A Report on

Joint All India Council for Technical Education—Gujarat Technological University Sponsored

One Week

e- Faculty Development Programme

On

"Emerging Trends and regulations in Products of Herbal Origin"

Organized By

Graduate School of Pharmacy, Gujarat Technological University, Gandhinagar

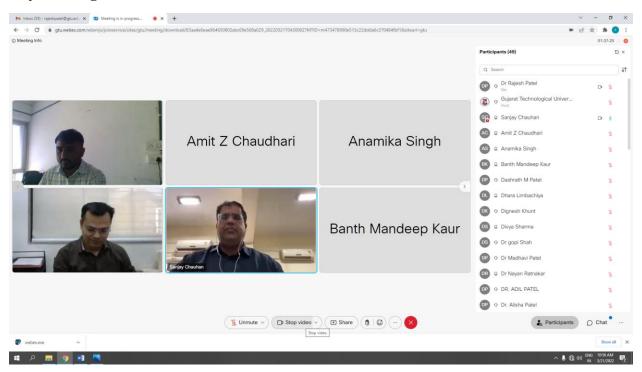
March 21-26, 2022

Programme Co-ordinator:

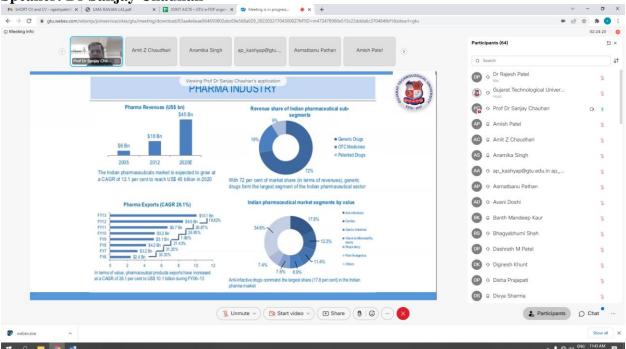
Dr. Rajesh Patel

Photographs of FDP

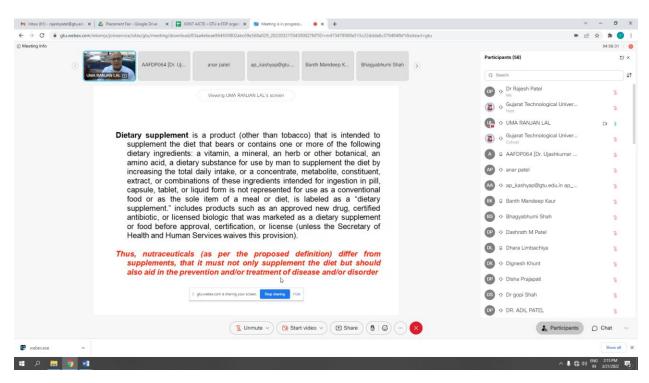
Day: 1 Inaugural Function



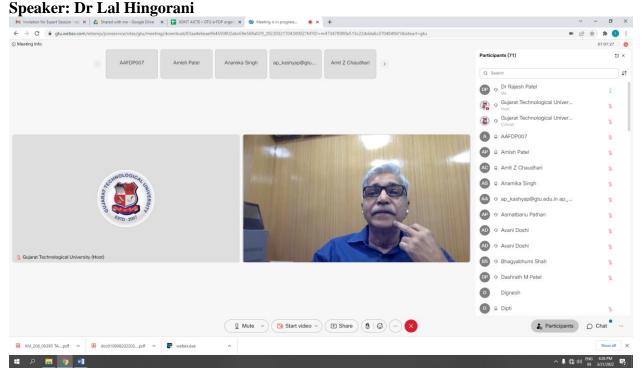
Session 1: Scope of Entrepreneurship in Products of Herbal origin Speaker: Dr Sanjay Chauhan



