

# **CONTENTS**

<i>Preface</i> .....	(vii)
<i>Acknowledgements</i> .....	(ix)

## **CHAPTER 1**

<b>Introduction to Research and Bio-statistics in Pharmaceuticals.....</b>	<b>1</b>
--	----------

## **CHAPTER 2**

### **Information Sources**

2.0    Introduction .....	3
2.1    Primary Sources.....	3
2.2    Secondary Sources.....	4

## **CHAPTER 3**

### **Literature Search**

3.0    Introduction .....	7
3.1    Type of Index as Volumes.....	8
A.       Dictionary of Organic Compounds.....	8
i.      Name Index .....	8
ii.     CAS Registry Number Index .....	9
iii.    Molecular Formula Index.....	9
B.       Chemical Abstract Services (CAS).....	9
i.      Name Index .....	9
ii.     Chemical Substance Index .....	9
iii.    Molecular Formula Index.....	10
iv.    Patent Index.....	10
v.     General Subject Index.....	11
vi.    Abstract Index .....	13
vii.   Author Index .....	14
viii. Ring Systems .....	14

## **CHAPTER 4**

### **Meta-Analysis**

4.0	Introduction .....	15
4.1	Limitations of Meta-Analysis .....	17
4.2	Advantages of Meta-Analysis.....	17
4.3	Disadvantages of Meta-Analysis .....	17
4.4	Case Studies.....	17
4.5	Steps/Criteria for Meta-Analysis .....	20

## **CHAPTER 5**

### **Distinguishing Research Proposal, Research Report, Research Paper, Patent Document and Synopsis**

5.0	Introduction .....	21
5.1	Research Proposal.....	22
5.2	Research Report.....	22
5.3	Research Paper.....	23
5.4	Patent Document.....	23
5.5	Synopsis.....	24

## **CHAPTER 6**

### **Detailed Contents of a Research Paper**

6.0	Introduction .....	29
6.1	Title.....	30
6.2	Author Names.....	30
6.3	Abstract.....	30
6.4	Keywords.....	31
6.5	Introduction .....	31
6.6	Materials and Methodology .....	32
6.7	Procedure .....	32
6.8	Results .....	32
6.9	Discussion.....	33
6.10	Conclusion .....	33

6.11	Acknowledgements.....	33
6.12	References (Bibliography).....	33
6.13	Errata .....	34
6.14	Spell Check.....	35
6.15	Foot Notes.....	35
6.16	Plagiarism .....	35

## CHAPTER 7

### Clinical Trials and Clinical Study Design

7.0	Introduction to Clinical Trials .....	37
7.1	Classification of Clinical Study Design.....	37
7.1.1	Type A Design .....	38
i.	Case Study Design .....	38
ii.	Observational Study Design.....	38
a.	Case-Control Study Design.....	39
b.	Cross-Sectional Study Design .....	40
c.	Longitudinal Study Design.....	41
d.	Cohort Study Design .....	41
i.	Prospective Cohort Study .....	41
ii.	Retrospective Cohort Study.....	42
e.	Ecological Study Design .....	43
iii.	Interventional Study Design.....	44
7.1.2	Type B Design .....	44
i.	Treatment Study Design.....	44
ii.	Preventive Study Design .....	44
iii.	Diagnostic Study Design.....	44
iv.	Screening Study Design .....	45
v.	Quality of Life Study Design .....	45
7.1.3	Type C Design .....	45
i.	Treatment Study Design.....	45
a.	Randomized Controlled Trials .....	45
i.	Blind Trials.....	45
ii.	Non-blind Trials .....	46
b.	Adaptive Clinical Trials .....	46
c.	Non-randomized Trials.....	46

ii.	Observational Study Design.....	46
a.	Case-Control Study .....	46
i.	Nested Case-Control Study (NCC).....	46
b.	Cross-Sectional Study .....	47
i.	Community Survey Study .....	47
c.	Cohort Study .....	47
i.	Prospective Cohort Study .....	47
ii.	Retrospective Cohort Study.....	47
iii.	Time Series Study.....	47
1.	Long Term Time Series .....	47
2.	Short Term Time Series .....	47
a.	Cyclic trend .....	47
b.	Seasonal trend .....	48
c.	Irregular trend (random trend).....	48
iii.	Seasonal Study Design.....	52
iv.	Longitudinal Study.....	52

