

GUJARAT TECHNOLOGICAL UNIVERSITY**BE - SEMESTER-VI • EXAMINATION – SUMMER 2014****Subject Code: 163605****Date: 28-05-2014****Subject Name: Technology of Solid Dosage Forms & Medicinal Natural****Time: 10.30 am - 01.00 pm****Total Marks: 70****Instructions:**

1. Attempt all questions.
2. Make suitable assumptions wherever necessary.
3. Figures to the right indicate full marks.

- Q.1 (a)** Twenty tablets were subjected to an in-process QC test during manufacturing. The weights (in grams) were found to be as follows: 0.418, 0.405, 0.539, 0.430, 0.431, 0.421, 0.422, 0.431, 0.522, 0.422, 0.431, 0.429, 0.409, 0.421, 0.521, 0.431, 0.423, 0.419, 0.423, 0.417. Check if this set of tablets complies with the weight variation test (U.S.P.). Suggest two most important remedies to correct the problem of weight variation, if found. **07**
- (b)**
- (i) What are the specifications for evaluating disintegration test for enteric coated tablets? **07**
 - (ii) State one advantage of sugar coating over film coating.
 - (iii) When and why would a tablet be coated as enteric? Give two examples of polymers that may be used for this purpose.
 - (iv) A certain pharmaceutical company has synthesized a novel low-dose (potent) drug for epilepsy which they wish to formulate as a tablet. What tablet type should they opt for?
 - (v) What are the three major equipments used for tablet coating?
 - (vi) Why are plasticizers required for film coating?
 - (vii) A certain pharma company has synthesized a new drug that is bright yellow in colour and they wish to formulate it as a tablet. What tablet defect are they likely to face?
- Q.2 (a)**
- (i) Explain the scope of medicinal natural products in the field of drug development. **03**
 - (ii) What are the steps involved in the identification of active compound (lead) from medicinal extract? Explain the different natural sources from which drug compounds are derived. Give relevant examples. **04**
- (b)**
- (i) Which are the different chemical constituents derived from plants. **01**
 - (ii) Explain each category of the above with examples. **04**
 - (iii) Differentiate between primary and secondary metabolites. **02**
- OR**
- (b)** Explain the shikimic acid pathway for the synthesis of synthesis of phenyl alanine. Also mention the steps for the synthesis of phenolic compounds from phenyl alanine. **07**
- Q.3 (a)**
- (i) Discuss the tablet manufacturing process using a single station tablet press with a schematic explaining the basic operations involved. Also mention the important process controls/precautions to be kept in mind during tableting. **06**
 - (ii) What is the major difference between a hard gelatin and soft gelatin capsule? **01**
- (b)** What do you mean by the term extraction in phytochemistry? Explain the different conventional and modern techniques of extraction of phytoconstituents. **07**

OR

Q.3	(a)	(i) What are capsules? Highlight the main aspect/strategy of the following capsule filling processes in one line: Augur feed system, Tamping method, Vacuum filling and Drugpack system.	05
		(ii) What troubleshooting strategy do you suggest for 'orange peel effect' and 'rough surface' during tablet coating?	02
	(b)	(i) Define chromatography. What is the basic principle?	03
		(ii) Give an account of TLC. Explain the method of the same in detail.	04
Q.4	(a)	(i) What is the concept of film coating? If you have to choose between film coating and sugar coating which will you opt. Justify	03
		(ii) What are the important considerations while formulating liquid filled capsules?	02
		(iii) Explain briefly how a dissolution study for tablets is carried out.	02
	(b)	Define Beer Lambert's law. Explain UV-VIS and IR spectrophotometry with its applications.	07
		OR	
Q.4	(a)	(i) What would happen to an enteric polymeric at low pH values and at high pH values?	07
		(ii) What are the applications of sustained release polymers in tablet technology? Give one example.	
		(iii) What is tablet chipping? State one reason why this happens.	
		(iv) How would you troubleshoot the problem of 'picking'?	
		(v) A certain pharmaceutical company has synthesized a new analgesic drug which they wish to formulate as a conventional oral tablet; however it degrades at acidic pH. What do you suggest?	
		(vi) When would a soft gelatin capsule be used (over a hard gelatin capsule)?	
		(vii) When would a drug be formulated as a capsule (over a tablet)?	
Q.5	(b)	What do you mean by critical point? Define supercritical fluid. Explain the method of supercritical fluid extraction with suitable diagram.	07
		OR	
	(a)	(i) A certain pharma company wishes to formulate their newly synthesized drug as a tablet. The drug has the following properties/characteristics: high dose, degrades in presence of water, bad flow properties. What method of granulation do you suggest? Justify.	03
		(ii) What is the concept of an effervescent tablet? Discuss with respect to formulation considerations.	02
		(iii) Discuss the role of binder and disintegrant in tablet formulation. What needs to be considered with respect to these two excipients while formulating chewable tablets and dispersible tablets?	02
	(b)	What are isoprenoids or terpenes? How are they classified? Give the pathway that leads to the synthesis of different types of isoprenoids.	07
		OR	
Q.5	(a)	(i) Discuss the rationale for coating a tablet based on the following points: therapy, technology and marketing.	03
		(ii) A certain pharma company during the R&D exercise of their new tablet formulation found that it breaks off horizontally into layers? What problem are they facing? If you were consulted, what troubleshooting strategies would you suggest?	02
		(iii) Explain the three capsule finishing processes.	02
	(b)	(i) Give the detailed account of any 1 drug belonging to any of the chemical class of the phytoconstituents.	05
		(ii) Define phytochemistry and pharmacognosy	02
