

Fist name : Last name :.....

Series N° 2

For each question, choose the correct answer(s). (One or more answers may be correct.)

1. Non-compliant medicines may include:

- A. Substandard medicines
- B. Falsified medicines
- C. GMP-certified medicines
- D. Degraded medicines

2. The three pillars required for Marketing Authorization are:

- A. Quality
- B. Safety
- C. Efficacy
- D. Profitability

3. Hydrolysis mainly affects:

- A. Esters
- B. Amides
- C. Lactones
- D. Alkanes

4. Cross-contamination occurs when:

- A. Residues from one product transfer to another
- B. The product is correctly labeled
- C. The API is degraded
- D. The equipment is new

5. Which are physico-chemical methods?

- A. HPLC
- B. Electrophoresis
- C. UV-Vis
- D. GC

6. Biological methods include:

- A. Sterility testing
- B. Antibiotic assay
- C. Karl Fischer
- D. Pyrogen testing

7. Quantitative control includes:

- A. Assay of API
- B. Impurity levels
- C. Water content
- D. Dissolution rate

8. If no pharmacopoeial monograph exists for a product, the manufacturer must:

- A. Skip analytical testing
- B. Use any available method
- C. Develop internal specifications and fully validate the method
- D. Only perform qualitative control

9. The pyrogen test in pharmaceutical quality control is performed to:

- A. Detect the presence of viable microorganisms
- B. Detect fever-producing substances such as bacterial endotoxins
- C. Measure sterility of the finished product
- D. Determine the water content of injectable solutions

10. Major pharmacopoeias include:

- A. United States Pharmacopeia
- B. European Pharmacopoeia
- C. British Pharmacopoeia
- D. ISO 9001