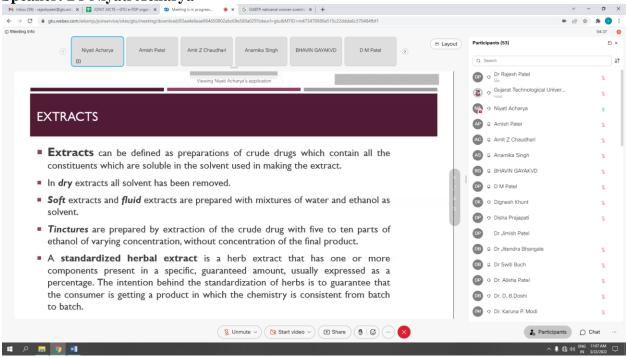
Session 2: Nutraceuticals and functional food-as Indian perspective Speaker: Dr Uma Ranjan Lal



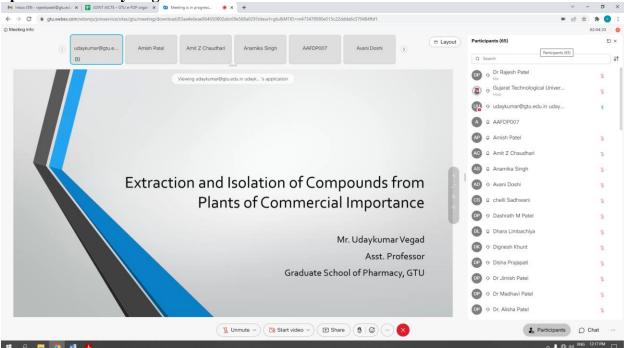
Session 3: Recent trends in Herbal techniques



Day-2 Session 1: Recent Trends in Extraction and Isolation techniques Speaker: Dr Niyati Acharya

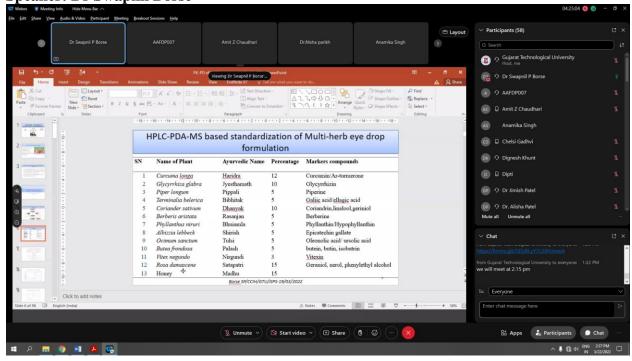


Session 2: Extraction and Isolation of Compounds from Plant of Commercial importance Speaker: Mr Uday Vegad



Session 3: PK-PD & Interaction studies for Herbal drug Development

Speaker: Dr Swapnil Borse

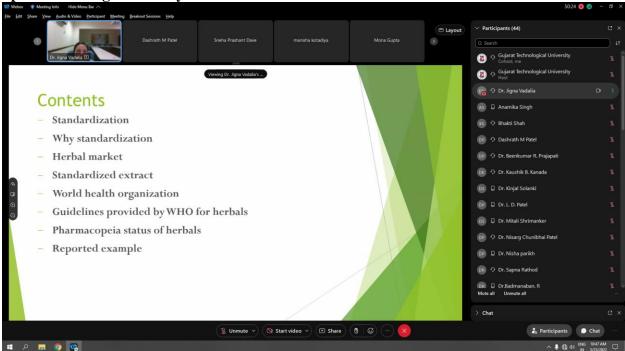


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Day 3

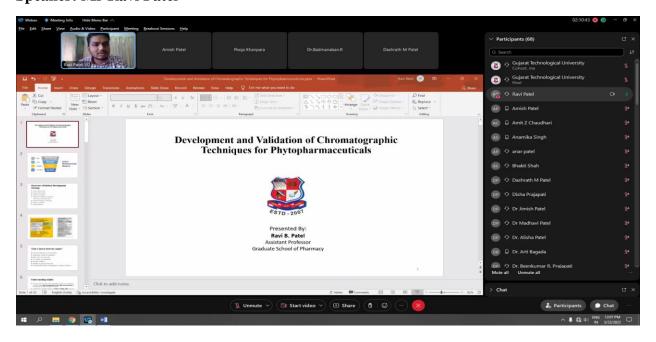
Session 1: Standardization of Herbal Extract