## CHAPTER 8

### **Principles of Experimental Designs**

8.0	Introduction .....	53
8.1	Types of Principles .....	53
i.	Principle of Replication .....	53
ii.	Principle of Randomization .....	54
iii.	Principle of Local Control.....	54
8.2	Types of Experimental Designs.....	54
i.	Informal Experimental Designs .....	54
a.	Before and after without control design .....	54
b.	After only with control design.....	55
c.	Before and after with control design .....	55
ii.	Formal Experimental Designs.....	55
a.	Completely randomized design .....	55
i.	Two group sample randomized experimental design .....	55
ii.	Random replication design .....	55
b.	Randomized block design .....	55
c.	Latin square design.....	56
d.	Factorial design .....	56

8.3	Experimental Planning of a Factorial Design.....	59
8.4	Hand Analysis of Factorial Experiments (Method of Yates).....	61

**CHAPTER 9****Need of Sampling and Sampling Techniques**

9.0	Introduction .....	63
9.1	Types of Sampling Techniques.....	63
i.	Non-probability sampling technique.....	63
ii.	Probability sampling techniques .....	64
i.	Simple random sampling.....	64
ii.	Complex random sampling .....	64
a.	Systematic complex random sampling .....	64
b.	Stratified complex random sampling.....	65
c.	Cluster type complex random sampling .....	65
d.	Multi-stage sampling .....	66
e.	Sampling with probability proportional to size .....	66
f.	Sequential sampling.....	68

**CHAPTER 10****Measurement and Scaling**

10.0	Introduction .....	69
10.1	Classification of Measurement Scales .....	69
i.	Nominal Scale.....	69
ii.	Ordinal Scale.....	69
iii.	Interval Scale .....	70
iv.	Ratio Scale .....	70
10.2	Salient Features of Measurement Scales .....	70
i.	Validity .....	70
ii.	Reliability.....	70
iii.	Practicality .....	70
iv.	Accuracy .....	70
10.3	Designing of Measurement Scales.....	71
10.4	Basis for Design of Measurement Scales .....	73
i.	Subject Orientation .....	73
ii.	Response Form.....	74

iii.	Degree of Subjectivity .....	74
iv.	Scale Properties.....	74
v.	Number of Dimensions .....	74
vi.	Contribution of Scale Techniques.....	74
a.	Arbitrary approach.....	74
b.	Consensus approach .....	74
c.	Item analysis approach .....	74
d.	Cumulative approach.....	74
e.	Factor approach .....	74

## **CHAPTER 11**

### **Scaling Techniques**

11.0	Introduction .....	77
11.1	Classification of Scaling Techniques.....	77
i.	Comparison Scaling .....	77
a.	Paired comparison .....	77
b.	Rank order .....	77
c.	Constant sum .....	78
ii.	Non-Comparison Scaling.....	78
a.	Continuous rating or graphical rating.....	78
b.	Itemized rating.....	78
1.	Likert scale .....	78
2.	Semantic differential scale.....	79
3.	Stapel scale .....	79
c.	Simple/multiple category scale .....	80
d.	Verbal frequency scale .....	80
iii.	Multi-dimensional Scaling.....	81

## **CHAPTER 12**

### **Introduction to Presentation of Data and Missing Data**

12.1	Presentation of Data.....	83
12.2	Missing Data.....	92

## **CHAPTER 13**

### **Probability, Permutations and Combinations**

13.0	Introduction .....	93
13.1	Probability .....	93
13.2	Permutations and Combinations .....	95

**CHAPTER 14****Statistics, Bio-statistics and their Relation to Distribution Trends**

14.0	Introduction .....	97
14.1	Bernoulli Distribution.....	99
14.2	Chebyshev's Theorem .....	99
14.3	Binomial Distribution .....	100
14.4	Poisson Distribution.....	106
14.5	Gaussian or Normal Distribution.....	109

