BP701T · B.Pharm Semester VII · Theory Notes

Biostatistics and Research Methodology

Unit V — Research Methodology (6 hours)

Unit V (6 hours)

Pills & Python Notes

From-zero teaching standard: every technical term is defined before use.

Syllabus coverage: Unit V (6 hours).

PILLS & PYTHON

Pharmacy • Data • AI • Healthcare

Instagram @pillsandpython · pillsandpython.com · YouTube @PillsAndPython

CHAPTER 12: Research Methodology — Research Types, Designs and Test Selection

1. Learning Objectives

After studying this chapter, you will be able to:

- Define research and explain its importance in pharmacy.
- Classify research into its main types with examples.
- Distinguish descriptive, observational, and experimental research designs, giving pharmacy examples of each.
- Select a research design based on the research question.
- Define the population and sample, choose a sample size and a sampling method.
- Choose methods of data collection and data analysis suited to the question.
- Use the decision-tree approach to select the correct statistical test from the research question and the type of data.

2. Definitions

- **Research:** A systematic, planned search for new knowledge — asking a clear question, collecting evidence in an organised way, and drawing honest conclusions.
- **Research methodology:** The complete plan of *how* the research will be done: the design, the population and sample, the sampling method, the data-collection tools, and the analysis methods.
- **Research design:** The blueprint of the study — what will be compared with what, who will be studied, and when measurements are taken.
- **Population:** The entire group about which we want conclusions (e.g., all hypertensive patients in a city).
- **Sample:** The smaller, manageable part of the population actually studied (e.g., 200 of those patients).
- **Sampling method:** The rule used to pick the sample from the population (random, stratified, etc.).
- **Variable:** Anything that can take different values — the thing we measure (blood pressure) or the thing we change (drug dose).

3. Terminology Table

Term	Simple meaning
Research question	The single clear question the study must answer
Population	The whole group of interest
Sample	The part of the population actually studied

Term	Simple meaning
Sampling frame	The list (or source) from which the sample is drawn
Random sampling	Every member has an equal chance of selection — like a fair lottery
Stratified sampling	Population split into groups (strata); random sample taken from each
Systematic sampling	Pick every kth member from a list
Convenience sampling	Pick whoever is easily available (weakest method)
Independent variable	The factor the researcher changes or groups by (e.g., drug vs placebo)
Dependent variable	The outcome measured (e.g., blood pressure fall)
Confounding variable	A hidden third factor that can fake or hide a real effect
Descriptive statistics	Numbers that summarise data (mean, %, charts)
Inferential statistics	Tests that generalise from sample to population (t-tests, chi-square)

4. Simple Explanations

4.1 Research — meaning and importance, from absolute zero

Technical concept: research is systematic investigation aimed at discovering or confirming facts.

Simple explanation: Research is asking a sharp question and answering it with evidence instead of opinion. A pharmacist who wonders "does our new tablet dissolve as fast as the market leader?" and then measures 20 tablets of each under identical conditions is doing research. Without research, pharmacy would run on guesswork: wrong doses, unstable formulations, unproven claims.

Example. A hospital pharmacist notices many diabetic patients skip doses. She designs a short study: interview 100 patients, count the reasons, and test whether a reminder chart improves adherence. That is research — question → evidence → conclusion. **Diagram:**

```
Curiosity ("why? / does it work?")
        |
        v
Sharp research question
        |
        v
Plan (methodology) --> Collect data --> Analyse --> Conclude --> Share
```

Key takeaway: research = a clear question answered with planned, honest evidence; it is how pharmacy replaces guesswork with knowledge.

4.2 Types of research

Technical concept: research is classified by purpose and by approach.

Simple explanation:

- **Basic (fundamental) research:** knowledge for its own sake — e.g., studying how a drug molecule binds its receptor. No immediate product in mind.
- **Applied research:** solving a practical problem — e.g., developing a stable tablet formula for that molecule.
- **Quantitative research:** works with numbers — "by how much did BP fall?" (uses t-tests, ANOVA).
- **Qualitative research:** works with words and meanings — "why do patients stop taking medicines?" (uses interviews, themes).
- **Descriptive research:** describes *what exists* — no comparison, no treatment given.
- **Analytical/observational research:** compares groups *as they are*, without the researcher assigning any treatment.
- **Experimental research:** the researcher *assigns* the treatment and compares outcomes — the strongest design for cause and effect.

Example. Basic: mapping a new drug's mechanism. Applied: formulating it as a capsule. Quantitative: measuring dissolution %. Qualitative: asking patients why they dislike the capsule's size. **Key takeaway:** purpose (basic/applied) and approach (quantitative/qualitative; descriptive/observational/experimental) together classify any study.

4.3 Types of research designs

Technical concept: the design is the study's blueprint.

Simple explanation — the three big families:

1. **Descriptive design:** "Take a photograph." Measure and describe one group at one time; no comparison, no intervention. Example: a survey of self-medication practices among 500 college students.
2. **Observational (analytical) design:** "Watch and compare." Compare groups that *already differ* (smokers vs non-smokers; one hospital's patients vs another's). The researcher does not assign anything — nature or choice already did. Subtypes: cross-sectional (one snapshot in time), case-control (start from disease, look back at exposures), cohort (start from exposure, follow forward to disease).
3. **Experimental design:** "Do and compare." The researcher *assigns* the treatment — drug vs placebo — ideally at random (randomised controlled trial, RCT). Because the researcher controls who gets what, this design best proves cause and effect.

Example. Descriptive: "What % of our OPD patients are anaemic?" Observational: "Is anaemia more common in vegetarians than non-vegetarians here?" Experimental: "Does iron syrup X raise haemoglobin more than syrup Y? (patients randomly given X or Y)." **Key takeaway:** descriptive = photograph; observational = watch and compare; experimental = assign and compare.

4.4 Research methodology based on the research question

Technical concept: the question dictates every later choice — design, population, sample size, sampling, data collection, analysis.

