2025
【藥物開發及臨床試驗從業人員培訓班】
筆試解答

一、是非題

1. F 學名藥的開發資訊可以完全從原廠藥的專利說明書中取得。
2. F 學名藥的臨床試驗通常是與安慰劑對照組進行生物等效性的比較。
3. T 廠商申請藥品查驗登記時，所檢附資料應依通用技術文件格式(CTD)呈現。

二、選擇題

1. 依據我國《專利法》規定，藥品專利權最多可以延長多久？
   A. 1 年
   B. 3 年
   C. 5 年
   D. 10 年

2. 以下哪一項**不**屬於新藥開發中的藥物探索(Drug discovery)階段？
   A. 標的確效 (Target validation)
   B. 化合物篩選 (Compound screening)
   C. 臨床前試驗 (Pre-clinical tests)
   D. 先導化合物優化 (lead optimization)

3. 藥品的臨床前試驗 (Pre-clinical tests)**不**包含以下哪個項目？
   A. 藥理學試驗
   B. 藥物動力學試驗
   C. 毒理學試驗
   D. 生物相容性試驗

4. 依據 GDP 規範，藥品在運輸時須符合以下哪些要求？(複選)
   A. 藥品可以隨意堆放，只要外包裝沒有毀損即可
   B. 運送過程中需維持適當的溫、濕度條件
   C. 須留有完整的追溯記錄與文件
   D. 車輛及設備都需要定期清潔與維護

5. 關於藥品的上市後安全監視，以下哪些是藥商的責任？(複選)
   A. 應訂定藥品安全性監視計畫
   B. 減少上市後的生產批次檢測
   C. 主動收集藥品上市後的安全資訊
   D. 若發生不良反應，應於期限內完成不良反應通報

6. 下列關於臨床試驗知情同意書的敘述，哪一項是錯誤的？
   A. 知情同意書必須以受試者能理解的語言書寫
   B. 受試者有權在試驗過程中隨時退出，不需提供理由

C. 研究員應向受試者詳細解釋試驗的風險和利益
D. 受試者在簽署知情同意書後，不得退出臨床試驗

7. According to GCP, who is primarily responsible for ensuring the ethical conduct of the clinical trials?
   A. Sponsor
   B. IRB
   C. Investigator
   D. Clinical Research Coordinator(CRC)

8. What does "double-blind" mean in a clinical trial?
   A. Participants know their treatment, but investigators don't
   B. Only investigators know the treatment allocation
   C. Treatment allocation is revealed after the trial is completed
   D. Neither the participants nor the investigators know the treatment allocation

9. Which neurotransmitter is primarily targeted by antipsychotic drugs?
   A. Dopamine
   B. Serotonin
   C. Acetylcholine
   D. Glutamate

10. What is the significance of the Orphan Drug Act?
   A. To promote the use of generic drugs
   B. To facilitate the development of drugs for rare diseases
   C. To prioritize pediatric drug approvals
   D. To speed up clinical trial timelines

11. What is the active ingredient in Veklury(韋如意)?
   A. Ibuprofen
   B. Diclofenac
   C. Remdesivir
   D. Aspirin

12. Which of the following tests is used to establish the shelf life of a drug during storage?
   A. Stability test
   B. Safety test
   C. Bioavailability test
   D. Uniformity test

13. What does ICH stand for? (*註)
   A. International Convention on Harmonisation
   B. International Conference on Harmonisation
   C. International Convention on Homogenization
   D. International Conference on Homogenization

14. Which of the following does **NOT** require prescription?
    A. Barbiturates
    B. Probiotics
    C. Serum
    D. Benzodiazepines

15. Which one of the following terms is defined as the rate and extent to which the active constituent or active moiety of a drug is absorbed from a drug product and reaches the circulation?
    A. Potency
    B. Bioequivalence
    C. Chemical equivalence
    D. Bioavailability

16. Which of the following covid-19 vaccines utilizes viral vector as the base?
    A. Moderna
    B. AstraZeneca
    C. BioNTech (Pfizer)
    D. Medigen

17. Which of the following is NOT considered a serious Adverse Drug Reaction (sADR)?
    A. A life threatening event
    B. A persistent incapacity
    C. Temporary dizziness
    D. Death

(*註) ICH 原名 International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use。

2015 年時，ICH 進行了組織改革，並更名為 International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use。

為維護應試者權益，本題送分，特此公告。