Speaker: Dr Jigna Vadaliya

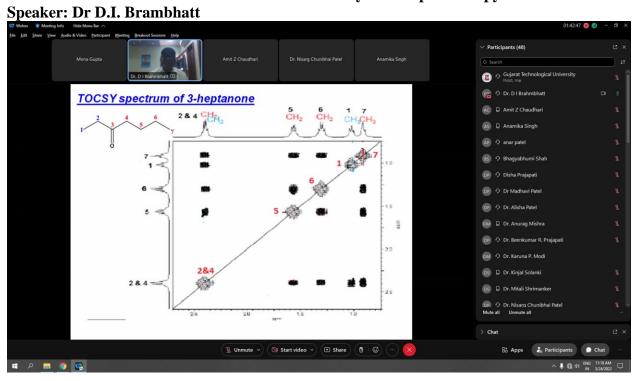


Session 2: Development and Validation of Chromatographic techniques for Phytopharmaceuticals as per regulatory requirements

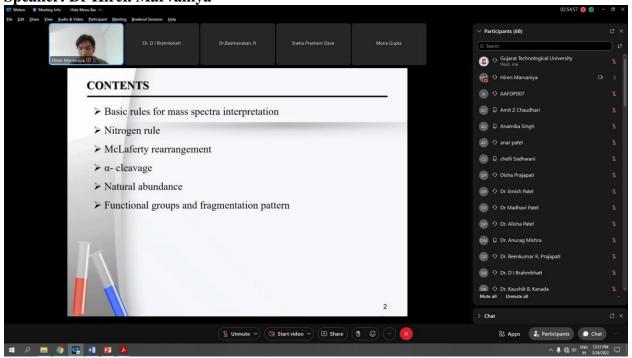
Speaker: Mr Ravi Patel



Day 4
Session 1: Characterization of Herbal constituent by NMR Spectroscopy



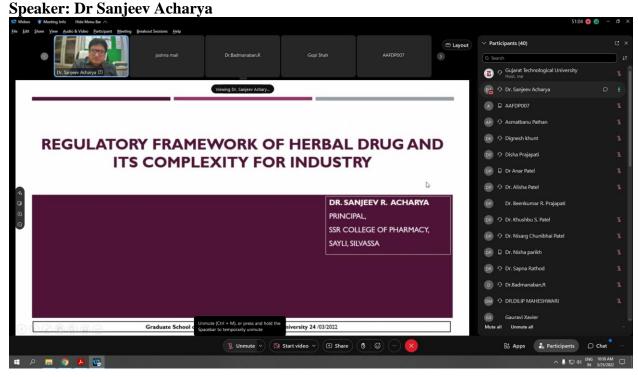
Session 2: Characterization of Herbal constituent by Mass Spectroscopy Speaker: Dr Hiren Marvaniya



Session 3: Characterization of Herbal constituent by IR Spectroscopy



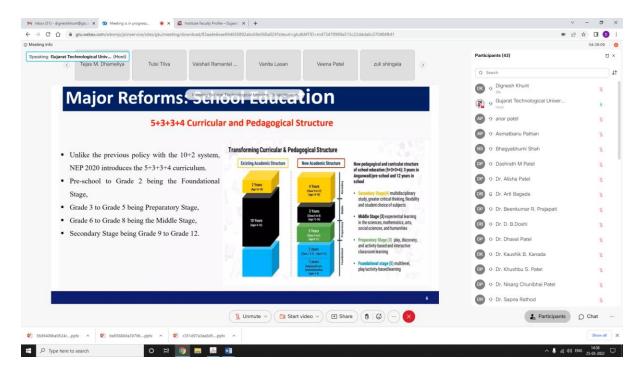
Day 5
Session 1: Regulatory Framework of Herbal Drug and Its Complexity