Simple explanation — the chain:

1. **Selection of research design:** "Does drug A lower BP more than drug B?" → experimental (RCT). "How common is hypertension in our city?" → descriptive survey. "Is hypertension linked to salt intake here?" → observational.
2. **Defining the population and sample:** Population = all adults aged 30–60 in the city; sample = 400 of them attending three clinics. Inclusion/exclusion criteria sharpen this (include: diagnosed hypertension; exclude: pregnancy, kidney disease).
3. **Selecting sample size:** big enough for reliable answers, small enough to be affordable. Larger samples give narrower, more trustworthy estimates and higher power (Chapter 10). Too small → the study cannot detect real effects; wastefully large → time and money burned.
4. **Selecting the sampling method:** simple random (lottery from the patient list), stratified (equal numbers of men/women, then random within each), systematic (every 10th patient on the register), or convenience (whoever walks in — weakest, used only in pilot work).
5. **Method of data collection:** questionnaires/interviews (knowledge, attitudes), direct measurement (BP, weight, assay values), observation, or existing records (prescriptions, lab reports). Tools must be valid (measures what it claims) and reliable (gives the same result on repeat).
6. **Data analysis:** first describe (means, percentages, charts — descriptive statistics), then test (inferential statistics — the hypothesis tests of Chapters 10–11, chosen via the decision tree below).

Example. Question: "Do our two paracetamol brands differ in dissolution?" Design: experimental comparison; population: all tablets of the two batches; sample: 12 tablets per brand (random sampling from each batch); data collection: dissolution apparatus, % released at 30 min; analysis: independent samples t test (or Mann-Whitney if skewed). **Key takeaway:** the research question is the boss — design, sample, collection, and analysis all obey it.

4.5 Decision-tree approach for selection of statistical tests

Technical concept: test selection follows the research question + the type of data.

Simple explanation: Ask four questions in order: (1) What is the research question — difference between groups, or relationship between variables? (2) What type is the outcome data — numbers (continuous), ordered scores, or counts (categories)? (3) How many groups, and are they independent or related? (4) Are the numbers bell-shaped (roughly normal)? The answers walk you down the tree to exactly one test.

TEXTUAL DECISION TREE (read top to bottom):

```
START: What is your research question?
  |
  +-- Q1: "Do GROUPS DIFFER?" (comparison question)
  |       |
  |       +-- What TYPE is the outcome data?
  |               |
  |               +-- COUNTS / CATEGORIES (yes-no, cured/not, blood group)
  |               |         --> CHI-SQUARE test
  |               |            (2x2 table: test of independence;
  |               |             one variable vs expected ratio: goodness of fit)
  |               |
  |               +-- NUMBERS (continuous: BP, weight, assay %)
  |               |       |
  |               |       +-- Are data approx. NORMAL (bell-shaped)?
  |               |               |
  |               |               +-- YES --> PARAMETRIC branch:
  |               |               |       How many groups? Related or independent?
  |               |               |         1 sample vs target      --> single sample t test
  |               |               |         2 INDEPENDENT groups    --> independent samples t test
  |               |               |         2 RELATED (before/after)--> paired t test
  |               |               |         3+ INDEPENDENT groups   --> one-way ANOVA
  |               |               |         3+ RELATED measurements --> repeated-measures ANOVA
  |               |               |
  |               |               +-- NO --> NON-PARAMETRIC branch (ranks):
  |               |                       2 INDEPENDENT groups    --> Mann-Whitney U
  |               |                       2 RELATED measurements  --> Wilcoxon signed-rank
  |               |                       3+ INDEPENDENT groups   --> Kruskal-Wallis
  |               |                       3+ RELATED measurements --> Friedman test
  |               |
  |               +-- ORDERED SCORES (pain 0-10, grades, ranks)
  |                         --> treat like NON-PARAMETRIC branch above
  |
  +-- Q2: "Are two VARIABLES RELATED?" (relationship question)
          |
          +-- Both variables NUMBERS (dose vs response, time vs degradant)
          |       --> CORRELATION (strength) + REGRESSION (prediction line)
          |       --> t-test for correlation / slope (Ch. 10, df = n - 2)
          |
          +-- Both variables CATEGORIES (gender vs ADR yes/no)
                  --> CHI-SQUARE test of independence
```

Worked walk-throughs (example → diagram → takeaway):

- "Do two tablet brands differ in mean hardness?" → groups differ → numbers → normal → 2 independent groups → **independent samples t test**.
- "Did pain scores (0–10) fall after the drug in the same patients?" → groups differ → ordered scores → **Wilcoxon signed-rank**.
- "Is ADR occurrence related to dosage form (tablet/syrup/injection)?" → groups differ → counts → **chi-square**.
- "Does impurity rise with storage time?" → variables related → both numbers → **correlation + regression slope t-test**.

Key takeaway: question type → data type → groups → normality → the test picks itself.

4.6 Descriptive research design — examples of application

Simple explanation: describe a situation as it is, without comparing or intervening. Tools: surveys, questionnaires, record reviews. Analysis: percentages, means, charts.

Pharmacy examples: (1) A survey of antibiotic self-medication among 600 outpatients — "% who bought antibiotics without prescription." (2) Drug-utilisation review: "which antihypertensives were prescribed most in our hospital last year?" (3) A knowledge-attitude-practice (KAP) study on generic medicines among interns. **Key takeaway:** descriptive = "what is happening?" answered with counts and averages.

4.7 Observational research design — examples of application

Simple explanation: compare groups as nature left them; the researcher assigns nothing. Strong for finding associations; weaker for proving cause (hidden confounders may lurk).

Pharmacy examples: (1) Case-control: compare past NSAID use in 100 ulcer patients vs 100 ulcer-free controls — "was NSAID exposure more common in cases?" (2) Cohort: follow 500 statin users and 500 non-users for two years — "who develops muscle pain more often?" (3) Cross-sectional: one-day survey linking salt intake and BP across 1,000 adults. **Key takeaway:** observational = compare existing groups; great for associations, cautious on causation.

4.8 Experimental research design — examples of application

Simple explanation: the researcher assigns the treatment (preferably by randomisation), controls conditions, and compares outcomes. Randomisation balances known and unknown confounders, so a difference can be blamed on the treatment — the gold standard for cause and effect.

Pharmacy examples: (1) RCT: 200 hypertensives randomly given new drug vs standard drug; compare BP fall (independent samples t test). (2) Formulation experiment: three binder levels × two drying temperatures tested on tablet hardness (two-way ANOVA — see Chapter 13's factorial designs for the planning side). (3) Crossover: each volunteer tries formulation A then B (with washout); compare within-subject (paired t test). **Key takeaway:** experimental = you assign the treatment; randomisation is what lets you claim causation.

5. Classifications

- **By purpose:** basic (knowledge) vs applied (problem-solving).
- **By data:** quantitative (numbers) vs qualitative (words/meanings).
- **By design family:** descriptive (photograph) vs observational (watch and compare: cross-sectional, case-control, cohort) vs experimental (assign and compare: RCT, crossover).
- **By sampling:** probability methods (simple random, stratified, systematic — every member has a known chance) vs non-probability (convenience, purposive — quick but biased).
- **By analysis:** descriptive statistics (summarise) vs inferential statistics (generalise: the tests of Chapters 10–11, chosen by the decision tree).

