



Course Assessment

Time: 10 min

Marks: 10

1. Which of the following is NOT a method commonly used in drug discovery from natural sources?

- High-through put screening
- X-ray crystallography
- Nuclear magnetic resonance spectroscopy
- Polymerase chain reaction (PCR)

2. What is the primary advantage of using natural products in drug discovery?

- They are easily synthesized in the laboratory.
- They have well-defined mechanisms of action.
- They offer diverse chemical structures and bioactivities.
- They have fewer side effects compared to synthetic compounds.

3. Which of the following is an example of a natural product-derived drug that has been successfully developed for clinical use?

- Aspirin
- Paracetamol (acetaminophen)
- Metformin
- Morphine

4. What is the term for the process of modifying natural compounds to improve their pharmacological properties?

- Bioinformatics
- Combinatorial chemistry
- Medicinal chemistry
- Pharmacognosy

5. Which technique is commonly used to isolate bioactive compounds from plant extracts?

- Polymerase chain reaction (PCR)
- Nuclear magnetic resonance spectroscopy (NMR)
- Gas chromatography-mass spectrometry (GC-MS)
- Electroencephalography (EEG)

6. What is the primary purpose of phytochemical analysis techniques?

- To study the genetic makeup of plants
- To identify medicinal properties of plants
- To analyze soil composition for plant growth
- To measure plant photosynthesis rates

7. Why is herbal drug standardization important in traditional medicine?

- To increase the cost of herbal remedies
- To ensure consistent quality and efficacy
- To decrease the availability of herbal medicines
- To simplify the manufacturing process

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8. What is the primary objective of screening the pharmacological activity of natural products?

- To determine the colour and taste of natural products
- To identify potential bioactive compounds for drug development
- To classify natural products based on their geographical origin
- To assess the physical properties of natural products

9. Why are in vivo assays important in pharmacological screening of natural products?

- They are less costly than in vitro assays
- They provide insights into the potential toxicity of natural products
- They are conducted in test tubes or culture dishes
- They are primarily used for screening large numbers of compounds

10. Which of the following techniques is NOT commonly used for the identification of bioactive compounds from natural sources?

- Mass spectrometry
- Chromatography
- Immuno histo-chemistry
- Spectrophotometry

Feel free to adapt these questions based on the specific focus and content of your Value-added course.

Answers:

Questions	1	2	3	4	5	6	7	8	9	10
Answers	d	c	d	c	c	b	b	b	c	c

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 **CERTIFICATE OF COMPLETION**

This is presented to L. Saravani for
successful completion of Value added course on
**"DRUG DISCOVERY FROM
NATURAL PRODUCTS"**
Held from 11th July to 29th July, 2022


T.Saritha Jyostna
Principal



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This is presented to Kurupati Sranya Sree for
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**"DRUG DISCOVERY FROM
NATURAL PRODUCTS"**
Held from 11th July to 29th July, 2022


T.Saritha Jyostna
Principal

Value added course on "Drug Discovery from Natural Products"



PRINCIPAL

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Value Added Course on “Pharmaceutical Audits & Inspections: Preparing for Regulatory Scrutiny”

Course Assessment

Time: 10 mins

Marks: 10

Please tick the right answer:

1. Which regulatory body conducts Good Manufacturing Practices (GMP) inspections in the United States?

- a) World Health Organization (WHO)
- b) International Council for Harmonisation (ICH)
- c) Food and Drug Administration (FDA)
- d) European Medicines Agency (EMA)

2. What is the primary objective of conducting internal audits in a pharmaceutical QMS?

- a) Identifying and recalling defective products
- b) Evaluating system effectiveness and identifying areas for improvement
- c) Training personnel on GMP regulations
- d) Investigating customer complaints

3. What is the term used for the minimum concentration of a drug required to elicit a desired therapeutic effect?

- a) Maximum tolerated dose
- b) Minimum effective concentration (MEC)
- c) Lethal dose
- d) Therapeutic window

4. What type of document outlines standard procedures and policies for pharmaceutical manufacturing?

- a) Standard Operating Procedures (SOPs)
- b) Batch Records
- c) Quality Assurance Reports
- d) Product Specifications

5. What is a key characteristic distinguishing immediate-release from sustained-release dosage forms?

- a) Chemical composition
- b) Drug release rate
- c) Dosage size
- d) Route of administration

6. What type of inspection focuses primarily on data integrity and documentation management?

- a) cGMP inspection
- b) Data integrity inspection
- c) For-cause inspection
- d) Pre-approval inspection

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7. What is the most effective way to mitigate potential audit risks in a pharmaceutical company?

