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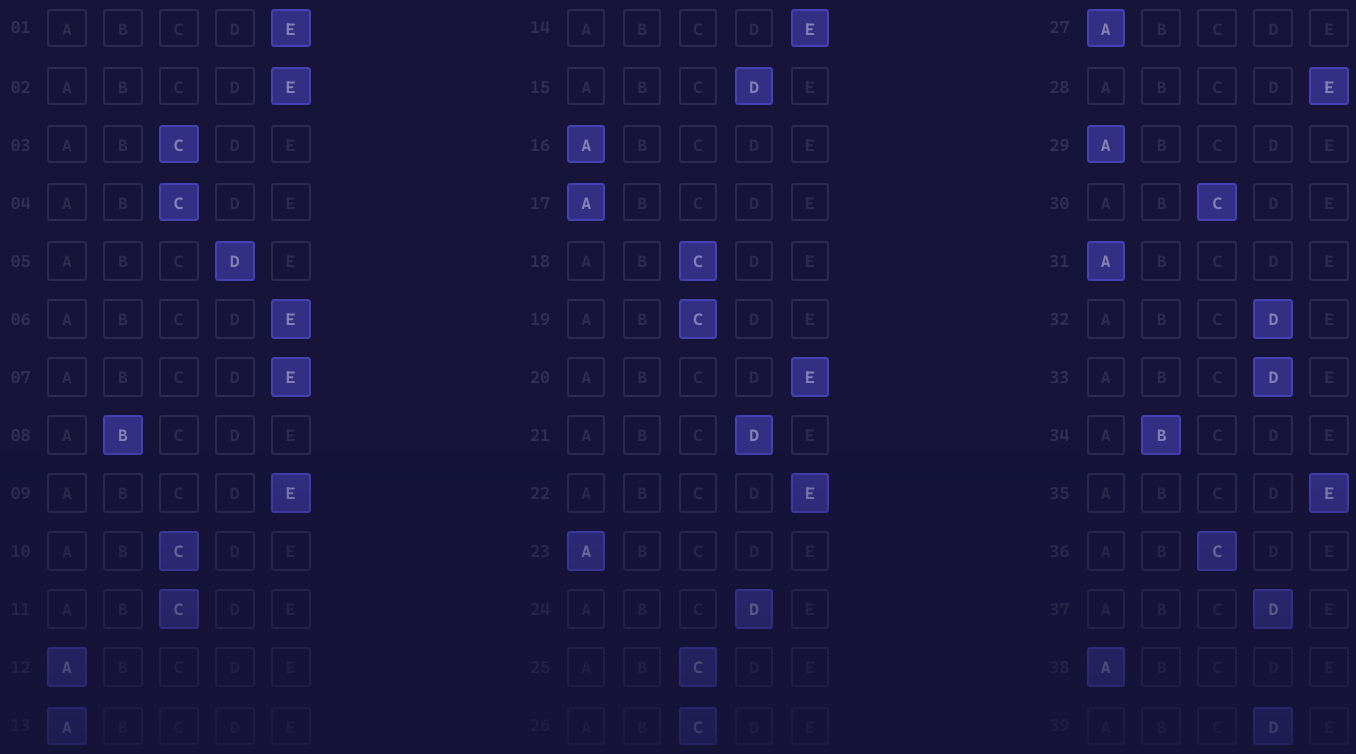

PRACTICE QUESTIONS

TTBU - The Testing Board Ukraine

EPUIP

English Prof. Exam Pharmacy Industrial Pharmacy (Ukr)

EDITION	QUESTIONS	FORMAT
Demo	9	Limited Edition PDF

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Before you begin

What this is

9 practice questions for TTBU - The Testing Board Ukraine `EPUIP`, each with its answer key and an explanation. Answer a question before you read its key — the explanation is worth more once you have committed.

If something looks wrong

Send us three things and we will check it:

- the exam code, `EPUIP`
- the question number
- the email address on your order

Write to **support@mometrix.net**. We reply within one business day.

QUESTION 1 MULTIPLE CHOICE

Which of the following terms correctly describe unit operations used during the manufacture of solid oral dosage forms? (Choose two.)

A **Granulation**

B Fermentation

C **Tablet compression**

D Lyophilisation of injectables

ANSWER **A** · **C**

WHY Granulation and tablet compression are standard unit operations in solid oral dosage form manufacture. Fermentation is a biological process used to produce certain APIs (e.g., antibiotics) and lyophilisation is applied to parenteral/injectable products, neither of which is a unit operation for solid oral dosage forms.