6. Processes

6.1 The research methodology chain (step-by-step)

1 Write ONE clear research question.

2 Select the design the question demands (descriptive / observational / experimental).

3 Define the population; write inclusion and exclusion criteria.

4 Fix the sample size (large enough for power, small enough to afford).

5 Choose the sampling method (prefer probability sampling).

6 Choose data-collection tools (questionnaire, measurement, records); check validity and reliability.

7 Plan the analysis: descriptive first, then the inferential test from the decision tree.

8 Collect, analyse, conclude — and report honestly, including negative results.

6.2 Choosing a sampling method (mini-process)

```
Do you have a list of the whole population?
  YES --> SIMPLE RANDOM (lottery) or SYSTEMATIC (every kth)
Do important subgroups need fair representation?
  YES --> STRATIFIED (random within each subgroup)
No list, only whoever is available?
  --> CONVENIENCE (pilot work only; admit the limitation)
```

7. Textual Diagrams/Flowcharts

The two required diagrams of this chapter are the **research chain flowchart** (section 4.1: curiosity → question → plan → collect → analyse → conclude → share) and the **statistical test selection decision tree** (section 4.5). Together they carry the whole chapter: the first plans the study, the second analyses it.

8. Infographic Concept

INFOGRAPHIC CONCEPT: "The Research Compass." A compass with four needles: North = "QUESTION: difference or relationship?", East = "DATA: numbers, scores, or counts?", South = "GROUPS: how many? independent or related?", West = "SHAPE: bell-shaped or not?" The compass face is the decision tree; wherever the four needles point, a single test name lights up (t, ANOVA, Mann-Whitney, chi-square ...). Around the rim runs the methodology chain: Question → Design → Population → Sample → Collect → Analyse → Conclude. Motto at the bottom: "The question chooses the design; the data choose the test."

9. Tables

9.1 The three design families compared

Feature	Descriptive	Observational	Experimental
Researcher assigns treatment?	No	No	Yes
Comparison groups?	Usually none	Yes (existing groups)	Yes (assigned groups)
Can prove cause and effect?	No	Suggests only	Yes (with randomisation)
Pharmacy example	Self-medication survey	Case-control: NSAIDs and ulcers	RCT: new vs standard drug
Typical analysis	%, means, charts	Chi-square, t-tests, odds ratios	t-tests, ANOVA

9.2 Sampling methods at a glance

Method	How it works	Strength	Weakness
Simple random	Lottery from the full list	Unbiased	Needs a complete list
Stratified	Random within each subgroup	Fair to small subgroups	Needs subgroup info
Systematic	Every kth member	Simple, even spread	Risk if the list has a pattern
Convenience	Whoever is available	Fast, cheap	Biased; weak evidence

10. Worked Examples

WORKED EXAMPLE 1 — Walking the decision tree. Research question: "Does counselling improve medicine adherence scores (0–20 scale) in the same 40 patients, measured before and after?"

- Q1: groups differ? Yes (before vs after). Data type: ordered scores. Groups: 2, related (same patients).
- Tree path: groups differ → ordered scores → non-parametric → 2 related → **Wilcoxon signed-rank test**.

Answer: Wilcoxon signed-rank test.

WORKED EXAMPLE 2 — Walking the decision tree. "Do three brands of amoxicillin capsules differ in mean assay %?" (n = 10 per brand, data bell-shaped.)

- Groups differ → numbers → normal → 3+ independent groups → **one-way ANOVA**.

Answer: one-way ANOVA (not three t-tests).

WORKED EXAMPLE 3 — Systematic sampling arithmetic. A clinic register lists 1,200 hypertensive patients; the study needs 120.

- Sampling interval k = population/sample = 1200/120 = 10.
- Pick a random start between 1 and 10 (say 7), then select patients 7, 17, 27, … until 120 are chosen.

Answer: every 10th patient from a random start.

WORKED EXAMPLE 4 — Full methodology sketch. Question: "Is headache relief (yes/no) associated with dosage form (tablet vs capsule)?" Design: observational cross-sectional survey of 300 patients. Population: adult outpatients; sample: 300 by systematic sampling from the OPD register. Data collection: short questionnaire. Analysis: counts → chi-square test of independence, df = (2−1)(2−1) = 1.

11. Analogies

- **Photograph vs film direction (designs):** descriptive research takes a photograph; observational research watches a street scene and compares passers-by; experimental research directs the film — casting actors (randomisation) and shooting the scene.

- **Fishing net (sampling):** the population is the lake, the sample is the catch. A random net catches a fair mix; fishing only near the shore (convenience sampling) catches only shore fish — a biased sample.
- **Recipe (methodology):** the research question is the dish you want; the design is the recipe; sampling is choosing ingredients; analysis is tasting and judging. Change the dish, and the whole recipe changes.
- **Compass (decision tree):** four needles (question, data type, groups, shape) always point to exactly one test — no guessing.

12. Pharmacy Relevance

- **Formulation development:** "which binder level gives hardest tablets?" → experimental design + ANOVA.
- **Quality control:** batch sampling plans are stratified/systematic sampling in action.
- **Clinical pharmacy:** ADR case-control studies, drug-utilisation reviews (descriptive), and RCTs of counselling interventions.
- **Regulatory work:** bioequivalence studies are experimental crossover designs analysed by ANOVA/t-tests.
- **Hospital projects:** KAP surveys on antibiotic use (descriptive) feed directly into antimicrobial-stewardship programmes.

13. India Context

India's vast patient pool makes it a major site for clinical and observational research, and Indian B.Pharm/M.Pharm dissertations most often use descriptive surveys (drug utilisation, KAP studies) and small experimental formulation comparisons — exactly the designs in this chapter. Hospital-based ADR reporting and prescription audits in Indian teaching hospitals are classic observational designs. Choosing the right design and the right test from the decision tree is what separates a publishable Indian pharmacy project from a rejected one.

14. Key Points

- Research = a clear question answered with planned evidence; methodology = the full plan.
- The research question dictates the design, sample, collection, and analysis.
- Designs: descriptive (photograph), observational (watch and compare), experimental (assign and compare; randomisation proves causation).
- Sample: representative subset; prefer probability sampling (random, stratified, systematic).
- Sample size balances power against cost.
- Data collection tools must be valid and reliable.
- Analyse in two layers: descriptive (summarise) then inferential (test).
- The decision tree: question → data type → groups → normality → the test.