- a) Hiring additional quality control personnel
- b) Increasing product testing frequency
- c) Implementing a robust Quality Management System (QMS)
- d) Outsourcing manufacturing activities

8. What is the main purpose of conducting mock audits in a pharmaceutical setting?

- a) Identifying product defects
- b) Training auditors on inspection procedures
- c) Preparing personnel for the real inspection experience
- d) Evaluating the effectiveness of current audits

9. Which of the following factors does NOT significantly impact the bioavailability of a drug?

- a) First-pass metabolism
- b) Solubility
- c) Dosage form color
- d) Route of administration

10. How does continuous improvement relate to audit preparedness in the pharmaceutical industry?

- a) It has no bearing on audit readiness.
- b) It allows companies to hide potential issues from auditors.
- c) It reflects a reactive approach to addressing problems after audits.
- d) It proactively identifies and addresses areas for improvement, minimizing audit risks.

Feel free to adapt these questions based on the specific focus and content of your Value-added course.

Answers for the Multiple-Choice Questions:

Questions	1	2	3	4	5	6	7	8	9	10
Answers	c	b	b	a	b	b	c	c	c	d

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**Value added course "Pharmaceutical Audits & Inspections: Preparing for
Regulatory Scrutiny"**

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Value Added Course on “QbD Implementation Strategies: From Theory to Practice”
Course Assessment

Time: 10 mins

Marks: 10

Please tick the right answer:

1. What is the primary goal of Quality by Design (QbD) in pharmaceutical development?

- a. Cost reduction
- b. Faster product release
- c. Robust product quality
- d. Regulatory compliance

2. Which phase of drug development is most closely associated with QbD principles?

- a. Pre-clinical
- b. Phase I
- c. Phase II
- d. Phase III

3. Which QbD element emphasizes identifying and controlling sources of variability in the manufacturing process?

- a. Design space
- b. Risk assessment
- c. Control strategy
- d. Critical Quality Attributes (CQAs)

4. What is the purpose of a Design of Experiments (DOE) in the context of QbD?

- a. To identify critical quality attributes
- b. To establish a control strategy
- c. To optimize process parameters
- d. To conduct risk assessments

5. Which regulatory agency encourages the application of QbD principles in pharmaceutical development?

- a. FDA (Food and Drug Administration)
- b. EMA (European Medicines Agency)
- c. MHRA (Medicines and Healthcare products Regulatory Agency)
- d. All of the above

6. What is the key benefit of establishing a Design Space in QbD?

- a. Increased production speed
- b. Flexibility in manufacturing
- c. Reduced raw material costs
- d. Simplified regulatory submissions

7. In QbD terminology, what does the acronym CQA stand for?

- a. Critical Quality Analysis
- b. Critical Quantitative Assessment

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- c. Critical Quality Attributes
- d. Control Quality Assurance

8. What role does the QbD concept of "Knowledge Space" play in pharmaceutical development?

- a. Defining process parameters
- b. Establishing design space boundaries
- c. Identifying prior knowledge gaps
- d. Conducting risk assessments

9. Which QbD tool is commonly used for systematic identification and evaluation of potential risks in the manufacturing process?

- a. Ishikawa diagram
- b. Failure Mode and Effect Analysis (FMEA)
- c. Control chart
- d. Pareto analysis

10. What is the primary purpose of a Control Strategy in QbD?

- a. To ensure regulatory compliance
- b. To minimize production costs
- c. To define process parameters
- d. To maximize manufacturing speed

Feel free to adapt these questions based on the specific focus and content of your certificate course.

