SPLE Pharmaceutical Sciences notes

High-yield, original notes for the SPLE Pharmaceutical Sciences domain (35% of the exam, SCFHS blueprint Area 2.0). Every fact below carries its primary source. No sign-up, no cost.

SCFHS SPLE Applicant Guide SPLE0622, Appendix B Area 2.0 Pharmaceutical Sciences (35%): 2.4 pharmaceutics and biopharmaceutics, 2.5 pharmacokinetics, 2.6 sterile and nonsterile compounding including pharmaceutical calculations (Appendix B, guide pp.15-16).

Contents

- Pharmacokinetics rules
- Biopharmaceutics
- Dosage forms
- Compounding standards
- Stability
- Worked calculations

Pharmacokinetics rules

Blueprint 2.5. The core first-order relationships tested by the calculation questions.

Concept	Formula or rule	How it is used	Source
Elimination half-life	Half-life equals 0.693 divided by the elimination rate constant	After each half-life the amount halves: one half, one quarter, one eighth after three half-lives	Shargel, Wu-Pong and Yu, Applied Biopharmaceutics and Pharmacokinetics, 7th edition, McGraw-Hill — pharmacokinetics chapters, 2016 Fact note-ps-pk-01 · **Report a mistake**
Loading dose	Loading dose equals volume of distribution times target concentration divided by bioavailability	Used when the target level is needed quickly instead of waiting for accumulation	Shargel, Wu-Pong and Yu, Applied Biopharmaceutics and Pharmacokinetics, 7th edition, McGraw-Hill — pharmacokinetics chapters, 2016 Fact note-ps-pk-02 · **Report a mistake**
Infusion steady state	Infusion rate equals clearance times target steady-state concentration	Steady state is approached after about four to five half-lives without a loading dose	Shargel, Wu-Pong and Yu, Applied Biopharmaceutics and Pharmacokinetics, 7th edition, McGraw-Hill — pharmacokinetics chapters, 2016 Fact note-ps-pk-03 · **Report a mistake**

Concept	Formula or rule	How it is used	Source
Total clearance	After an intravenous dose, clearance equals dose divided by area under the curve	Combines all elimination routes into one flow-equivalent value	Shargel, Wu-Pong and Yu, Applied Biopharmaceutics and Pharmacokinetics, 7th edition, McGraw-Hill — pharmacokinetics chapters, 2016 Fact note-ps-pk-04 · **Report a mistake**
Volume of distribution	Volume equals amount in the body divided by plasma concentration	A large value signals extensive tissue distribution, not a real anatomical volume	Shargel, Wu-Pong and Yu, Applied Biopharmaceutics and Pharmacokinetics, 7th edition, McGraw-Hill — pharmacokinetics chapters, 2016 Fact note-ps-pk-05 · **Report a mistake**
Saturable metabolism	Near metabolic capacity, small dose increases cause disproportionately large level rises	Phenytoin is the classic example; check levels after small dose changes	Shargel, Wu-Pong and Yu, Applied Biopharmaceutics and Pharmacokinetics, 7th edition, McGraw-Hill — pharmacokinetics chapters, 2016 Fact note-ps-pk-06 · **Report a mistake**
Organ clearance limits	Renal loss lowers renally cleared drug clearance; high hepatic extraction clearance follows liver blood flow	Reduce dose or extend interval in renal failure; expect flow-limited changes after hepatic blood flow falls	Shargel, Wu-Pong and Yu, Applied Biopharmaceutics and Pharmacokinetics, 7th edition, McGraw-Hill — pharmacokinetics chapters, 2016 Fact note-ps-pk-07 · **Report a mistake**
Protein binding	Low albumin raises the free fraction of highly bound drugs	Interpret free levels where available; a low total level can still be active or toxic	Shargel, Wu-Pong and Yu, Applied Biopharmaceutics and Pharmacokinetics, 7th edition, McGraw-Hill — pharmacokinetics chapters, 2016 Fact note-ps-pk-08 · **Report a mistake**

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Biopharmaceutics

Blueprint 2.4 and 2.5.2. Why a dosage form does or does not deliver drug to the circulation.