15. Common Confusions

- **Population vs sample:** the population is the whole group of interest; the sample is the part studied. Conclusions always aim at the population.
- **Observational vs experimental:** both compare groups, but only experimental *assigns* the treatment. An "experimental-looking" comparison of existing groups is still observational.
- **Correlation vs causation:** observational designs can show association, not proof — only randomised experiments approach proof.
- **Qualitative vs quantitative:** interviews about *why* (qualitative) vs measurements of *how much* (quantitative) — different questions, different tools.
- **The tree needs the data type first:** students often jump to a favourite test; the tree forces question → data type → groups → shape, in order.

16. Common Mistakes

- Writing a vague research question ("study of diabetes") instead of one sharp question.
- Choosing convenience sampling for a confirmatory study and then generalising boldly.
- Picking the statistical test before checking the data type and shape.
- Running an experiment without randomisation and still claiming causation.
- Collecting data first and deciding the analysis later — analysis must be planned before collection.
- Ignoring inclusion/exclusion criteria, letting an undefined population creep in.

17. Mnemonics

- **"Q-D-P-S-C-A": Q**uestion → **D**esign → **P**opulation → **S**ample → **C**ollect → **A**nalyse — the methodology chain.
- **"Photo, Watch, Direct":** descriptive = photo, observational = watch, experimental = direct.
- **"Question picks Design; Data picks Test."**

18. Exam Summary

Research is systematic investigation; research methodology is the complete plan (design, population, sample, sampling, collection, analysis). Research is classified by purpose (basic/applied), data (quantitative/qualitative), and design family: descriptive (describe as-is), observational (compare existing groups: cross-sectional, case-control, cohort), and experimental (assign treatment, preferably randomised — proves causation). The research question dictates every choice: define the population with inclusion/exclusion criteria, fix an adequate sample size, prefer probability sampling (random, stratified, systematic), collect with valid reliable tools, and analyse in two layers (descriptive, then inferential). The statistical test is selected by a decision tree: question type (difference vs relationship) → data type (counts, numbers, ordered scores) → number and relatedness of groups → normality → the test (t-tests, ANOVA, Mann-Whitney, Wilcoxon, Kruskal-Wallis, Friedman, chi-square, correlation/regression).

19. One-Minute Revision

Research = question + planned evidence. Q-D-P-S-C-A: Question → Design → Population → Sample → Collect → Analyse. Designs: photo (descriptive), watch (observational), direct (experimental + randomisation = causation). Sampling: random, stratified, systematic beat convenience. Decision tree: question → data type → groups → shape → test. Question picks design; data picks test.

20. Questions

Short-answer:

1 Define research and research methodology.

2 Distinguish basic from applied research with pharmacy examples.

3 Distinguish observational from experimental designs.

4 What are inclusion and exclusion criteria? Why are they needed?

5 Compare stratified and systematic sampling.

6 Why is randomisation important in experimental designs?

7 Distinguish descriptive from inferential statistics.

8 A study compares pain scores (0–10) before/after a drug in the same patients. Which test does the tree give?

Long-answer:

1 "The research question dictates the methodology." Explain with the full chain (design → population → sample → collection → analysis) using a pharmacy example.

2 Describe descriptive, observational, and experimental designs with one pharmacy example each; compare their strength for proving causation.

3 Reproduce and explain the decision tree for selecting a statistical test; apply it to four different research questions.

4 Describe the main sampling methods with merits and limitations.

5 Plan a complete small study: "Do two brands of cetirizine tablets differ in disintegration time?" (question, design, population, sample, sampling, collection, analysis with the test chosen via the tree).

MCQs (answer key below):

1 Research methodology is: (a) the results (b) the complete plan of the study (c) the references (d) the abstract

2 "How common is anaemia in our OPD?" needs: (a) experimental (b) descriptive (c) RCT (d) crossover

3 A case-control study: (a) assigns treatment (b) starts from disease, looks back (c) follows exposure forward (d) has no comparison

4 Randomisation mainly: (a) increases n (b) balances confounders (c) blinds patients (d) cuts cost

5 Stratified sampling ensures: (a) speed (b) fair subgroup representation (c) no list needed (d) zero bias always

6 Which sampling is weakest? (a) random (b) stratified (c) systematic (d) convenience

7 Comparing two brands' mean assay (normal data, independent) → (a) paired t (b) independent t (c) chi-square (d) Friedman

8 ADR yes/no vs 3 dosage forms → (a) ANOVA (b) chi-square (c) paired t (d) correlation

9 Same volunteers taste 4 syrups (ranked) → (a) Kruskal-Wallis (b) Friedman (c) Mann-Whitney (d) one-way ANOVA

10 First step of the decision tree: (a) check normality (b) identify the research question type (c) compute n (d) pick α

Answer key: 1-b, 2-b, 3-b, 4-b, 5-b, 6-d, 7-b, 8-b, 9-b, 10-b.

Viva questions:

1 Your question is "why do patients default on TB treatment?" — quantitative or qualitative? Why?

2 You compared two existing hospitals' infection rates. Experimental or observational?

3 Why plan the analysis before collecting data?

4 Walk me down the tree for: "is smoking associated with cough (yes/no)?"

5 What is a confounding variable? Give an example.

Application-based:

1 A dissertation asks: "Do final-year students know more about generics than first-year students? (score 0–30, skewed data, two independent groups.)" Walk the decision tree and name the test.

2 Design a sampling plan for a prescription audit of 5,000 prescriptions needing 250: choose the method, compute the interval, and justify the choice.

21. References

- Bolton (Pharmaceutical Statistics)
- Daniel (Biostatistics)
- Montgomery (Design and Analysis of Experiments)

CHAPTER 13: Scientific Report Writing, Plagiarism, and Screening/Optimization Designs

1. Learning Objectives

After studying this chapter, you will be able to:

- Describe the standard structure of a scientific report and the purpose of each section.
- Define plagiarism, list its types, and explain how to avoid it.

- Describe the main referencing styles in generic terms and cite sources correctly.
- List sensible criteria for selecting a research journal for publication.
- Explain what abstracting services and databases do, in generic terms.
- Distinguish screening from optimisation in experimental design.
- Describe the Plackett-Burman design, factorial designs, D-optimal design, sequential simplex design, central composite design, and response surface methodology.
- Explain blocking and confounding in experimental designs.
- Compute main effects and interactions in a 2^2 factorial design by hand.

