Quality documentation		Internet A, B
37		Reports and documents,.		A, B
38		distribution records		A, B
39	Calibration and Validation	Introduction, definition and general principles of calibration, .		Internet A, B
40		qualification and validation		A, B
41		importance and scope of validation		A, B

42		types of validation		A, B
43		validation master plan.		A, B
44		Calibration of pH meter		Internet A, B
45		Qualification of UV-Visible spectrophotometer		A, B
46		General principles of Analytical method Validation		A, B
47		Warehousing: Good warehousing practice		A, B
48		materials management		Internet A, B