

QUIZ 2

MCQs. Choose the correct answer.

1. The basic tenets of PAT are:

- A. Measure, archive, report
- B. Measure, understand, control
- C. Measure, compare to cGMPs, report
- D. Measure, pass/fail, package/destroy

2. Technologies mentioned in the PAT guidance are:

- A. Near-Infrared (NIR) spectroscopy only
- B. NIR and Raman
- C. NIR, Raman and Infrared
- D. No techniques were specified

3. True or False, PAT is required by the FDA

- A. True
- B. False

5. PAT is established for which parameters?

- A. Raw materials used
- B. API synthesis routes
- C. Process parameters
- D. Manufacturing
- E. Documentation for validation
- F. a, c, d, e
- G. a, b,d,e

5. What types of analysis are included in Process Analytical Technology? Find one that is the LEAST correct.

- A) Chemical
- B) Physical
- C) Immunological
- D) Risk

Match the definition to the correct term

Defines particle size, bulk density, and surface morphology. This is necessary to avoid misleading predictions of stability or solubility of raw materials.	
An ordinary and simple method of determining particle size. It is widely used and involves passing the particulates through various meshes, with coarser meshes up top and finer meshes down bottom.	
Graphical examination of the raw material and is best used to differentiate between primary particles and aggregates, and to provide information on particle shape and morphology.	
These are based upon study of the terminal velocity acquired by particles suspended in a viscous liquid by dispersing the sample in liquid, then measuring the optical density of successive layers using visible light.	
This method can measure particle sizes below 1 micron (the most exact method covered) by measuring how well a particle passing through a laser beam scatters light.	
The ability of a molecule to crystallize into more than one crystal arrangement, which may have different melting points and solubility. This can affect shelf life, solubility, formulation properties and processing properties.	
A non-crystalline form that is often more soluble than a corresponding crystal form.	
A melting point experiment that places a compound on a stage which heats slowly so that some transitional melting stages may be observed.	
These are more precise methods of determining melting points that measure phase changes such as crystalline transitions, evaporation, sublimation, heats of fusion etc. into quantifiable data.	
A quantitative term used to express equilibrium concentration of solute in a solution.	

amorphous form	laser diffraction method	DSC & TGA	hot stage microscope
Microscopy	bulk characterization	solubility	
Sedimentation techniques	polymorphism	sieve analysis	(10 Marks)

No.	Statement	True @ False
1	A particle sample is mono disperse if all particles present the same size, whereas, a sample of particles that have variable sizes is known as poly disperse.	
2	Only the combination of the results of different techniques in particle analysis will enable the developer to understand the system and to draw conclusions for factors as physical stability.	
3	Microscopy Optical microscopy investigations can generally be applied to particles of 1µm and smaller.	
4	The size distribution of the particles can then be calculated using the principle that the angle of diffraction of the light is proportional to the particle size	
5	According to British pharmacopoeia, fine powder means 'not less than 95% by mass passes through a number 1400 sieve and not more than 40% by mass passes through a number 355 sieve.	

(5 Marks)

Fill in the blanks

1. What is rheology?

2. What are FOUR (4) dosage form formulations/analysis that are heavily influenced by rheology?

-----, -----, ----- and -----

3. What is a rheogram?

4. What are the 3 classes of flow for non-Newtonian systems?

-----, ----- and -----

5. What are the 4 instruments to determine viscosity? Which are single-point and which are multi-point?

i. ----- – (single/multi)

ii. ----- – (single/multi)

iii. ----- – (single/multi)

iv. ----- – (single/multi)

(10 Marks)