2. Definitions

- **Scientific report:** A formal written account of research, organised into standard sections so any reader can follow what was asked, what was done, what was found, and what it means.
- **Plagiarism:** Presenting someone else's words, ideas, or data as your own without proper credit — the most serious offence in scientific writing.
- **Referencing style:** The fixed format for citing sources in the text and listing them at the end (e.g., author–date or numbered systems).
- **Abstracting service / database:** An organised collection (usually electronic and searchable) that stores article titles, abstracts, authors, and keywords so researchers can find published work.
- **Screening design:** An experiment with many factors and few runs, used to find which factors actually matter ("separating the vital few from the trivial many").
- **Optimisation design:** An experiment with a few key factors, used to map the response surface and find the best settings.
- **Response surface methodology (RSM):** A set of statistical techniques for modelling and finding the optimum of a response that depends on several variables.
- **Blocking:** Grouping experimental runs into homogeneous blocks (same day, same analyst, same batch) so that unwanted variation is isolated and does not pollute the results.
- **Confounding:** Mixing of two or more effects so they cannot be told apart — common in fractional designs, where some effects are deliberately sacrificed.

3. Terminology Table

Term	Simple meaning
IMRaD	Introduction, Methods, Results, and Discussion — the backbone of a report
Abstract	A short standalone summary of the whole work
Citation	A pointer in the text to a source ("as shown by Sharma...")
Reference list	The full details of all cited sources at the end
Self-plagiarism	Reusing your own published work without disclosure

Term	Simple meaning
Peer review	Independent experts checking a manuscript before publication
Predatory journal	A fake/low-quality journal that publishes for fees without real peer review
Factor	An input variable the experimenter controls (e.g., binder %)
Level	A chosen value of a factor (low / high)
Response	The measured outcome (e.g., tablet hardness)
Main effect	The average change in response when one factor moves from low to high
Interaction	When the effect of one factor depends on the level of another
Axial (star) points	Extra runs along each factor's axis, used in central composite designs
Simplex	A geometric figure with one more vertex than factors (triangle for 2 factors)

4. Simple Explanations

4.1 Scientific report writing, from absolute zero

Technical concept: a scientific report communicates research in the standard IMRaD structure so it can be understood, checked, and reproduced.

Simple explanation: A report is not a story — it is a laboratory notebook written for strangers. Every section answers one question:

- **Title:** what is this about? Short, specific, honest.
- **Abstract:** the whole work in ~200 words — question, method, key result, conclusion. Written last, read first.
- **Introduction:** why did you do this? Background, the gap in knowledge, and your objective.
- **Materials and Methods:** what exactly did you do? Enough detail that another lab could repeat the work.
- **Results:** what did you find? Tables, graphs, statistics — facts only, no opinions.
- **Discussion:** what does it mean? Compare with earlier work, explain surprises, admit limitations.
- **Conclusion:** the take-home message in 2–3 lines.
- **References:** every source cited, in the required style.

Example. A B.Pharm project on herbal tablet hardness: the Introduction explains why hardness matters (friability, patient handling); Methods names the press, the 2^2 design, the t-test; Results gives the hardness table with p-values; Discussion compares with the marketed product; Conclusion names the best formula.
Diagram:

```
TITLE  -->  ABSTRACT (mini-whole)
   |
INTRODUCTION ("why?") --> METHODS ("how?") --> RESULTS ("what?") --> DISCUSSION ("so what?")
   |
CONCLUSION ("take-home") + REFERENCES ("whose shoulders?")
```

Key takeaway: IMRaD = why → how → what → so what; Methods must allow repetition; Results carry facts, Discussion carries meaning.

4.2 Plagiarism

Technical concept: plagiarism is the uncredited use of others' (or one's own previously published) words, ideas, figures, or data.

Simple explanation: Copying a paragraph from a book into your dissertation without quotation marks and a citation is plagiarism — even if you change a few words (mosaic plagiarism). Reusing your own published text without disclosure is self-plagiarism. Even ideas need credit.

How to avoid it: (1) take notes in your own words; (2) quote any copied phrase and cite it; (3) paraphrase honestly, then cite; (4) cite every figure, table, and dataset you did not create; (5) run a plagiarism check before submission. "I forgot" is not a defence.

Example. Writing "Tablets must disintegrate within 15 minutes" is common knowledge — no citation needed. Writing "Sharma reported 98% dissolution in 30 minutes for formulation F3" without naming Sharma is plagiarism. **Key takeaway:** others' words, ideas, figures, data — credit every one, every time.

4.3 Referencing styles (generic description)

Technical concept: a referencing style fixes how citations look in the text and how the reference list is ordered.

Simple explanation — the three families:

1. **Author–date system:** the text shows "(Sharma, 2021)"; the list is alphabetical by author. Easy to read; common in theses.
2. **Numbered citation system:** the text shows "[3]"; the list is numbered in order of appearance. Compact; common in pharmacy journals.
3. **Footnote system:** small raised numbers point to notes at the page bottom.

Whichever the journal or university demands, be perfectly consistent: every in-text citation must match exactly one reference-list entry, and vice versa. **Key takeaway:** pick the required family and apply it identically throughout.

4.4 Selection of research journals

Technical concept: the journal must fit the work's scope, quality, and audience.

Simple explanation — the checklist:

- **Scope match:** a pharmaceutics paper belongs in a pharmaceutics journal, not a clinical one. Read the journal's "aims and scope."

- **Real peer review:** genuine journals describe their review process and list a real editorial board of known scientists.
- **Indexing:** reputable journals are indexed in recognised bibliographic databases (section 4.5) — indexing means the work will actually be found.
- **Publication ethics:** clear policies on authorship, conflicts of interest, and corrections.
- **Beware predatory journals:** warning signs — spam emails inviting submission, guaranteed acceptance in days, hidden fees, fake impact claims, no real editorial board. Publishing there can damage a career.

Example. A student formulation study fits a national pharmacy journal with proper peer review — not a journal emailing "publish in 7 days, 100% acceptance." **Key takeaway:** scope → real peer review → indexing → ethics; run from guaranteed-acceptance offers.

4.5 Abstracting services and databases (generic description)

Technical concept: these are searchable stores of the published literature.

Simple explanation: An **abstracting service** collects article titles, authors, abstracts, and keywords from thousands of journals into one searchable store ("show me papers on floating tablets"). A **bibliographic database** does the same electronically, often with full-text links and citation tracking. Search these before starting research (avoid repeating finished work; build your reference list); being indexed in them after publishing is what makes your paper discoverable. **Key takeaway:** search them before you start, get indexed in them after you publish.

4.6 Screening and optimisation — the concept

Technical concept: formulation development happens in two phases with different goals.

