

## Part I

Topic	Primary text	Supplement with
Pharmacokinetics	Goodman and Gilman <sup>1</sup> (Chapters 2 & 6)	
Pharmacodynamics	Goodman and Gilman <sup>1</sup> (Chapters 3, 4, 5)	
Drug interactions	Stockley <sup>2</sup> (Chapter 1)	Katzung <sup>3</sup>
Pharmacogenetics	Goodman and Gilman <sup>1</sup> (Chapter 7)	Katzung <sup>3</sup>
Commonly used medicines	SAMF <sup>4</sup> EML <sup>5</sup>	Katzung <sup>3</sup>
Drug hypersensitivity	Goodman and Gilman <sup>1</sup> (Chapter 34)	
Pharmacoeconomics	Walley <sup>6</sup> (Chapters 7 – 8)	Module Course at local institution
Drug discovery, pre-clinical evaluation and clinical development	Katzung <sup>3</sup> (Chapter 1)  EMA guidelines ( <a href="https://www.ema.europa.eu/en/strategies-identify-mitigate-risks-first-human-early-clinical-trials-investigational-medicinal">https://www.ema.europa.eu/en/strategies-identify-mitigate-risks-first-human-early-clinical-trials-investigational-medicinal</a> <a href="https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-investigation-drug-interactions-revision-1_en.pdf">https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-investigation-drug-interactions-revision-1_en.pdf</a> )	Goodman and Gilman <sup>1</sup> (Chapter 1) Griffin <sup>11</sup> ICH E8 <sup>13</sup>
Evidence-based medicine	Grimes and Schulz <sup>7</sup>	
Biostatistics	Harris <sup>8</sup>	Kirkwood and Stern <sup>9</sup>
Pharmacovigilance and pharmaco-epidemiology	Strom <sup>10</sup> (Chapters 1, 2,13)	WHO: World Health Organization. (2002). The importance of pharmacovigilance. World Health

		Organization. [https://apps.who.int/iris/handle/10665/42493]
Ethical principles	Moodley <sup>12</sup> (Relevant chapters to be selected by the candidate based on competency of the topic)	SA GCP guidelines <sup>14</sup> , Griffin <sup>11</sup> , (Chapter 32) ( <i>Griffin highlights UK-based regulation and ethical principles related to medicinal products; whereas SA GCP highlights research ethical principles in line with ICH guidelines</i> )
Dispensing, pharmaceutical laws and drug regulation	Katzung <sup>3</sup>	SAHPRA regulations

<sup>1</sup> Laurence L. Brunton, Randa Hilal-Dandan, Björn C. Knollmann. Goodman & Gilman's: The Pharmacological Basis of Therapeutics. Latest edition, McGraw-Hill.

<sup>2</sup> Ivan H. Stockley (edited by K. Baxter or C. Preston) Stockley's Drug Interactions: A source book of interactions, their mechanisms, clinical importance and management. Latest edition, Pharmaceutical Press

<sup>3</sup> Katzung, BG. Basic & Clinical Pharmacology. Latest edition. Lange **\*Core text\***

<sup>4</sup> South African Medicines Formulary (SAMF). Latest edition

<sup>5</sup> The Essential Medicines List - South Africa, Latest edition

<sup>6</sup> Walley T et al. Pharmacoeconomics. Latest edition, Churchill Livingstone

<sup>7</sup> David A. Grimes and Kenneth F. Schulz. The Lancet Handbook of Essential Concepts in Clinical Research. Elsevier

(Accessible from: <https://www.thelancet.com/series/epidemiology-2002> and <https://www.thelancet.com/series/epidemiology>)

<sup>8</sup> Harris M, Medical Statistics Made Easy, Latest edition, Taylor & Francis

<sup>9</sup> Kirkwood and Stern, Medical Statistics. Latest edition, Wiley

<sup>10</sup> Strom BL. Pharmacoepidemiology. Latest edition. Wiley

<sup>11</sup> Griffin, JP. Textbook of Pharmaceutical Medicine, 7<sup>th</sup> edition, Wiley

<sup>12</sup> Moodley K. Medical Ethics, Law and Human Rights: A South African Perspective. Latest edition, Van Schaik

<sup>13</sup> ICH E8 - General Considerations for Clinical Trials (Available from: [https://database.ich.org/sites/default/files/E8\\_Guideline.pdf](https://database.ich.org/sites/default/files/E8_Guideline.pdf))

<sup>14</sup> Department of Health Ethics in Health Research: Principles, Processes and Structures, 2<sup>nd</sup> edition, DoH