QUESTION 2 MULTIPLE CHOICE

Which of the following documents are mandatory components of a pharmaceutical Quality Management System according to EU GMP guidelines? (Choose two.)

A **A Site Master File**

B A batch leaflet for patients

C **A Product Quality Review**

D A marketing authorisation for cosmetics

ANSWER **A** · **C**

WHY The Site Master File (SMF) and Product Quality Review (PQR) are mandatory GMP documents. A patient batch leaflet is not a GMP requirement (the package leaflet is a regulatory labelling document), and marketing authorisation for cosmetics is unrelated to medicinal product manufacture.

QUESTION 3 TRUE FALSE

In pharmaceutical packaging terminology, a 'blister pack' refers to a primary packaging format in which individual doses are sealed between a formed plastic film and a backing layer (typically aluminium foil).

A **True**

B False

ANSWER **A**

WHY True. A blister pack is a unit-dose primary packaging format consisting of a thermoformed plastic cavity containing a single dose, sealed against an aluminium foil lid — a standard pharmaceutical packaging term.

QUESTION 4 SINGLE CHOICE

Which English term denotes a sterile, pyrogen-free aqueous solution intended for parenteral administration in a single dose?

A Elixir

B **Injection**

C Suspension

D Emulsion

ANSWER **B**

WHY 'Injection' is the official pharmacopoeial term for a sterile, pyrogen-free solution for parenteral use. Elixir is an oral hydroalcoholic preparation, while suspensions and emulsions are dispersed dosage forms typically not used for direct parenteral injection in this context.

QUESTION 5 SINGLE CHOICE

In GMP terminology, 'process validation' is defined as:

A The confirmation by examination of a product's efficacy in clinical trials

B **The documented evidence that a process, operated within established parameters, can perform effectively and reproducibly to produce a medicinal product meeting its predetermined specifications**

C The statistical analysis of stability data for the active substance only

D The marketing authorisation procedure for a new finished product

ANSWER B

WHY This is the standard EU GMP / ICH Q7 definition of process validation. Clinical efficacy, stability statistics and marketing authorisation belong to different regulatory domains and do not define process validation.

QUESTION 6 SINGLE CHOICE

The analytical technique used to separate, identify and quantify components in a mixture by passing it through a stationary phase under a mobile phase is called:

A Titration

B **Chromatography**

C Lyophilisation

D Membrane filtration

ANSWER B

WHY Chromatography (including HPLC and GC) is the standard separation technique described. Titration is a volumetric chemical method; lyophilisation is freeze-drying; membrane filtration is a sterilisation/microbiology method.

QUESTION 7 SINGLE CHOICE

According to ICH Q1A, long-term stability testing of a finished pharmaceutical product intended for room-temperature storage should be conducted at:

A **25 °C / 60% RH**

B -20 °C / uncontrolled humidity

C 40 °C / 75% RH

D 5 °C / 60% RH

ANSWER **A**

WHY ICH Q1A defines the long-term (real-time) storage condition for climatic zone I/II products as 25 °C ± 2 °C / 60% RH ± 5% RH. 40 °C / 75% RH is the accelerated condition; refrigerated and frozen conditions apply to other product categories.

QUESTION 8 SINGLE CHOICE

In the EU regulatory framework, the document containing detailed information on the manufacturing process, control of starting materials, characterisation of the active substance and finished product, and stability data is known as the:

A Periodic Safety Update Report

B **Common Technical Document (CTD) Module 3 — Quality**

C Patient Information Leaflet

D Summary of Product Characteristics

ANSWER **B**

WHY Module 3 of the ICH Common Technical Document (CTD) — Quality — contains the chemical, pharmaceutical and biological information for both active substance and finished product. The other options are part of the dossier but serve different purposes (safety, labelling, prescribing information).

QUESTION 9 SINGLE CHOICE

According to EU GMP Annex 1, the maximum permitted number of particles ≥ 0.5 µm per m^3 for a Grade A cleanroom (at rest) is:

A **3 520**

B 352 000

C 100 000

D 3 500 000

ANSWER **A**

WHY EU GMP Annex 1 specifies that Grade A (at rest) must not exceed 3 520 particles of ≥ 0.5 µm per cubic metre — the cleanest grade used for aseptic operations. The other limits correspond to lower grades (B, C, D).