Simple explanation: Suppose 7 factors might affect your tablet (binder %, disintegrant %, compression force, mixing time, ...). Testing all combinations (2^7 = 128 runs) is wasteful. **Phase 1 — screening:** use a cheap design (Plackett–Burman) with ~8–12 runs to find the 2–3 factors that actually matter; ignore the rest. **Phase 2 — optimisation:** study only those 2–3 factors in detail, map how the response curves, and locate the best settings (factorial + central composite + RSM, or sequential simplex).

Example. Screening 7 excipient/process factors in 12 runs shows only binder % and compression force matter; optimisation then maps hardness over those two and finds the sweet spot. **Diagram:**

```
7 candidate factors
      |
  SCREENING (Plackett-Burman: few runs, many factors)
      |  "vital few" identified
      v
2-3 key factors
      |
  OPTIMISATION (factorial/CCD/simplex: map the surface, find the peak)
      |
      v
Best settings --> confirmatory run
```

Key takeaway: screen first (many factors, few runs → find the vital few), then optimise (few factors, mapped surface → best settings).

4.7 Plackett-Burman design (screening)

Technical concept: a highly efficient two-level screening design for N−1 factors in N runs (N a multiple of 4: 8, 12, 16, 20...).

Simple explanation: With just 12 runs you can screen up to 11 factors — each factor tested at a low (−) and high (+) level in a balanced pattern. The price: interactions are tangled with main effects, so the design only estimates each factor's overall (main) effect. That is fine for screening, where you only ask "does this factor matter at all?"

Example. 7 factors in 8 runs: each column of the 8-run pattern is one factor's −/+ plan; after the runs, each factor's main effect = (average of + runs) − (average of − runs); the biggest effects graduate to optimisation. **Key takeaway:** Plackett–Burman = maximum factors per run; finds the vital few; cannot see interactions.

4.8 Factorial designs

Technical concept: every combination of every factor's levels is tested — a 2^2 design has 4 runs, 2^3 has 8.

Simple explanation: Factorial designs are the workhorses: because all combinations are present, they estimate **main effects** *and* **interactions** cleanly. Draw the 2^2 design as a square: corners = the 4 runs; the effect of A = (right side average) − (left side average); interaction = whether A's effect changes from the bottom edge to the top edge.

Example (fully worked in Calculation Box 1): binder % (A) × compression force (B) on hardness — both main effects and their interaction computed by hand. **Diagram:**

```
        B- (low force)    B+ (high force)
A- (low binder)     5.0              6.0
A+ (high binder)    7.0              9.0
Effect of A = avg(right col... see box) ; interaction = diagonal difference
```

Key takeaway: factorial = all combinations; gives main effects AND interactions; the square picture makes the arithmetic obvious.

4.9 D-optimal design

Technical concept: a computer-generated design that maximises the determinant of the information matrix — i.e., squeezes the most information from a fixed number of runs.

Simple explanation: Standard designs assume you can run any combination freely. Real life has constraints: "binder % + disintegrant % cannot exceed 10%," or a factor is categorical (supplier X/Y). The D-optimal algorithm picks the most informative set of *allowed* runs for your model and run budget — the most efficient custom design possible.

Example. Only 14 runs affordable, with two excipient levels forbidden from both being high: D-optimal selects the 14 most informative allowed combinations. **Key takeaway:** D-optimal = custom, computer-chosen runs; best under constraints or tight budgets.

4.10 Sequential simplex design

Technical concept: a step-by-step hill-climbing method that assumes no mathematical model.

Simple explanation: For 2 factors, the "simplex" is a triangle. Run the 3 corner experiments, throw away the worst corner, and reflect it through the opposite edge to make a new triangle — the triangle crawls uphill toward better responses, one experiment at a time. Stop when the triangle gets tiny around the peak. No equations, no surface fitting — just "keep the good, flip the bad."

Example. Optimising an HPLC mobile phase: start with 3 solvent blends (triangle), drop the worst, reflect to a new blend; after a few reflections the triangle huddles around the best blend. **Diagram:**



Key takeaway: simplex = crawling triangle; model-free hill-climbing; stop when it stops improving.

4.11 Central composite design (CCD) and response surface methodology

Technical concept: CCD is the classic optimisation design; RSM is the modelling framework that uses it.

Simple explanation: A CCD for 2 factors = the 4 factorial corners + 4 "star" (axial) points sticking out along each axis + a few centre repeats. The stars let the model bend — they reveal curvature (is the optimum a peak or still climbing?). **RSM** then fits a second-order (curved) equation to all the data, draws contour maps (like a topographic map of the response), and reads off the peak — the optimal settings. Centre repeats measure pure experimental noise.

Example. Hardness mapped over binder % and force: the fitted curved surface peaks at one setting, and contour rings around the peak show how flat or sharp the optimum is. A confirmatory run at the predicted optimum validates the model. **Key takeaway:** CCD adds star points to catch curvature; RSM fits the curved surface and points to the peak.

4.12 Blocking and confounding

Technical concept: blocking removes nuisance variation; confounding is the unavoidable mixing of effects in fractional designs.

Simple explanation — blocking: If 8 runs must span two days, day-to-day drift could fake a factor effect. Run 4 experiments per day with the factor pattern balanced across days — "day" becomes a **block**, and its effect is subtracted out. Blocks = runs done under uniform conditions (same day, analyst, or material batch).

Simple explanation — confounding: A full 2^3 needs 8 runs; a half-fraction uses 4 — but then effects share the same arithmetic and cannot be separated: e.g., the main effect of C is **confounded** (aliased) with the AB interaction. Designers choose fractions so main effects are confounded only with negligible high-order interactions — this quality grade is the design's **resolution**.

Example. Comparing two analysts' assay results: treat analyst as a block — each analyst tests every formulation, so analyst-to-analyst bias cannot masquerade as a formulation difference. **Key takeaway:** block what you cannot control (days, analysts, batches); in fractional designs, know which effects are confounded.

5. Classifications

- **Report sections:** front matter (title, abstract) → body (IMRaD) → back matter (references, appendices).
- **Plagiarism types:** verbatim copying, mosaic (patch-writing), paraphrasing without credit, self-plagiarism, data/figure theft.
- **Referencing families:** author–date, numbered citation, footnote.
- **Designs by purpose:** screening (Plackett–Burman, fractional factorial — many factors, few runs, main effects only) vs optimisation (full factorial, CCD + RSM, sequential simplex, D-optimal — few factors, curvature and optima).
- **Designs by construction:** standard textbook layouts (factorial, CCD) vs computer-generated custom layouts (D-optimal) vs model-free search (simplex).
- **Nuisance handling:** blocking (isolate it) vs confounding (accept and manage it in fractional designs).