## Part II

Topic	Primary text	Supplement with
Rational use of all major therapeutic classes	Katzung <sup>3</sup>	SAMF <sup>4</sup> EML <sup>5</sup> Goodman and Gilman <sup>1</sup>
Special risk populations	SAMF <sup>4</sup> (pages 1 – 28): Prescribing in special populations	Katzung <sup>3</sup>
TDM	Portfolio of Learning	Journal articles
Complementary and traditional medicines / natural medicinal products	No comprehensive text currently available. Sparse data for CAMs exist, but the following CAMs currently have the most admissible evidence-base: -Cannabis -St John's wort -Gingko biloba -Rooibos tea (Aspalathlis Linearis) -African potato (Hypoxis hemerocallidea) -Aloe ferox -Echinacea -Kava -Artemisia	The top ten common medicinal plants <sup>16</sup> Street <sup>17</sup> Van Rensburg <sup>18</sup> The use of nonpharmaceutical forms of Artemisia <sup>19</sup>
Poisoning	SAMF <sup>4</sup> (pages 616 – 642)	Katzung <sup>3</sup> Afrifox
Drugs of abuse	SAMF <sup>4</sup> (pages 635 – 639)	Katzung <sup>3</sup> Afrifox
Drug discovery, evaluation and development	Katzung <sup>3</sup> (Chapter 1) EMA guidelines	The Evolution of Master Protocol Clinical Trial Designs: A Systematic Literature Review, Meyer. EL, 2020

	( <a href="https://www.ema.europa.eu/en/strategies-identify-mitigate-risks-first-human-early-clinical-trials-investigational-medicinal">https://www.ema.europa.eu/en/strategies-identify-mitigate-risks-first-human-early-clinical-trials-investigational-medicinal</a> <a href="https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-investigation-drug-interactions-revision-1_en.pdf">https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-investigation-drug-interactions-revision-1_en.pdf</a> )  ICH E8 <sup>15</sup>	( <a href="https://www.sciencedirect.com/science/article/pii/S0149291820302447">https://www.sciencedirect.com/science/article/pii/S0149291820302447</a> ) Griffin <sup>11</sup> (Chapter 7)
Medico-legal and regulatory aspects	Moodley <sup>12</sup> SAHPRA website (Examples: Clinical Trial Participant Time, Inconveniences and Expenses (TIE) Compensation Model; Post Clinical Trial Access)	Muller <sup>13</sup> , Section 4: chapter 23 (Biosimilars)
Adverse events	Portfolio of Learning SAHPRA website (Examples: Safety Reporting During Clinical Trials)	Strom <sup>10</sup> (Chapter 2, chapter 13)
Clinical patient care	Katzung <sup>3</sup> Portfolio of Learning	SAMF <sup>4</sup> EML <sup>5</sup> Toy <sup>14</sup>

<sup>1</sup> Laurence L. Brunton, Randa Hilal-Dandan, Björn C. Knollmann. Goodman & Gilman's: The Pharmacological Basis of Therapeutics. Latest edition, McGraw-Hill.

<sup>2</sup> Ivan H Stockley (edited by K. Baxter or C. Preston) Stockley's Drug Interactions: A source book of interactions, their mechanisms, clinical importance and management. Latest edition, Pharmaceutical Press

<sup>3</sup> Katzung, BG. Basic & Clinical Pharmacology. Latest edition. Lange **\*Core text\***

<sup>4</sup> South African Medicines Formulary (SAMF). Latest edition

<sup>5</sup> The Essential Medicines List - South Africa, Latest edition

<sup>6</sup> Walley T et al. Pharmacoeconomics. Latest edition, Churchill Livingstone

- <sup>7</sup> David A. Grimes and Kenneth F. Schulz. The Lancet Handbook of Essential Concepts in Clinical Research. Elsevier
- <sup>8</sup> Harris M, Medical Statistics Made Easy. Latest edition, Taylor & Francis
- <sup>9</sup> Kirkwood and Stern, Medical Statistics. Latest edition, Wiley
- <sup>10</sup> Strom BL. Pharmacoepidemiology. Latest edition. Wiley
- <sup>11</sup> Griffin, JP. Textbook of Pharmaceutical Medicine, 7<sup>th</sup> edition, Wiley
- <sup>12</sup> Moodley K, Medical Ethics, Law and Human Rights: A South African Perspective. Latest edition, Van Schaik
- <sup>13</sup> Muller, M. Clinical Pharmacology: Current Topics and Case Studies. 2010
- <sup>14</sup> Eugene C. Toy; David S. Loose; Shelley A. Tischkau; Anush S. Pillai. Case Files: Pharmacology (3<sup>rd</sup> edition). McGraw-Hill/ LANGE (56 Cases).
- <sup>15</sup> ICH E8 - General Considerations for Clinical Trials (Available from: [https://database.ich.org/sites/default/files/E8\\_Guideline.pdf](https://database.ich.org/sites/default/files/E8_Guideline.pdf))
- <sup>16</sup> The top ten common medicinal plants document
- <sup>17</sup> Street RA, Prinsloo G. Commercially Important Medicinal Plants of South Africa: A Review. Journal of Chemistry, 2013. Available from: <https://doi.org/10.1155/2013/205048>
- <sup>18</sup> Van Rensburg R, Pillay-Fuentes Lorente V, Blockman M, et al. Medical cannabis: What practitioners need to know. SAMJ. 2020 Mar;110(3):192-6. Available from: <http://dx.doi.org/10.7196/samj.2020.v110i3.14403>
- <sup>19</sup> World Health Organization. The use of nonpharmaceutical forms of Artemisia. WHO, Geneva, 2019. Available from: <https://www.who.int/publications/i/item/the-use-of-non-pharmaceutical-forms-of-artemisia>