MALIBA PHARMACY COLLEGE
MID SEMESTER EXAMINATION APRIL 2014
SECOND SEMESTER M.PHARM. – PHARMACEUTICAL ANALYSIS
040060203 QUALITY CONTROL & QUALITY ASSURANCE

DATE: 09/04/2014 **MAXIMUM MARKS: 70**

Instructions:
1] Attempt any five questions
2] Figures to the right indicate full marks

Q.1	a	Describe the responsibilities of QA unit as per GLP guidelines	7
	b	Describe the different climatic zones as per ICH guideline. What is meant by 'significant change'?	7
Q.2	a	Discuss presentation, recording and interpretation of stability data.	7
	b	Describe GMP requirements for building and facilities.	7
Q.3	a	Describe GMP requirements for warehousing and distribution.	7
	b	Differentiate between accelerated, intermediate and long term stability testing as per ICH guidelines.	7
Q.4	a	Classify impurities and give rationale for reporting and control of impurities as per ICH Q3A guideline.	7
	b	Explain the importance of documentation. Describe the content of a master formula record.	7
Q.5	a	Discuss the GMP followed during packaging and labeling operations.	7
	b	Describe the animal care facilities required as per GLP.	7
Q.6	a	Describe the protocol for stability testing.	7
	b	Explain the significance of hydrolytic, oxidative and photo degradation stress study for API.	7

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