Answers for the multiple choice questions

Question	1	2	3	4	5	6	7	8	9	10
Answer	c	d	c	c	d	b	c	c	b	a

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This is presented to K. RISHIPRIYA
for successful completion of **VALUE ADDED COURSE** on
**“QbD IMPLEMENTATION STRATEGIES: FROM THEORY TO
PRACTICE”**

Held from 1st December to 19th December, 2022

T. Saritha Jyostna

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**“QbD IMPLEMENTATION STRATEGIES: FROM THEORY TO
PRACTICE”**

Held from 1st December to 19th December, 2022

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**Value added course” QbD implementation strategies: from theory
to practice”**

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**Value Added Course on “Artificial Intelligence (AI) in the Pharmaceutical Industry”
Course Assessment**

Time: 10 mins

Marks: 10

Please tick the right answer:

1. Which of the following is NOT a potential benefit of AI in drug discovery?

- a) Identifying new drug targets based on large datasets
- b) Predicting the efficacy and toxicity of potential drug candidates
- c) Automating repetitive tasks in the drug development process
- d) Replacing human scientists entirely in drug research

2. What type of AI is commonly used for analyzing gene expression data in drug discovery?

- a) Natural Language Processing (NLP)
- b) Deep Learning
- c) Evolutionary Algorithms
- d) Rule-based expert systems

3. Which of the following is a challenge associated with using AI in clinical trials?

- a) Lack of access to high-quality data
- b) Difficulty in interpreting the results of AI models
- c) Ethical concerns about using AI in decision-making
- d) All of the above

4. What is the term used for AI systems that can learn and improve their performance over time?

- a) Supervised learning
- b) Unsupervised learning
- c) Reinforcement learning
- d) All of the above

5. Which AI technique can be used to personalize drug treatments based on individual patient characteristics?

- a) Decision trees
- b) Support Vector Machines (SVMs)
- c) Recommender systems
- d) All of the above

6. What is the potential impact of AI on the cost and time it takes to develop new drugs?

- a) Increase costs and time significantly
- b) Decrease costs and time slightly
- c) Decrease costs and time significantly
- d) No impact

7. What are the ethical considerations surrounding the use of AI in the pharmaceutical industry?

- a) Bias in algorithms
- b) Transparency and explainability of AI models
- c) Data privacy and security

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d) All of the above

8. What are some of the key regulatory challenges associated with using AI in drug development?

- a) Lack of clear guidelines for AI validation and approval
- b) Difficulty in ensuring the safety and efficacy of AI-driven drugs
- c) Concerns about the potential misuse of AI technology
- d) All of the above

9. What is the future outlook for AI in the pharmaceutical industry?

- a) AI will replace all human scientists in the drug discovery process.
- b) AI will have a limited impact and remain a niche technology.
- c) AI will be a major driver of innovation and accelerate drug development.
- d) The future of AI in pharmaceuticals is uncertain.

10. What are some of the skills and knowledge needed to work with AI in the pharmaceutical industry?

- a) Programming skills in Python or R
- b) Understanding of machine learning algorithms
- c) Knowledge of biology and chemistry
- d) All of the above

Feel free to adapt these questions based on the specific focus and content of your Value-Added course.

Answers

- 1. d) Replacing human scientists entirely in drug research
- 2. b) Deep Learning
- 3. d) All of the above
- 4. d) All of the above
- 5. d) All of the above
- 6. c) Decrease costs and time significantly
- 7. d) All of the above
- 8. d) All of the above
- 9. c) AI will be a major driver of innovation and accelerate drug development.
- 10 d) All of the above