Session 2: Patenting In Herbal product

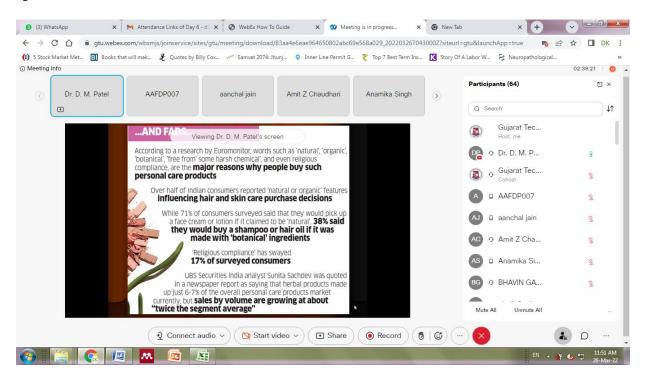


Session 3: NEP2020 Speaker: Dr Rajesh Patel

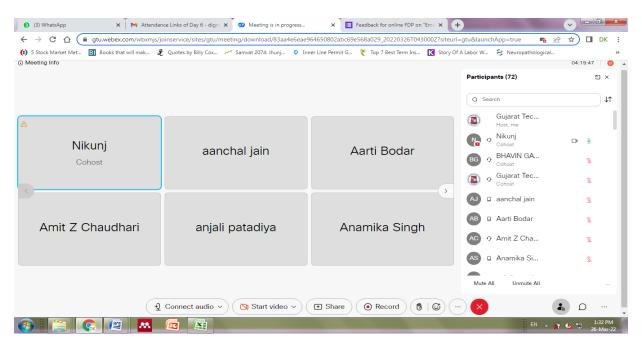


Day 6

Session 1: Herbal Cosmetics: Growing Business in absence of Streamline regulations Speaker: Dr D M Patel



Session 2: Young Entrepreneur's success story in Herbal Cosmetic Speaker: Mr Nikunj Bali



Session 3: Examination and Valedictory Function

Online FDP on "Emerging Trends and regulations in Products of Herbal Origin" was organized by Graduate School of Pharmacy between 21/03/2022 to 26/03/2022.

Total 217 faculty was registered from 60 colleges of Gujarat which is affiliated with AICTE and GTU. Out of this, 90 Participant has completed the FDP as per norms. Seventeen (17) Resource person across the country from various academic institute and pharmaceutical company has deliver their talk in this FDP.

FDP was inaugurated by Dr Hardik Soni, Assistant General Manager - R&D, Vasu Healthcare Pvt. Ltd. & Dr Sanjay Chauhan, Director of Graduate school of Pharmacy, GTU.

During inauguration session **Dr Soni** has told about importance of choosing herbal related topics in faculty development programme which enhance the courage among the young faculty to do the good research on Herbal products.

After the inauguration, first session was taken by **Dr Sanjay Chauhan**, Director GTU-GSP. In that he has discussed the scope of Entrepreneurship in Products of Herbal Origin. He has highlights the key point with respect to worldwide markets of herbal products and how to overcome the challenges associated with herbal markets.

Dr Uma Ranjan Lal, Deputy Manager (R&D) AYURVET LIMITED, BADDI, has deliver his talk on Nutraceuticals and functional food-as Indian perspective. Nutrients, herbals and dietary supplements are the major constituents of Nutraceuticals which make them instrumental in maintaining health, act against various disease conditions and thus promote the quality of life. In the global marketplace Nutraceuticals and functional foods have become a multi-billion dollar industry and estimates within Canada suggest that the Canadian Nutraceuticals and functional food industry has potential to grow to \$50 billion US. Japan is the second largest market in the world for Nutraceuticals products after the United States. Its Nutraceuticals market has exhibited a steady average growth rate of 9.6% per annum.

Dr Lal Hingorani, CMD, Pharmanza Herbal Pvt Ltd, Director Pharmanza India Pvt Ltd, has delivered his talk on recent trend in herbal products. Herbal medicines have been used since the dawn of civilization to maintain health and to treat various diseases. To compete with the growing pharmaceutical market, there is an urgency to utilize and scientifically validate more medicinally useful herbal products. He also added the therapeutic efficacy of various herbal medicines, adverse

drug reactions, drug interactions, standardization and stability testing of herbal medicines, pharmacovogilance and regulatory status of herbal medicines need to be point of care for herbal medicine.

