UKA TARSADIA UNIVERSITY

M.Pharm. Sem II

REGULATORY AFFAIRS AND NEW DRUG APPLICATION (040030203)

Instructions: All questions are compulsory **Total marks: 70**

SECTION - I

Q.1	**a**	**Write the structure and responsibilities of USFDA**	**5**
		OR	
	a	**Write the structure and responsibilities of USFDA**	**5**
	b	**What is the need to have drug regulatory bodies? Discuss about the drug regulatory body of India**	**6**
Q.2	**a**	**Describe the objectives and activities of ISO**	**6**
		OR	
	a	**Describe the objectives and activities of ASTM**	**6**
	b	**Explain the procedure for drug registration in India**	**6**
Q.3		**Answer any 2 of the following:**	
	a	**What is IND application? Write briefly the format and content of IND application**	**6**
	b	**Write a note on Investigator Brochure?**	**6**
	c	**Describe the information to be submitted in ANDA application**	**6**
		SECTION II	
Q.4	**a**	**Describe the functions of food inspector.**	**5**
		OR	
	a	**Write the main provisions of Food Safety and Standard Act.**	**5**
	b	**Discuss the GMP guidelines for manufacturing and packaging operations in bulk drug manufacturing.**	**6**
Q.5	**a**	**What are the regulations in India for manufacturing of herbal products?**	**6**
		OR	
	a	**Discuss the rules and regulations for manufacture and sale of cosmetics in India**	**6**
	b	**What is the role of pharmacopoeia? Enlist the content of a monograph. Compare IP with BP and USP in term of volumes, issues and general content**	**6**
Q.6		**Answer any 3 of the following:**	
	a	**Write a note on WHO**	**4**
	b	**Write a note on safety in pharmaceutical industry**	**4**
	c	**Write a note on the Air Prevention and Control of Pollution Act.**	**4**
	d	**What are Drug Master Files? Write briefly content of DMF**	**4**

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