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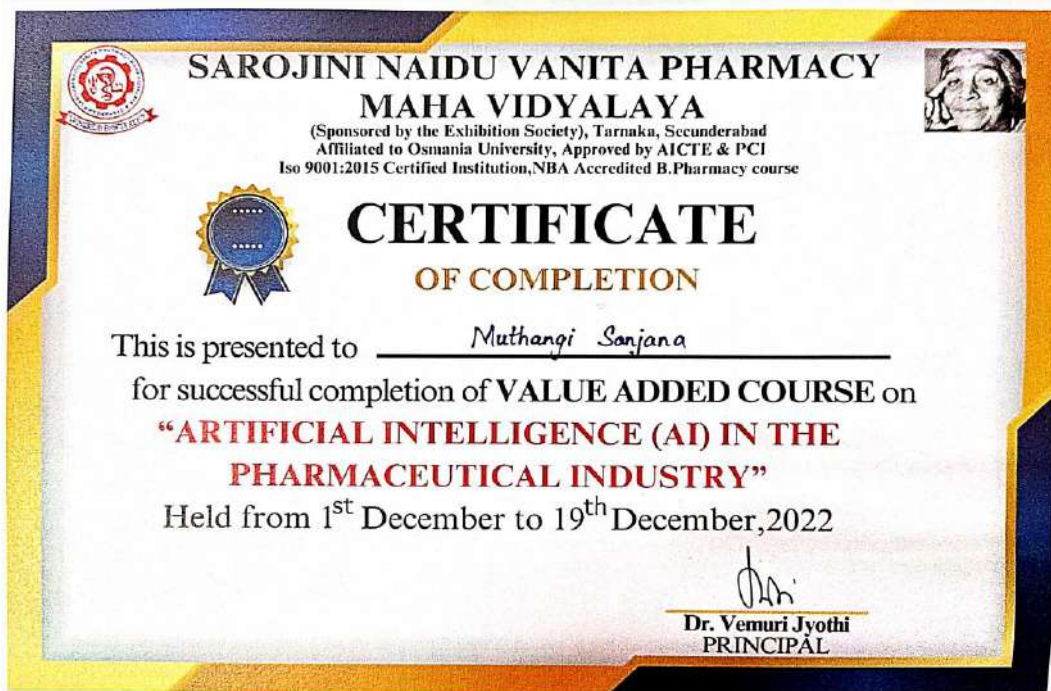


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**Value added course" Artificial Intelligence (AI) in the
Pharmaceutical Industry"**

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Value Added Course on "On Animal Handling"
Course Assessment

Time: 10 mins

Marks: 10

Please tick the right answer:

1. What is the first step in safely approaching an unfamiliar dog?

- A) Make direct eye contact with the dog
- B) Approach the dog from behind
- C) Extend your hand for the dog to sniff
- D) Speak loudly to get the dog's attention

2. Which of the following is a recommended safety protocol when handling livestock?

- A) Stand directly in front of the animal to maintain control
- B) Approach the animal from its blind spot
- C) Keep calm and move slowly around the animal
- D) Use sudden movements to assert dominance over the animal

3. What is the purpose of using a muzzle on a dog during handling?

- A) To prevent the dog from barking
- B) To restrict the dog's vision
- C) To prevent the dog from eating or drinking
- D) To prevent the dog from biting

4. Which of the following restraint techniques is suitable for restraining a small bird?

- A) Grasping the bird firmly around its body
- B) Holding the bird's wings gently against its body
- C) Holding the bird's legs with one hand and its body with the other
- D) Using a towel to cover the bird completely

5. When transporting animals, what should be provided to ensure their comfort and safety?

- A) A cramped enclosure to minimize movement
- B) Adequate ventilation and temperature control
- C) Loud music to soothe the animals
- D) Limited access to water to prevent spills

6. What should be done if an animal shows signs of distress during handling?

- A) Increase the handling intensity to desensitize the animal
- B) Ignore the signs and continue with the handling procedure
- C) Stop handling immediately and assess the situation
- D) Punish the animal to discourage further distress signals

7. Which of the following is a legal requirement for transporting livestock?

- A) Providing insufficient ventilation to reduce stress
- B) Overloading the transport vehicle to maximize profit
- C) Providing adequate space and access to food and water
- D) Transporting animals without proper documentation

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8. What is the recommended approach when introducing two unfamiliar dogs to each other?

- A) Allow them to approach each other freely without interference
- B) Intervene immediately if any signs of aggression are displayed
- C) Keep them on leashes and allow them to sniff each other briefly
- D) Ensure they are both off-leash and let them establish dominance

9. Which of the following is a sign of a comfortable and relaxed cat during handling?

- A) Purring loudly
- B) Ears flat against the head
- C) Dilated pupils
- D) Tail held high and twitching gently

10. What is the primary goal when handling wild animals?

- A) Domesticating them for human interaction
- B) Minimizing stress and preserving their wild nature
- C) Training them to perform specific behaviors
- D) Encouraging aggressive behavior for protection purposes

Feel free to adapt these questions based on the specific focus and content of your Value-Added course.

