MALIBA PHARMACY COLLEGE
MID SEMESTER EXAMINATION APRIL 2014
M.PHARM. Sem II QUALITY ASSURANCE
040030203 Regulatory Affairs & New Drug Application

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

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

Q.1	a	Write the full form of (any 4): TGA, MHRA, ISO, CDSCO, FSSAI and DMF.	2
	b	Enlist the content of 'General Notices' in IP.	2
	c	Write the benefits of ISO certification.	2
	d	Describe the types of WHO certificates.	4
	e	What are the duties of Food safety officer?	4
Q.2	a	Discuss the salient features of The Air (Prevention and control of Pollution) Act.	8
	b	What are the objectives and provisions of the Consumer Protection Act?	6
Q.3	a	Describe the history and different functions of USFDA.	8
	b	Write a note on standards institute BIS.	6
Q.4	a	Explain the salient features of Industries (Development & Regulation) Act.	8
	b	Discuss the safety and health requirements in pharmaceutical industry.	6
Q.5	a	Discuss the organization structure and activities of CDSCO.	8
	b	Describe the content of a monograph of pharmacopoeia.	6
Q.6	a	What are drug master files? Discuss its types and explain any one in detail.	8
	b	Write the composition and activities of ICH.	6
Q.7	a	What are biotechnology-derived products? Discuss the regulatory aspects for manufacture of such products.	8
	b	Discuss the GMP guidelines for manufacture and packaging of bulk drugs.	6

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