Contents

Preta	ace	(v)		
	Section 1: Herbal Products and Regulations			
1.	Overview on Herbal Product Regulations: Challenges and Solution	3		
	Section 2: Herbs and Derived Products			
2.	Extraction, Purification, Preliminary Phytochemical Screening and Structural Elucidation of Natural Products	19		
3.	Herbal Formulations: Traditional, Conventional and NDDS	53		
4.	Herbal Cosmetics and Regulations	90		
5.	Nutraceuticals and Regulations	143		
6.	Labeling and Packaging of Herbal Products	163		
Section 3: Traditional Medicines Regulations				
7.	Indian Systems of Medicines, Regulations and Related Guidelines	173		
8.	WHO - General Guidelines for Methodologies on Research and Evaluation of Traditional Medicine 2000	193		
9.	Drug & Cosmetic Act, 1940-Schedule T Good Manufacturing Practice of Indian Systems of Medicine	200		
Section 4: Quality Control, Standarisation, Regulations for Herbal Products				
10.	WHO Good Agricultural and Collection Practices [GAP, GCP, GACP] 2003	217		
11.	NMPB Guidelines and Standard for Good Field Collection Practices for Indian Medicinal Plants 2009	224		

viii	Contents

12.	WHO Guidelines on Good Herbal Processing Practice for Herbal Medicine 2018	236			
13.	WHO Good Storage and Distribution Practices 2019	252			
14.	Herbal Monograph, Pharmacopoeias, Markers	258			
15.	WHO Guidelines for Selecting Marker Substances of				
	Herbal Origin for Quality Control of Herbal Medicines 2017	275			
16.	WHO and ICH Guidelines of Quality Control Herbal Materials	286			
17.	Stability Testing and Shelf Life Determination of Herbal Medicines	332			
Section 5: Pre-clinical and Toxicity Regulations for Herbal Products					
18.	CPCSEA and OECD Guidelines for Animal Experimentation	353			
19.	Human Dose Calculation Guidelines	368			
20.	WHO Guidelines for Assessment, Evaluation of Toxicity,				
	Safety and Efficacy of Herbal Medicines 2000	393			
21.	General Guidelines for Safety/Toxicity Evaluation of				
	Ayurvedic Formulations 2018	405			
Section 6: Pharmacovigilance and Clinical Trial Regulations for Herbal Products					
	<u> </u>				
22.	<u> </u>				
22.	Clinical Trial Regulations for Herbal Products	417			
	Clinical Trial Regulations for Herbal Products WHO Guidelines on Safety Monitoring of Herbal Medicines in	417			
23.	Clinical Trial Regulations for Herbal Products WHO Guidelines on Safety Monitoring of Herbal Medicines in Pharmacovigilance Systems 2004				
23. 24.	Clinical Trial Regulations for Herbal Products WHO Guidelines on Safety Monitoring of Herbal Medicines in Pharmacovigilance Systems 2004 Fundamentals of Clinical Trials and Phases of Trials	429			
23.24.25.	Clinical Trial Regulations for Herbal Products WHO Guidelines on Safety Monitoring of Herbal Medicines in Pharmacovigilance Systems 2004 Fundamentals of Clinical Trials and Phases of Trials AYUSH Guidelines of Good Clinical Practices 2018	429 466			
23.24.25.26.	Clinical Trial Regulations for Herbal Products WHO Guidelines on Safety Monitoring of Herbal Medicines in Pharmacovigilance Systems 2004 Fundamentals of Clinical Trials and Phases of Trials AYUSH Guidelines of Good Clinical Practices 2018 CDSCO Guidelines of Good Clinical Practices 2013	429 466 471			
23.24.25.26.	Clinical Trial Regulations for Herbal Products WHO Guidelines on Safety Monitoring of Herbal Medicines in Pharmacovigilance Systems 2004 Fundamentals of Clinical Trials and Phases of Trials AYUSH Guidelines of Good Clinical Practices 2018 CDSCO Guidelines of Good Clinical Practices 2013 Ethical Principles for Clinical Trials	429 466 471 484			
23.24.25.26.27.	Clinical Trial Regulations for Herbal Products WHO Guidelines on Safety Monitoring of Herbal Medicines in Pharmacovigilance Systems 2004 Fundamentals of Clinical Trials and Phases of Trials AYUSH Guidelines of Good Clinical Practices 2018 CDSCO Guidelines of Good Clinical Practices 2013 Ethical Principles for Clinical Trials ICH Guidelines of Good Clinical Practices 2016	429 466 471 484			
23.24.25.26.27.	Clinical Trial Regulations for Herbal Products WHO Guidelines on Safety Monitoring of Herbal Medicines in Pharmacovigilance Systems 2004 Fundamentals of Clinical Trials and Phases of Trials AYUSH Guidelines of Good Clinical Practices 2018 CDSCO Guidelines of Good Clinical Practices 2013 Ethical Principles for Clinical Trials ICH Guidelines of Good Clinical Practices 2016 Section 7: Herbal Industry, IPR and Regulatory Affairs	429 466 471 484			
23.24.25.26.27.	Clinical Trial Regulations for Herbal Products WHO Guidelines on Safety Monitoring of Herbal Medicines in Pharmacovigilance Systems 2004 Fundamentals of Clinical Trials and Phases of Trials AYUSH Guidelines of Good Clinical Practices 2018 CDSCO Guidelines of Good Clinical Practices 2013 Ethical Principles for Clinical Trials ICH Guidelines of Good Clinical Practices 2016 Section 7: Herbal Industry, IPR and Regulatory Affairs Herbal Industry: Infrastructure, Formulation, Production and	429 466 471 484 495			
23.24.25.26.27.28.29.	Clinical Trial Regulations for Herbal Products WHO Guidelines on Safety Monitoring of Herbal Medicines in Pharmacovigilance Systems 2004 Fundamentals of Clinical Trials and Phases of Trials AYUSH Guidelines of Good Clinical Practices 2018 CDSCO Guidelines of Good Clinical Practices 2013 Ethical Principles for Clinical Trials ICH Guidelines of Good Clinical Practices 2016 Section 7: Herbal Industry, IPR and Regulatory Affairs Herbal Industry: Infrastructure, Formulation, Production and Pilot Plant Scale-Up Management of Herbal Products	429 466 471 484 495			

	Content	s ix		
32.	Intellectual Property Rights and Herbal Products	598		
33.	Geographical Indications of Goods (Registration and Protection) Act, 1999	631		
	New Drug Application: NDA, INDA, ANDA, BLA, OTC Master Formula, SMF-Site Master File, DMF-Drug Master File,	640		
	Dossier and CTD, Chemistry Manufacturing & Controls (CMC) Dossier	655		
Annexures				
1.	Analytical Profiles of Herbal Drugs	675		
2.	List of GMP Certified Herbal Raw Material and Phytochemical Suppliers			
	in India	683		