Answers for the multiple choice questions

Question	1	2	3	4	5	6	7	8	9	10
Answer	D	C	D	B	B	C	C	C	A	B

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Value added course" Animal handling"

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**Value Added Course on “Certification on-Regulatory Affairs in Pharmaceutics”
Course Assessment**

Time: 10 mins

Marks: 10

Please tick the right answer:

1. Which of the following is NOT a primary responsibility of regulatory affairs professionals in pharmaceutics?

- a) Ensuring compliance with drug regulations
- b) Preparing and submitting regulatory documentation
- c) Conducting clinical trials
- d) Marketing and promoting drugs

2. The Common Technical Document (CTD) is a standardized format for submitting marketing authorization applications in:

- a) The United States
- b) The European Union
- c) Japan
- d) All of the above

3. The purpose of an Investigational New Drug (IND) application in the US is to:

- a) Obtain marketing approval for a new drug
- b) Get permission to conduct clinical trials
- c) Register a new drug product
- d) Report adverse events associated with a marketed drug

4. Good Manufacturing Practices (GMPs) are regulations that ensure the:

- a) Quality and safety of drug products
- b) Ethical conduct of clinical trials
- c) Efficacy of new drugs
- d) Proper labeling and packaging of drugs

5. The International Conference on Harmonization (ICH) is a global initiative that aims to:

- a) Harmonize technical requirements for registering pharmaceuticals
- b) Facilitate the exchange of clinical trial data
- c) Promote research and development of new drugs
- d) All of the above

6. Which regulatory agency is responsible for approving new drugs in India?

- a) Central Drugs Standard Control Organization (CDSCO)
- b) Indian Council of Medical Research (ICMR)
- c) Department of Pharmaceuticals (DoP)
- d) Ministry of Health and Family Welfare (MoHFW)

7. Orphan drugs are intended for the treatment of rare diseases. What is the typical period of market exclusivity granted to orphan drugs in the United States?

- a) 5 years
- b) 7 years

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- c) 10 years
- d) 12 years

8. Good Manufacturing Practices (GMPs) are regulations that ensure the quality and safety of pharmaceutical products. Which of the following is NOT a core principle of GMPs?

- a) Quality assurance
- b) Process validation
- c) Risk management
- d) Cost-effectiveness

9. The Food and Drug Administration (FDA) in the United States requires an Investigational New Drug (IND) application before initiating which of the following?

- a) Phase I clinical trials
- b) Phase II clinical trials
- c) Phase III clinical trials
- d) All of the above

10. Pharma co-vigilance refers to the:

- a) Process of monitoring the safety of drugs after they have been marketed
- b) Development and testing of new drugs
- c) Manufacture and distribution of drugs
- d) Regulatory approval process for new drugs

Feel free to adapt these questions based on the specific focus and content of your Value-Added course.

Answers for the multiple choice questions

Question	1	2	3	4	5	6	7	8	9	10
Answer	d	d	b	a	a	a	b	d	d	a

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This is presented to S. Vaishali
for successful completion of **VALUE ADDED COURSE** on
“REGULATORY AFFAIRS IN PHARMACEUTICS”
Held from 24th April to 11th May, 2023

T. Saritha
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Held from 24th April to 11th May, 2023

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Value added course” Regulatory Affairs in Pharmaceutics”

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**Valued added course on "Clinical Trials and Research Methods"
Course Assessment**

Time: 10 mins

Marks: 10

Please tick the right answer:

1) What is the primary objective of a clinical trial in drug development?

- a. To maximize profits for pharmaceutical companies
- b. To investigate the efficacy and safety of a new drug
- c. To skip regulatory requirements
- d. To prioritize marketing strategies over research findings

2) What does the term "research methodologies" encompass in pharmaceutical studies?

- a. Memorization of study results
- b. Designing and conducting experiments
- c. Ignoring the study design
- d. Avoiding critical appraisal

3) Why are ethical considerations crucial in clinical research?

- a. To manipulate research findings
- b. To comply with regulatory requirements
- c. To ignore participant welfare
- d. To prioritize financial gains over ethics

4) What is the purpose of hands-on training in a clinical trials workshop?