Dr Niyati Acharya, Head of Department at Institute of Pharmacy, Nirma University, has deliver her talk on recent trends in Extraction and Isolation technique. In her talk she added the path "from plants to pure molecules" is a rather complex issue. It is influenced by a wide range of factors, from ecological elements of the environment to threats of the modern society, urbanization, and industry development. Furthermore, the amount of active principles in the plant is influenced by ecological factors, species, zoning, culture technology, the biological value of the cultivar, and processing methods. The unambiguous identification is often difficult due to changes in plant taxonomy. Some species of medicinal plants are threatened by over-harvesting in several parts of the world.

Mr Uday Vegad, Assistant Professor, GTU-GSP, has deliver his talk on Extraction and Isolation of Compounds from Plant of Commercial importance. During his talk he shows some practical demonstration on how the companies are extracting the herbal constituent from plants for their commercial purpose.

Dr Swapnil Borse, Scientist, AYUSH - Center of Excellence, CCIH, ISHS, Savitribai Phule Pune University [SPPU], has deliver his talk on PK-PD & Interaction studies for Herbal drug Development. During his talk he has highlighted on Integrative medicine refers to the blending of conventional and evidence-based complementary medicines and therapies with the aim of using the most appropriate of either or both modalities for ultimate patient benefits. One of the major hurdles for the same is the chances of potential herb—drug interactions (HDIs). These HDIs could be beneficial or harmful, or even fatal; therefore, a thorough understanding of the eventualities of HDIs is essential so that a successful integration of the modern and complementary alternative systems of medicine could be achieved.

Dr Jigna Vadaliya, Assistant Professor, GTU-GSP, give her talk on Standardization of herbal products. Herbal formulations have reached extensive acceptability as therapeutic agents for several diseases. The development of authentic analytical methods which can reliably profile the phytochemical composition, including quantitative analyses of marker/bioactive compounds and other major constituents, is a major challenge to scientists. Standardization is an important step for the establishment of a consistent biological activity, a consistent chemical profile, or simply a

quality assurance program for production and manufacturing of herbal drugs. WHO specific guidelines for the assessment of the safety, efficacy and quality of herbal medicines as a prerequisite for global harmonization are of utmost importance. An overview covering various techniques employed in extraction and characterization of herbal medicines as well as herbal Nano medicines standardization is reported. In addition, phytosomes increased bioavailability, bhasma as a metal Nano carrier drug delivery system, potential of metabolomics in the development of improved phototherapeutic agents, DNA based molecular markers in distinguishing adulterants, and SCAR markers for authentication and discrimination of herbs from their adulterants are reported. The extraction of high-valued herbal compounds using microwave—assisted extraction and supercritical phase extraction technology followed by the standardization utilizing various spectroscopic, chromatographic and thermo gravimetric techniques individually and/or in combination has been discussed in relation to herbal drugs. Capillary electrophoresis and polarography techniques contributions towards standardization of herbal drugs is also reported. Nanotechnology based Chinese herbal drugs possess improved solubility and enhanced bioavailability.

Mr. Ravi Patel, Assistant Professor, GTU-GSP, has delivered his talk on Development and Validation of Chromatographic techniques for Phytopharmaceuticals as per regulatory requirements. Standardization of polyherbal medicine though being the need of the hour is a toilsome task. Among the various methods employed for quality control and standardization of polyherbal medicine, phytochemical profiling is of utmost importance as it signifies the quality as well as efficacy of the medicine. The validated method can be employed as standardization tool for herbal formulations with accuracy and precision. The developed method will assist in maintaining the good quality and batch to batch uniformity of polyherbal formulations.

Dr Kashyap Thummar, Assistant Professor, GTU-GSP has given his talk on Hyphenated Techniques in herbal finger printing. He added Herbal drugs must be marketed as safe and therapeutically active formulation whose performance is consistent and predictable new and better medina plant agents are being produced at an accelerated rate. At the same time more exacting and sophistical analytical tools and methods are being used their evaluations and elites source identification. Based on the conception of phytoequivalence, the chromatographic and spectral fingerprints of herbal medicines could be utilized for addressing the problem of quality control of herbal medicines. Several novel chemo metric methods for evaluating the fingerprints of herbal