6. Processes

6.1 Writing a scientific report (step-by-step)

1 Finalise the analysis; note every result honestly, including negative ones.

2 Draft Methods first, then Results (tables/figures with titles).

3 Write the Introduction (background → gap → objective), then the Discussion (compare, explain, admit limitations).

4 Write the Conclusion (2–3 lines) and the Abstract last.

5 Format references; check every citation matches the list. Run a plagiarism check; proofread; submit.

6.2 From screening to optimisation (step-by-step)

1 List all candidate factors and their low/high levels.

2 Screen with Plackett–Burman: few runs, estimate main effects, keep the 2–3 significant factors.

3 Optimise: factorial + CCD (or simplex); fit the RSM model; read the optimum from the surface.

4 Run confirmatory experiments at the predicted optimum; report.

7. Textual Diagrams/Flowcharts

The chapter's diagrams are: the IMRaD flow (section 4.1), the screening→optimisation funnel (section 4.6), the 2^2 factorial square (section 4.8), the simplex reflection triangle (section 4.10), and the CCD layout described below:

```
CCD for 2 factors (9 + centre repeats):
          *  (star: high B)
          |
  * -- +--+-- * -- + (star: low A ... centre ... star: high A)
          |
          *  (star: low B)
Corners (+): the 2x2 factorial square around the centre
```

8. Infographic Concept

INFOGRAPHIC CONCEPT: "From Funnel to Peak." Left: a wide funnel labelled SCREENING swallowing 11 factor cards and dripping out 3 golden "vital few" cards (Plackett–Burman badge: "12 runs, 11 factors"). Right: a 3D mountain labelled RESPONSE SURFACE — a hiker (the sequential simplex triangle) climbing step by step, contour rings circling the summit flag "OPTIMUM," with star points marking the CCD. Below: a report document split into IMRaD bands, a red stamp "PLAGIARISM = career poison," and three citation cards (author–date, numbered, footnote). Motto: "Screen the many, climb to the one, report it honestly."

9. Tables

9.1 Screening vs optimisation designs

Feature	Screening	Optimisation
Goal	Find which factors matter	Find the best settings
Factors	Many (5–11+)	Few (2–3)
Runs	Few	More per factor
Estimates	Main effects only	Main effects + interactions + curvature
Typical designs	Plackett–Burman, fractional factorial	Full factorial, CCD + RSM, simplex, D-optimal

9.2 Optimisation designs compared

Design	Runs (2 factors)	Needs a model?	Handles constraints?	Finds curvature?
Full factorial (2^2)	4	For interpretation	No	No
Central composite	~9–13	Yes (RSM)	No	Yes
Sequential simplex	Open-ended	No	Easily	By climbing
D-optimal	User-fixed	Yes	Yes — its strength	If model includes it

9.3 Types of plagiarism

Type	What happens	Prevention
Verbatim copying	Copied text, no quotes/credit	Quote + cite, or rewrite
Mosaic (patch-writing)	Slightly altered copied text	Full paraphrase + cite
Paraphrase without credit	Idea reused, no citation	Cite the source
Self-plagiarism	Reusing own published text	Disclose/quote it
Figure/data theft	Others' figures or data as own	Permission + citation

10. Worked Examples and Calculation Boxes

CALCULATION BOX 1 — 2^2 factorial: main effects and interaction (tablet hardness, kg/cm²). Factor A = binder % (−: 2%, +: 4%); factor B = compression force (−: low, +: high). Runs: (1) A−B− → 5.0; a: A+B− →

7.0; b: A−B+ → 6.0; ab: A+B+ → 9.0.

- Main effect of A = (avg at A+) − (avg at A−) = [(7.0 + 9.0)/2] − [(5.0 + 6.0)/2] = 8.0 − 5.5 = 2.5 kg/cm².
- Main effect of B = (avg at B+) − (avg at B−) = [(6.0 + 9.0)/2] − [(5.0 + 7.0)/2] = 7.5 − 6.0 = 1.5 kg/cm².
- Interaction AB = [(ab + (1))/2] − [(a + b)/2] = [(9.0 + 5.0)/2] − [(7.0 + 6.0)/2] = 7.0 − 6.5 = 0.5 kg/cm².
- **Interpretation:** both factors raise hardness; binder (A) matters more (2.5 > 1.5); the small positive interaction (0.5) means high binder and high force together give slightly more than the sum of their separate effects.

WORKED EXAMPLE 2 — Plackett–Burman screening read-out. Seven factors, 8 runs; main effects: binder +2.1, force +1.8, others ≤ 0.4 in size. **Decision:** carry binder and force to optimisation; fix the rest at economical levels.

WORKED EXAMPLE 3 — Blocking plan. Eight optimisation runs across two analysts: each analyst does 4 runs with two A−/two A+ and two B−/two B+ (balanced); analyst becomes a block, so analyst bias is separated from factor effects.

WORKED EXAMPLE 4 — Spotting confounding. A half-fraction 2^3 (4 runs) screening 3 factors: each main effect is confounded with a two-factor interaction (e.g., C ≡ AB) — acceptable for screening if interactions are assumed negligible; verify any "significant" effect with follow-up runs.

11. Analogies

- **Funnel and mountain (screen → optimise):** screening pours suspects through a funnel, keeping only the vital few; optimisation climbs the response mountain to plant the flag on the peak.
- **Casting a play (journal selection):** sending a tragedy script to a comedy theatre wastes everyone's time — match the paper's scope to the journal's stage.
- **Exam seating plan (blocking):** seating friends apart so whispering cannot fake anyone's score — blocks isolate what you cannot eliminate.

12. Pharmacy Relevance

- **Tablet/capsule development:** Plackett–Burman screens excipient/process factors; CCD + RSM optimises the formula — the standard modern workflow.
- **Analytical methods:** simplex or RSM optimises HPLC mobile phase, pH, and flow rate.
- **Stability/packaging:** factorial designs test temperature × humidity × pack type efficiently.
- **QC labs:** blocking by analyst/day removes nuisance variation from method comparisons.
- **Publishing:** every dissertation ends as a report — IMRaD, referencing, and journal selection turn a project file into a paper.

13. India Context

Indian pharmacy colleges now routinely run plagiarism checks before accepting dissertations — honest paraphrasing and correct referencing are no longer optional. Formulation researchers increasingly use screening and optimisation designs (factorial, CCD, RSM) because they cut experimental runs and material cost, a real advantage for cost-sensitive development. Choosing an indexed, peer-reviewed journal — and avoiding predatory publishers that flatter young researchers with email invitations — protects both the work and the author's career.