- a. To avoid practical application
- b. To simulate clinical trial scenarios
- c. To discourage data collection
- d. To ignore statistical analysis

5) What is the significance of guest lectures in a clinical trials workshop?

- a. To avoid industry insights
- b. To engage students with real-world perspectives
- c. To limit interactions with professionals
- d. To prioritize theoretical discussions over practical insights

6) Which phase of a clinical trial typically involves a larger group of participants?

- a. Phase I
- b. Phase II
- c. Phase III
- d. Phase IV

7) What does a well-designed research protocol include?

- a. Ambiguous research questions
- b. Lack of ethical considerations
- c. Clear objectives and methodologies
- d. Ignoring regulatory requirements

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8) What is the primary goal of statistical analysis in clinical research?

- a. To manipulate data
- b. To enhance research transparency
- c. To avoid data interpretation
- d. To prioritize anecdotal evidence over statistical findings

9) How can ethical dilemmas in research be addressed?

- a. By ignoring ethical principles
- b. By engaging in questionable practices
- c. By adhering to ethical guidelines and seeking guidance
- d. By avoiding ethical discussions

10) What skills are enhanced through hands-on training in data collection?

- a. Avoiding practical application
- b. Developing statistical analysis skills
- c. Ignoring research findings
- d. Application of evidence-based practices in data collection

Answers for the multiple choice questions

Question	1	2	3	4	5	6	7	8	9	10
Answer	b	b	b	d	b	c	c	b	c	b

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Value added course" Clinical Trials and Research Methods"

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Value Added Course on “Hands-on Training on Analytical Instruments”
Course Assessment

Time: 10 mins

Marks: 10

Please tick the right answer:

1. Which of the following is NOT a primary consideration when choosing an analytical instrument?

- a) Sensitivity - Ability to detect small amounts of analyte
- b) Selectivity - Ability to differentiate the analyte from other components
- c) Cost - Initial purchase and maintenance expenses
- d) Sample type - Form and compatibility with the instrument
- e) User skill level - Expertise required for operation and analysis

2. In gas chromatography (GC), the separation of components is based on:

- a) Molecular weight
- b) Electrical charge
- c) Interaction with the stationary phase
- d) Chemical reactivity
- e) Density

3. In high-performance liquid chromatography (HPLC), the mobile phase is typically:

- a) Gas
- b) Liquid
- c) Solid
- d) Plasma
- e) Vacuum

4. In UV-visible spectroscopy, which parameter determines the wavelength of light absorbed by a molecule?

- a) pH
- b) Temperature
- c) Electronic transitions
- d) Concentration
- e) Solvent

5. Resolution in chromatography is affected by:

- a) Sample size only
- b) Detector sensitivity only
- c) Both column efficiency and peak width
- d) Flow rate only
- e) Injection technique only

6. During a hands-on training session, it is important to:

- a) Work alone to avoid distractions
- b) Follow safety protocols carefully
- c) Ignore data that does not fit your expectations
- d) Rely solely on the instructor for guidance

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e) Avoid asking questions

7. When calibrating an analytical instrument, it is important to use:

- a) Any available standards
- b) Standards with unknown concentrations
- c) Standards prepared from the same source as the samples
- d) Standards outside the expected range of the samples
- e) Standards that match the matrix of the samples

8. When interpreting data from an analytical instrument, it is important to consider:

- a) Only the main peak or signal
- b) Background noise and blank values
- c) Data outside the calibration range as irrelevant
- d) Only positive results as meaningful
- e) Ignore potential sources of error

9. Proper documentation of your work during hands-on training is important for:

- a) Impressing the instructor
- b) Reproducing your results later
- c) Sharing your findings with others
- d) Demonstrating your knowledge
- e) All of the above

10. Hands-on training on analytical instruments can help you:

- a) Learn theoretical concepts only
- b) Become familiar with instrument operation and data analysis
- c) Develop problem-solving skills
- d) Improve communication and teamwork
- e) All of the above

Feel free to adapt these questions based on the specific focus and content of your certificate course.

Answers for multiple choice questions:

Question	1	2	3	4	5	6	7	8	9	10
Answer	e	c	b	c	c	b	c	b	e	e

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