products. Chemical fingerprints obtained by chromatographic HPLC. HPTLC GC-MS-LC-MS, FT- IR techniques, are strongly recommended for the authentaion of traditional herbal medicines. **Dr D. I. Brambhatt**, Professor of Organic Chemistry & Head (Ex) Department of Chemistry Sardar Patel University, Vallabh Vidyanagar, deliver his talk on Characterization of herbal constituents by NMR spectroscopy. He has given the talk on utilization of 2D NMR spectroscopy. He discussed how in the fields of medicine and health, traditional high-performance liquid chromatography or UV-visible spectrophotometry is generally used for substance quantification. However, over time, nuclear magnetic resonance spectroscopy (NMR) has gradually become more mature. Nuclear magnetic resonance spectroscopy has certain advantages in the quantitative analysis of substances, such as being nondestructive, having a high flux and short analysis time. Nuclear magnetic resonance spectroscopy has been included in the pharmacopoeia of various countries.

Dr Hiren Marvaniya, Research Scientist, JSK Organics Pvt. Ltd, Ahmedabad. He has presented his talk on utilization of MS in Characterization of Herbal constituents. Analytical techniques such as NMR and MS are commonly used for metabolite profiling for the quality control of herbal drugs. The higher sensitivity of MS enables detection of trace components and hence MS is widely used for plant metabolite profiling. Basic concepts of MS are discussed before describing the applications. Coupling GC or LC with MS results in separation of the components prior to detection by MS resulting in enhanced sensitivity and specificity. The two approaches for metabolite analysis are: (1) targeted analysis of one or two marker compounds and (2) untargeted analysis involving determination of all the metabolites. Multiple reaction monitoring and parallel reaction monitoring are used for quantitative determination. The applications of MS in herbal drug research include identification and authentication, profiling, standardization, quality control, adulteration, toxicity studies, pharmacokinetic studies, MS imaging and heavy metal determination. Several examples are discussed.

Dr Palak Parikh, Assistant Professor at L. M. College of Pharmacy, Ahmedabad deliver her talk on use of IR Spectroscopy in Characterization of Herbal Constituents. IR spectroscopy is an extensively used tool for investigating the different structural aspects of these medicinal compounds. The results and achievements made through this tool are comprehensive, easy to interpret and relate with the other structural techniques. The said standing of IR spectroscopy accomplishments are very well reviewed here, particularly the achievements attained by infrared

spectroscopy alone or in hyphenation with liquid chromatographic approaches for the analysis of such compounds. Such couplings and strategies are vital to design to deal with the complex sources. IR scanning yields a simultaneous picture of the compounds present in an extract. The efficient and accurate extractions and identifications of pharmacological compounds help then in establishing the disease specific drugs.

Dr Sanjeev Acharya, Principal at S.S.R College of Pharmacy, Sayli, Silvassa, has given his talk on Regulatory Framework of Herbal Drug and Its Complexity. In his talk he explain about the current challenging aspect of herbal medicine or traditional system is maintenance of quality, safety and efficacy issues. As there is a global recognition for the herbal drugs as a healing aids, the demand for these traditional system have been increased drastically from 19 th century to 21 st century. As the main challenge of this herbal medicine / drugs is maintenance of DNA finger printing, phytochemical and therapeutic uniformity, lack of Good clinical practices, standard operating protocols, no proper protocols or guidelines on pharmacokinetic and pharmacodynamics issues, no standardization protocols, no control on residual limits (Pesticide residues, Microbe residues, heavy metal residues, solvent residues and teratogenicity). In order to meet this challenges the regulatory agencies EMEA, ICH AYUSH, WHO, USFDA trying to bring these herbal therapies/drugs under regulatory pipeline under the NDA approval process. In order to meet these current challenges, the Indian Herbal Pharmacopoeia has published 40 monographs monitored by Indian Drugs Manufacturers Association (IDMA).

Dr Manju Mishra, Associate Professor, GTU-GSP has given her talk on Patenting in Herbal Product. During her talk she has discussed on the following subject matters give us an idea of what type of patent applications that claim to contain natural and herbal products, will be considered by the patent office- A new method of usage of a known herb could be examined and considered as a patentable subject matter. A superior and better way of extracting an active ingredient from an herb or method of preparation of a composition using the extracted active ingredient from the herb. Sole herb discovery cannot be considered, it must be a composition that has a mixture of ingredients. The composition may be used for the treatment of an ailment or disease. The invention could be a process of preparing an herbal composition or an herbal composition itself or both. The invention must have industrial application.

