

**LECTURES' OUTLINE : PHT 436 (Pharmaceutical quality control and GMP)**  
**(2+1)**

Week	Lecture number	Topic
1	1	Introduction to drug product quality.
	2	Quality control of raw materials. In process control .
2	3	Cont.
	4	Application of statistics to analysis of data.
3	5	Cont.
	6	Stability and expiration dating.
4	7	QC of parenteral products.
	8	QC of ointments and creams.
5	9	QC of Suppositories.
	10	QC of suspensions and emulsions.
6	11	Concept of GMP
	12	Personnel, building and facilities.
7	13	Equipment.
	14	building and facilities
8	15	Packing and labeling control
	16	Storage and distribution
9	17	Validation .
	18	Complaint and recall.
		2 Exams

**LABORATORY PROJECTS' OUTLINE : PHT 436**

Week	Topic	Description
1	Quality control of uncoated and enteric coated tablets.	QC according to B.P. and USP : Hardness- Friability- Uniformity of dosage units.
2	Cont.	QC of uncoated tablets according to BP and USP : Disintegration and dissolution tests.
3	Capsules	QC of capsules according to BP and USP
4	Suppositories	QC of suppositories according to BP
5	Parenterals	QC of containers
6	Cont.	Sterility testing- Pyrogen test- microbial examination of water- Particulate matter test.
7	Cont.	QC test for NaCl and Ascorbic acid injections.
8	Topical preparations.	QC of topical preparations according to BP and USP
9-10	Final exam.	

**COURSE EVALUATION:**

First midterm exam.	15
Second midterm exam.	15
Performance ( lab.)	10
Final lab. exam.	20
Total	60
<u>Final examination:</u>	40
Total marks	100