**CHAPTER 15****Measures of Central Tendency and Variability**

15.0	Introduction .....	113
15.1	Measures of Central Tendency .....	113
15.1.1	Un-grouped.....	113
A.	Mean .....	113
B.	Median.....	114
C.	Mode.....	114
15.1.2	Grouped.....	114
A.	Mean .....	114
B.	Median.....	114
C.	Mode.....	115
15.2	Measures of Variability .....	115
A.	Range .....	115
B.	Deviation from the Mean .....	115
C.	Sum of Squared Deviations and Mean Square Deviation .....	116
D.	Variance .....	117
E.	Standard Deviation.....	117
F.	Coefficient of Variation .....	117

## **CHAPTER 16**

### **Standard Error, Confidence Level/Confidence Interval/Confidence Limits, Statistical Errors, Hypothesis**

16.1	Standard Error.....	127
16.2	Estimation of Confidence Level/Confidence Interval/ Confidence Limits .....	129
16.3	Application of Confidence Level/Confidence Interval/ Confidence Limits in Pharmaceuticals .....	129
16.4	Statistical Errors.....	132
16.5	Hypothesis and Steps involved in Statistical Analysis .....	138

## **CHAPTER 17**

### **Student ‘t’ Distribution and its Applications**

17.0	Introduction .....	141
17.1	Un-paired ‘t’ Test .....	142
17.2	Paired ‘t’ Test .....	144

## **CHAPTER 18**

### **Chi-square Distribution .....147**

## **CHAPTER 19**

### **F-Distribution (Variance Ratio) and ANOVA**

19.0	Introduction .....	151
19.1	F-Distribution .....	151
19.2	Analysis of Variance or ANOVA .....	152
19.2.1	One-way ANOVA.....	153
19.2.1.1	Multiple Comparisons .....	156
19.2.2	Two-way ANOVA .....	159
19.2.3	Crossover ANOVA Design.....	161
19.2.4	Three-way ANOVA .....	164

**CHAPTER 20****Non-Parametric Statistical Tests**

20.0	Introduction .....	171
20.1	Runs Test for Randomness .....	171
20.2	Sign Test.....	174
20.3	Signed Rank Test (also called as Wilcoxon Signed Rank Test).....	178
20.4	Rank Sum Test (Wilcoxon Rank Sum Test or Mann-Whitney U Test or Mann-Whitney-Wilcoxon Test or Wilcoxon-Mann-Whitney Test) .....	181
20.5	Non-Parametric One-way ANOVA (or Kruskal-Wallis Test).....	183
20.6	Friedman Test (A Non-Parametric Two-way ANOVA) .....	186

**CHAPTER 21****Sample Size Determination**

21.0	Introduction .....	189
21.1	Based on Past Experimental Data.....	189
21.2	Based on Theoretical Assumptions and No Past Reported Data .....	189
21.3	Online Version of Sample Size Calculator .....	192

**CHAPTER 22****Introduction to Epidemiology**

22.0	Introduction .....	195
22.1	Incidence.....	196
22.2	Incidence Proportion.....	196
22.3	Incidence Rate .....	196
22.4	Prevalence.....	197
22.5	Other Terminology .....	197

**CHAPTER 23****Introduction to SAS, SPSS, Epi Info and Minitab**

23.0	Introduction .....	199
23.1	Statistics Analysis Systems (SAS).....	199
23.1.1	Introduction .....	199

23.1.2	Mission .....	199
23.1.3	Products Provided by SAS .....	200
23.1.4	Application of the SAS Software .....	203
23.2	Statistical Package for Social Sciences (SPSS) .....	204
23.2.1	Introduction .....	204
23.2.2	Products.....	204
23.2.3	IBM SPSS Statistics Editions.....	206
23.2.3.1	SPSS Statistics standard edition capabilities.....	206
23.2.3.2	SPSS Statistics professional edition capabilities....	208
23.2.3.3	SPSS Statistics premium edition capabilities.....	210
23.2.4	About IBM Business Analytics .....	215
23.3	Epi Info .....	215
23.3.1	Introduction to CDC (Centers for Disease Control and Prevention).....	215
23.3.2	Role of CDC.....	215
23.3.3	Strategies of CDC.....	216
23.4	Minitab.....	223