14. Key Points

- **Report = IMRaD:** Introduction (why), Methods (repeatable how), Results (facts), Discussion (meaning); Abstract written last.
- **Plagiarism** (any uncredited words/ideas/data/figures, including self-plagiarism) is a career-ending offence — paraphrase fully and cite always.
- **Referencing families:** author–date, numbered, footnote — be perfectly consistent.
- **Journal choice:** scope → genuine peer review → indexing → ethics; avoid predatory journals.
- **Databases:** search before starting; be indexed after publishing.
- **Screen first** (Plackett–Burman: many factors, few runs) → **optimise** (factorial/CCD + RSM, simplex, D-optimal).
- **CCD** = factorial + star points + centre repeats → curvature → RSM surface → optimum.
- **Blocking** isolates nuisance variation; **confounding** mixes effects in fractional designs (check resolution).

15. Common Confusions

- **Screening vs optimisation:** screening asks "which factors matter?"; optimisation asks "what are the best settings?" — different questions, different designs.
- **Factorial vs CCD:** a plain factorial cannot see curvature; the CCD's star points exist precisely to detect it.
- **Blocking vs randomisation:** randomisation spreads unknown variation evenly; blocking deliberately isolates a *known* nuisance source.
- **Abstract vs conclusion:** the abstract summarises the whole work; the conclusion only states the take-home message.

16. Common Mistakes

- **Optimising all 7 factors at once** instead of screening first — wasted runs.
- **Running a CCD without centre repeats,** losing the noise estimate.
- **Copying methods text** from a paper without quotation or citation (plagiarism in the easiest section to write originally).

- **Reference-list entries that do not match** in-text citations.
- **Submitting to the first journal that emails an invitation** — the classic predatory trap.

17. Mnemonics

- **"IMRaD = I Met Real Doctors": I**ntroduction, **M**ethods, **R**esults, **a**nd **D**iscussion.
- **"Screen the crowd, climb the peak":** Plackett–Burman screens the crowd; simplex climbs the peak.
- **"Block the clock":** block anything that changes with time — days, shifts, analysts.
- **"C-C-D = Corners, Cross-stars, Duplicates (centre)"** — the three parts of a central composite design.

18. Exam Summary

A scientific report follows IMRaD — Introduction (why), Methods (repeatable how), Results (facts), Discussion (meaning) — plus title, abstract (written last), conclusion, references. Plagiarism = any uncredited use of words, ideas, figures, or data (including self-plagiarism); paraphrase fully, quote exactly, cite always. Styles: author–date, numbered, footnote — one applied consistently. Journals: scope, genuine peer review, indexing, ethics; avoid predators. Databases: search before research, be indexed after. Screening (Plackett–Burman — many factors, few runs) finds the vital few; optimisation (factorial, CCD + star points + RSM, simplex, D-optimal) finds the optimum. Blocking isolates nuisance variation; confounding mixes effects in fractional designs (check resolution).

19. One-Minute Revision

IMRaD: why → how → what → so what; abstract last. Plagiarism = uncredited use; paraphrase + cite. Styles: author–date, numbered, footnote. Journals: scope, peer review, indexing; dodge predators. Screen (vital few) → optimise (peak). Block nuisances; watch confounding. 2^2: effects = high − low averages; interaction = diagonal difference.

20. Questions

Short-answer:

1 List the sections of a scientific report and state each section's purpose in one line.

2 Define plagiarism and name four types.

3 Distinguish the author–date and numbered referencing systems.

4 Give four criteria for selecting a research journal.

5 What is the purpose of an abstracting service?

6 Distinguish screening from optimisation with one design example each.

7 What are star points in a CCD? Why are they added?

8 Define blocking and confounding with one example each.

Long-answer:

1 Describe the IMRaD structure of a scientific report, explaining what belongs in each section.

2 Explain plagiarism: types, consequences, and five practical ways to avoid it.

3 Describe the Plackett–Burman, factorial, D-optimal, sequential simplex, and central composite designs; state when each is used.

4 Explain response surface methodology: the model, the contour plot, and how the optimum is found and confirmed.

5 Explain blocking and confounding in experimental designs with pharmacy examples.

MCQs (answer key below):

1 IMRaD stands for: (a) Index, Methods, Results, Data (b) Introduction, Methods, Results, Discussion (c) Idea, Material, Reading, Draft (d) Issue, Model, Report, Decision

2 The abstract is written: (a) first (b) last (c) never (d) by the editor

3 Reusing your own published text without disclosure is: (a) fine (b) self-plagiarism (c) a citation (d) fair use

4 A numbered citation system shows: (a) (Sharma, 2021) (b) [3] (c) footnotes only (d) full titles

5 A predatory journal is recognised by: (a) slow review (b) guaranteed fast acceptance for fees (c) an editorial board (d) indexing

6 Screening designs aim to: (a) find optima (b) find the vital few factors (c) fit curved surfaces (d) maximise runs

7 Plackett–Burman with 12 runs can screen up to: (a) 5 (b) 7 (c) 11 (d) 12 factors

8 Star points in a CCD detect: (a) outliers (b) curvature (c) plagiarism (d) blocks

9 The sequential simplex moves by: (a) random jumps (b) reflecting the worst vertex (c) fitting equations (d) blocking

10 Blocking is used to: (a) increase factors (b) isolate nuisance variation (c) confound effects (d) reduce α

Answer key: 1-b, 2-b, 3-b, 4-b, 5-b, 6-b, 7-c, 8-b, 9-b, 10-b.

Viva questions:

1 Why must Methods be written so another lab can repeat the work?

2 You changed every third word of a copied paragraph. Plagiarism? Why?

3 When would you choose D-optimal over a central composite design?

4 Your CCD optimum predicts hardness 8.5 kg/cm^2. What do you do next?

5 In a half-fraction 2^3, what is confounded with the main effect of C?

Application-based:

1 A 2^2 experiment on disintegration time gives: (1) = 12 min, a = 8, b = 10, ab = 5 (A = disintegrant %, B = compression force). Compute both main effects and the interaction, and state which factor matters more.

2 You have 9 candidate factors for a sustained-release matrix tablet and budget for ~12 runs. Propose the screening → optimisation plan, naming the designs.

21. References

- Bolton (Pharmaceutical Statistics)
- Daniel (Biostatistics)
- Montgomery (Design and Analysis of Experiments)