SNS COLLEGE OF PHARMACY AND HEALTH SCIENCES

UNIT 2

COURSE NAME: QUALITY CONTROL &STANDARDIZATION OF HERBALS

TOPIC: ICH GUIDELINES FOR THE QUALITY CONTROL OF HERBAL MEDICINES

Q.No	Marks	Question	TNMGR	RRB	GPAT	NIPER	Bloom's Level
1	10	Discuss Good Manufacturing Practices (GMP) for herbal medicines with reference to quality assurance and regulatory compliance.	✔	✔	✔	✔	Evaluate
2	10	Explain Good Agricultural and Collection Practices (GAP) for medicinal plants and their importance in herbal drug quality.	✔	✔	✔	✔	Analyze
3	10	Describe Good Laboratory Practices (GLP) and their role in quality control and safety evaluation of herbal medicines.	✔	✔	✔	✔	Analyze
4	10	Compare GMP, GAP and GLP with respect to herbal medicine standardization and regulatory approval.	✔	✔	✔	✔	Analyze
5	10	Elaborate on WHO-GMP guidelines for herbal medicines and their	✔	✔	✔	✔	Evaluate

		implementation in pharmaceutical industries.					
6	10	Explain the impact of non-compliance with GMP, GAP and GLP on herbal drug safety and market authorization.	✔	✔	✔	✔	Evaluate
7	10	Discuss documentation and record-keeping requirements under GMP, GAP and GLP for herbal products.	✔	✔	✔	✔	Analyze
8	10	Describe quality control testing of herbal medicines under GLP including sampling and validation.	✔	✔	✔	✔	Apply
9	10	Explain the role of GMP, GAP and GLP in global acceptance and export of herbal medicines.	✔	✔	✔	✔	Evaluate
10	10	Design an integrated GMP–GAP–GLP compliance framework for herbal medicine manufacturing.	✔	✔	✘	✔	Create
11	5	Define GMP and state its objectives in herbal medicine production.	✔	✔	✔	✔	Understand
12	5	Explain the principles of GAP for medicinal plants.	✔	✔	✔	✔	Understand
13	5	Describe the significance of GLP in herbal drug analysis.	✔	✔	✔	✔	Understand

14	5	List the key components of GMP applicable to herbal drug manufacturing units.	✔	✔	✔	✔	Remember
15	5	Explain the role of personnel and training under GMP for herbal medicines.	✔	✔	✔	✔	Understand
16	5	Write a short note on harvesting and post-harvest handling under GAP.	✔	✔	✔	✔	Apply
17	5	State the importance of SOPs in GLP-compliant herbal laboratories.	✔	✔	✔	✔	Understand
18	5	Describe quality assurance activities under GMP for herbal drugs.	✔	✔	✔	✔	Understand
19	5	Mention the role of GMP, GAP and GLP in preventing adulteration of herbal medicines.	✔	✔	✔	✔	Analyze
20	5	List the advantages of implementing GMP, GAP and GLP in herbal medicine industries.	✔	✔	✔	✔	Understand
21	2	What does GMP stand for?	✔	✔	✔	✔	Remember
22	2	Define GAP in herbal medicine.	✔	✔	✔	✔	Remember
23	2	What is GLP?	✔	✔	✔	✔	Remember
24	2	Mention one objective of GMP.	✔	✔	✔	✔	Remember

25	2	State one objective of GAP.	✔	✔	✔	✔	Remember
26	2	Mention one objective of GLP.	✔	✔	✔	✔	Remember
27	2	Name one GMP requirement for herbal manufacturing units.	✔	✔	✔	✔	Remember
28	2	Give one example of GAP activity.	✔	✔	✔	✔	Remember
29	2	Mention one document maintained under GLP.	✔	✔	✔	✔	Remember
30	2	What is the role of SOPs in GMP?	✔	✔	✔	✔	Understand
31	2	Define quality control in herbal medicine.	✔	✔	✔	✔	Understand
32	2	What is meant by validation?	✔	✔	✔	✔	Understand
33	2	Mention one factor affecting herbal drug quality.	✔	✔	✔	✔	Remember
34	2	State one benefit of GAP compliance.	✔	✔	✔	✔	Understand
35	2	Give one advantage of GMP implementation.	✔	✔	✔	✔	Understand
36	2	Mention one advantage of GLP.	✔	✔	✔	✔	Understand
37	2	What is batch manufacturing record?	✔	✔	✔	✔	Remember
38	2	Define adulteration in herbal medicines.	✔	✔	✔	✔	Understand

39	2	Name one regulatory authority promoting GMP for herbals.	✔	✔	✔	✔	Remember
40	2	Why are GMP, GAP and GLP important for herbal exports?	✔	✔	✔	✔	Understand