## **CHAPTER 24**

Applications of SPSS, Epi Info and Minitab Softwares (Screen Shots) .....	225
--	-----

## **CHAPTER 25**

### **Linear Regression, Correlation and Correlation Coefficient**

25.0	Introduction .....	245
25.1	Linear Regression .....	245
25.2	Correlation .....	254
25.3	Correlation Coefficient .....	254
25.4	Establishing a Multiple Regression Analysis .....	256
25.4.1	Multi-linear Regression Analysis (Mathematical and Excel Calculations) .....	257

## **CHAPTER 26**

### **Inventory Control**

26.0	Introduction .....	265
------	--------------------	-----

26.1	Objectives .....	265
26.2	Methods of Establishing Inventory Control.....	265
i.	Always Better Control (ABC) Analysis.....	265
ii.	Economic Order Quantity (EOQ) .....	266
a.	Tabular method .....	266
b.	Graphical method .....	266
c.	Arithmetic method.....	267
iii.	Perpetual Inventory System .....	268
a.	Bin card method .....	268
b.	Store ledger method .....	268
c.	Continuous stock monitoring method .....	269
iv.	Review of Slow and Non-moving Items.....	269
a.	Periodic report.....	269
b.	Obsolete items .....	269
c.	Moving ratios .....	269
v.	Input-Output Ratio Analysis Method.....	269
vi.	Setting up of Various Levels.....	270
a.	Maximum stock level.....	270
b.	Minimum stock level (buffer stock level or safety stock level). .....	270
c.	Re-Order level.....	271
d.	Danger level .....	271
vii.	Material Budgeting .....	271
viii.	Establishing Effective Purchase Procedures .....	271
ix.	Scrap and Surplus Disposal.....	271
x.	VED Analysis (Vital, Essential, Desirable analysis) .....	272

## CHAPTER 27

### Accountancy and Book Keeping

27.0	Introduction .....	273
27.1	Types of Accounts .....	274
27.2	Types of Entry .....	275
27.3	Anatomy of a Journal.....	276
27.4	Rules for Journal Entries .....	276
27.5	Procedure for Making Entries in the Account Books (Journal).....	277
27.6	Posting of Ledger.....	282

**CHAPTER 28****Management Report**

28.0	Introduction .....	287
28.1	Objectives .....	287
28.2	Essentials of a Good Management Reporting System.....	287
28.3	Classification of Management Reporting .....	288
	I. According to Objects .....	288
	A. External Reports.....	288
	B. Internal Reports .....	288
	II. According to Period .....	288
	III. According to Functions.....	288
	A. Operating Reports .....	288
	i. Control Reports.....	288
	ii. Information Reports.....	288
	iii. Venture Measurement Reports .....	288
	B. Financial Reports.....	288
	i. Static Reports.....	288
	ii. Dynamic Reports .....	288
28.4	Structure of External Management Report .....	290

**CHAPTER 29****Role of Computers in Healthcare System**

29.0	Introduction .....	293
29.1	Role of Computers in Hospitals.....	293
29.2	Role of Computers in Inventory Control .....	294
29.3	Role of Computers in Pharmacy .....	294
29.4	Role of Computers for Diagnosis and Treatment .....	295
29.5	Role of Computers in Patient Record Database Management.....	295
29.6	Role of Computers in Literature Retrieval .....	295

**CHAPTER 30**

<b>Parenterals Admixture .....</b>	<b>297</b>
------------------------------------	------------

**Annexures**

<b>I. Standard Statistical Tables.....</b>	<b>299</b>
<b>II. SF-36v2® Health Survey Measurement Model.....</b>	<b>313</b>
<b>III. The RAND 36-Item Health Survey.....</b>	<b>315</b>
<b><i>Question Bank</i> (for Theory, Practical and Viva-voce).....</b>	<b>323</b>