Concept	Principle	Practical consequence	Source
Bioequivalence interval	The 90 percent confidence interval for area under the curve and peak concentration ratios must lie within 80.00 to 125.00 percent	The standard acceptance test for a generic oral product against its reference	FDA, Guidance for Industry: Bioavailability and Bioequivalence Studies for Orally Administered Drug Products — General Considerations, 2003 Fact note-ps-ba-01 · **Report a mistake**
BCS Class II behaviour	Low solubility with high permeability makes dissolution the rate-limiting step	Improve wetting, particle size, or salt form before expecting faster absorption	FDA, Guidance for Industry: Waiver of In Vivo Bioavailability and Bioequivalence Studies for Immediate-Release Solid Oral Dosage Forms Based on a Biopharmaceutics Classification System, 2017 Fact note-ps-ba-02 · **Report a mistake**
Dissolution rate	Smaller particles, a suitable salt, or a more soluble polymorph raise dissolution rate	Solid-state and particle choices change onset even when the dose is identical	Aulton and Taylor, Aulton's Pharmaceutics: The Design and Manufacture of Medicines, 5th edition, Elsevier — dosage form design and stability chapters, 2018 Fact note-ps-ba-03 · **Report a mistake**

Concept	Principle	Practical consequence	Source
pH and ionisation	A weak acid is mainly unionised below its pKa and crosses lipid membranes in that form	Explains site and timing differences in oral absorption	Aulton and Taylor, Aulton's Pharmaceutics: The Design and Manufacture of Medicines, 5th edition, Elsevier — dosage form design and stability chapters, 2018 Fact note-ps-ba-04 · **Report a mistake**
Food and first-pass effects	High-fat food delays gastric emptying and the peak; sublingual dosing partly bypasses first-pass metabolism	Separate timing advice from extent-of-absorption advice when counselling	Shargel, Wu-Pong and Yu, Applied Biopharmaceutics and Pharmacokinetics, 7th edition, McGraw-Hill — pharmacokinetics chapters, 2016 Fact note-ps-ba-05 · **Report a mistake**
Absolute bioavailability	Oral area under the curve divided by intravenous area under the curve at equal doses	Quantifies the fraction reaching the systemic circulation unchanged	Shargel, Wu-Pong and Yu, Applied Biopharmaceutics and Pharmacokinetics, 7th edition, McGraw-Hill — pharmacokinetics chapters, 2016 Fact note-ps-ba-06 · **Report a mistake**

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Dosage forms

Blueprint 2.4.1 to 2.4.3. Form, release design, and the counselling or quality test that follows.

Dosage form or test	Key principle	Pharmacy action	Source
Extended-release tablets	Crushing destroys the controlled-release mechanism and risks dose dumping	Counsel swallowing whole; the cited label states the whole or half tablet must not be crushed or chewed	**DailyMed — METOPROLOL SUCCINATE TABLET, FILM COATED, EXTENDED RELEASE label, 2.4 Administration** Fact note-ps-df-01 · **Report a mistake**
Gastro-resistant tablets	The coat resists stomach acid and dissolves at intestinal pH	Protects acid-labile drugs and releases them in the small intestine	Aulton and Taylor, Aulton's Pharmaceutics: The Design and Manufacture of Medicines, 5th edition, Elsevier — dosage form design and stability chapters, 2018 Fact note-ps-df-02 · **Report a mistake**
Suspensions and emulsions	Flocculated suspensions redisperse easily; creaming is reversible but coalescence is not	Shake suspensions before use; discard an emulsion that has cracked	Aulton and Taylor, Aulton's Pharmaceutics: The Design and Manufacture of Medicines, 5th edition, Elsevier — dosage form design and stability chapters, 2018 Fact note-ps-df-03 · **Report a mistake**
Suppository bases	Fatty bases melt at body temperature; water-soluble bases dissolve in rectal fluid	Choose and store the base for its intended release behaviour	Aulton and Taylor, Aulton's Pharmaceutics: The Design and Manufacture of Medicines, 5th edition, Elsevier — dosage form design and stability chapters, 2018 Fact note-ps-df-04 · **Report a mistake**
Patches and inhalers	Patches need intact skin and site rotation; a holding chamber reduces throat deposition	Heat and broken skin raise patch absorption; a chamber helps poor inhaler coordination	Aulton and Taylor, Aulton's Pharmaceutics: The Design and Manufacture of Medicines, 5th edition, Elsevier — dosage form design and stability chapters, 2018 Fact note-ps-df-05 · **Report a mistake**

Dosage form or test	Key principle	Pharmacy action	Source
Friability testing	A rotating drum test measures tablet weight loss from abrasion and chipping	Excessive loss is a mechanical strength failure at quality control	Aulton and Taylor, Aulton's Pharmaceutics: The Design and Manufacture of Medicines, 5th edition, Elsevier — dosage form design and stability chapters, 2018 Fact note-ps-df-06 · **Report a mistake**

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Compounding standards

Blueprint 2.6. USP chapters for sterile, nonsterile, and hazardous compounding and dating.

