

Detailed Topics for the

Summer School on Botanical Products Categories, Quality, Regulations and Marketing

Venue: TDU Campus, Bengaluru, India

Sl. No	Topic
	Section-1 Developing Quality Monographs
1	Raw Material/ Raw drugs Quality Standards
2	Developing raw drug repository and herbarium
3	GMP for Botanical derived active's
4	GMP for Ayurvedic finished dosage forms (including schedule-T)
5	HACCP for Botanical containing food formats as per FSSR
6	Confirmation of Identity of botanicals (Macro. Micro, DNA)
7	DNA fingerprint testing for confirmation of botanical identity
8	Quality Assurance during grinding and processing
9	Herbal drug extracts, specification
10	Essential oils as actives
11	Quality Standards for Finished Products
12	General Monographs in IP for botanicals, processed botanicals botanical products and GPP
13	Standard operating procedure for preparation, qualification, certification and supply of botanical reference substances and phytochemical reference substances
14	Challenges in raw botanical procurement, approaches for sustainability through cultivated sources and consumption report requirements
15	Identification Confirmation of powdered herbs through analytical microscopy
	Section-2 Product Development
16	Demand and supply of medicinal plants
17	Approaches to identifying active herbs for product development for specified indications
18	Pre-formulation studies including selection of excipients
19	Dose, usage level decision and Computing the quantity of Herb to be added to the product
20	Environmental Conditions during production
21	Granulation, compaction and other unit operations
22	Formulation development and scale-up for selected dosage forms (capsules and tablets)
23	Use of preservatives & preservation of Herbal products
24	Packaging development for botanical products
25	Modern dosage forms and delivery systems
26	Clinical studies and claim substantial data for botanicals
27	Claim substantiation of supplements/Nutraceuticals
28	Substitute /alternative botanicals –Scientific development
29	Nano particle technology and its applications to botanicals
30	Designing a factory lay out – herbal extracts, contemporary dosage forms
	Section-3 Stability Testing
31	Stability testing of raw and processed product
32	Formulation and Stability testing of cosmetics with botanicals added

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33	Stability testing for products in food format containing added botanicals
34	Stability testing for Nutraceutical products
35	Stability testing for Ayurvedic products
	Section-4 Regulatory
	4.1 Regulation and understanding
36	Over view of Botanical Drugs and Phytopharma Regulations
37	Regulations related to Botanical Cosmetics
38	Indian Regulations for Nutraceuticals, supplements, FSDU, FSMP
39	Over view of global nutraceutical regulation- US and Europe
40	Preparation, compilation of Dossiers for market authorization
41	Regulations for Ayurvedic products- Licensing, manufacture, labeling and recent amendments
	4.2. IPR Related Regulation
42	Trade Marks, Copy right and designs- Applications to herbal products and protecting your brand
43	Challenges for Process or Product or use or a combination patents for products with Botanicals in India and their merits and demerits
44	Approaches to patenting Herbal Innovations in India with case studies
	Section- 5 Routes to Marketing of Herbal Products
45	Ethical Marketing of a herbal product
46	Challenges of Herbal Supplements/Nutraceutical through FMCG Marketing and OTC marketing
47	Emerging routes of Online and Digital marketing
48	Consumer research for Herbal products with case studies
49	Advertising standards and self-regulation with case studies
	Section-6 Demos and Visits
50	HPTLC Demo
51	DNA Fingerprinting
52	Herbarium
53	Database
54	Herbal Garden