Dr Rajesh Patel, Associate Professor, GTU-GSP, he has present his talk on NEP-2020. During his talk he explained on some salient features of NEP-2020 like, Universalization from ECCE to Secondary Education by 2030, aligning with SDG4. Attaining Foundational Learning & Numeracy Skills through National Mission by 2025.100% GER in Pre-School to Secondary Level by 2030. Bring Back 2 Cr Out of School Children. Teachers to be prepared for assessment reforms by 2023. Inclusive & Equitable Education System by 2030. Board Exams to test core concepts and application of knowledge. Every Child will come out of School adept in at least one Skill. Common Standards of Learning in Public & Private Schools.

Dr D.M. Patel, Associate Professor, GTU-GSP has given his talk on Herbal Cosmetics: Growing Business in absence of Streamline regulations. He briefly said that Herbal cosmetics are like double edge sword. Something that has both good and bad parts and results.

Mr. Nikunj Bali, New Product Development Consultant, has deliver his talk on success story of Entrepreneurship in Herbal Cosmetics. During his talk he has discuss so many successes stories about young Entrepreneur who is growing speedily in the field of Herbal Cosmetics.

A Report with Outcome on e-FDP on "Emerging Trends and regulations in Products of Herbal Origin"

Herbal medicines have been used since the dawn of civilization to maintain health and to treat various diseases. To compete with the growing pharmaceutical market, there is an urgency to utilize and scientifically validate more medicinally useful herbal products. In this FDP, Faculties have got the ideas about the Isolation, Extraction and Standardization of Herbal Extract and medicine. With this FDP, Faculties have also learnt about the Pharmacokinetic and Pharmacodynamics studies involved during herbal drug development. In this Programme, Faculties have also get the understanding on how to characterize the herbal constituents by using different analytical techniques like IR, Mass, NMR. As the main challenge of this herbal medicine / drugs is maintenance of DNA finger printing, phytochemical and therapeutic uniformity, lack of Good clinical practices, standard operating protocols, no proper protocols or guidelines on pharmacokinetic and pharmacodynamics issues, no standardization protocols, no control on residual limits (Pesticide residues, Microbe residues, heavy metal residues, solvent residues and teratogenicity). Faculties have also get ideas on how to make regulatory registration in various market. Challenges associated with Patenting in herbal product is also discussed in this FDP. Brief discussion on use of Hyphenated analytical techniques for herbal drug evaluation is made during this FDP. During this FDP, faculties have got an idea on Development and Validation of Chromatographic techniques for Phytopharmaceuticals as per regulatory requirements. Among the various methods employed for quality control and standardization of poly herbal medicine, phytochemical profiling is of utmost importance as it signifies the quality as well as efficacy of the medicine. The validated method can be employed as standardization tool for herbal formulations with accuracy and precision. The developed method will assist in maintaining the good quality and batch to batch uniformity of poly herbal formulations. In this FDP, brief discussion on Young Entrepreneur's success story through Herbal Product& Herbal Cosmetic has done. In this, Entrepreneur highlights the key point with respect to worldwide markets of herbal products and how to overcome the challenges associated with herbal markets. One session on NEP-2020 has taken and some salient features of NEP-2020 like, Universalization from ECCE to Secondary Education by 2030, aligning with SDG4. Attaining Foundational Learning & Numeracy Skills through National Mission by 2025.100% GER in Pre-School to Secondary Level by 2030. Bring Back 2 Cr Out of School Children. Teachers to be prepared for assessment reforms by 2023.

Inclusive & Equitable Education System by 2030. Board Exams to test core concepts and application of knowledge. Every Child will come out of School adept in at least one Skill. Common Standards of Learning in Public & Private Schools are discussed.

In the last session, online examination was conducted and 90 participant has cleared the examination with minimum attendance criteria. After the completion of examination valedictory function was organized and feedback from all the participant was collected.