Standard	Requirement	Why it matters	Source
USP <797> sterile compounding	Critical sites need ISO Class 5 air in the primary engineering control	Cleaner than the ISO Class 7 buffer area around it	USP <797> Pharmaceutical Compounding — Sterile Preparations, United States Pharmacopeia, revised chapter effective 1 November 2023, 2023 Fact note-ps-cx-01 · **Report a mistake**
USP <795> nonsterile dating	A nonpreserved aqueous preparation is limited to 14 days refrigerated	Preserved aqueous, nonaqueous, and solid preparations carry longer chapter limits	USP <795> Pharmaceutical Compounding — Nonsterile Preparations, United States Pharmacopeia, revised chapter effective 1 November 2023, 2023 Fact note-ps-cx-02 · **Report a mistake**
USP <800> hazardous compounding	Sterile hazardous compounding needs negative pressure and external venting with protective equipment	Contains hazardous contamination and protects staff	USP <800> Hazardous Drugs — Handling in Healthcare Settings, United States Pharmacopeia, 2020 Fact note-ps-cx-03 · **Report a mistake**
Beyond-use dating	The pharmacy assigns a beyond-use date after compounding or repackaging	It is distinct from the manufacturer expiry date on the unopened product	USP <795> Pharmaceutical Compounding — Nonsterile Preparations, United States Pharmacopeia, revised chapter effective 1 November 2023, 2023 Fact note-ps-cx-04 · **Report a mistake**

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Stability

Blueprint 2.4.4. Chemical degradation and physical instability, and how storage controls them.

Factor	Effect	Pharmacy action	Source
First-order shelf life	Time to 90 percent remaining equals 0.105 divided by the rate constant	Defines the modelled shelf life endpoint in stability studies	ICH Harmonised Guideline Q1A(R2), Stability Testing of New Drug Substances and Products, 2003 Fact note-ps-st-01 · **Report a mistake**
Hydrolysis	Reaction with water breaks	Use tight containers and	Aulton and Taylor, Aulton's Pharmaceutics: The Design

Factor	Effect	Pharmacy action	Source
	aqueous products	potency loss	dosage form design and stability chapters, 2018 Fact note-ps-st-02 · **Report a mistake**
Temperature effect	Reaction rates rise with temperature under the Arrhenius relationship	Controlled cool storage slows degradation; heat accelerates it	ICH Harmonised Guideline Q1A(R2), Stability Testing of New Drug Substances and Products, 2003 Fact note-ps-st-03 · **Report a mistake**
Photodegradation	Light breaks down photosensitive medicines	Dispense and store in light-resistant amber containers	ICH Harmonised Guideline Q1A(R2), Stability Testing of New Drug Substances and Products, 2003 Fact note-ps-st-04 · **Report a mistake**
Emulsion cracking	Freezing can coalesce droplets into free oil that shaking cannot recombine	Discard a cracked emulsion; do not shake, warm, or dilute it back into use	Aulton and Taylor, Aulton's Pharmaceutics: The Design and Manufacture of Medicines, 5th edition, Elsevier — dosage form design and stability chapters, 2018 Fact note-ps-st-05 · **Report a mistake**

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Worked calculations

Blueprint 2.6.3. Three worked examples. Do each step yourself before reading the answer.

note-ps-calc-01

1. Alligation — mix 10 percent and 2 percent creams to make a 6 percent cream.
2. Parts of high strength equal 6 minus 2, which is 4. Parts of low strength equal 10 minus 6, which is 4.
3. Answer: mix four parts of each cream, a one to one ratio, to obtain the 6 percent target.

Source: Ansel and Stockton, Pharmaceutical Calculations, 15th edition, Wolters Kluwer — percentage, alligation and flow-rate chapters, 2017 · Fact note-ps-calc-01 · **Report a mistake**

note-ps-calc-02

1. Percentage strength — prepare 240 millilitres of a 0.5 percent weight in volume solution.
2. 0.5 percent means 0.5 grams in each 100 millilitres, so multiply 0.5 by 240 divided by 100, which is 2.4.
3. Answer: weigh 1.2 grams of powder and make the final volume up to 240 millilitres.

Source: Ansel and Stockton, Pharmaceutical Calculations, 15th edition, Wolters Kluwer — percentage, alligation and flow-rate chapters, 2017 · Fact note-ps-calc-02 · **Report a mistake**

note-ps-calc-03

2. Rate equals volume divided by time, so divide 1000 millilitres by 8 hours.
3. Answer: set the pump to 125 millilitres per hour and check the total volume again at handover.

Source: Ansel and Stockton, Pharmaceutical Calculations, 15th edition, Wolters Kluwer — percentage, alligation and flow-rate chapters, 2017 · Fact note-ps-calc-03 · **Report a mistake**

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