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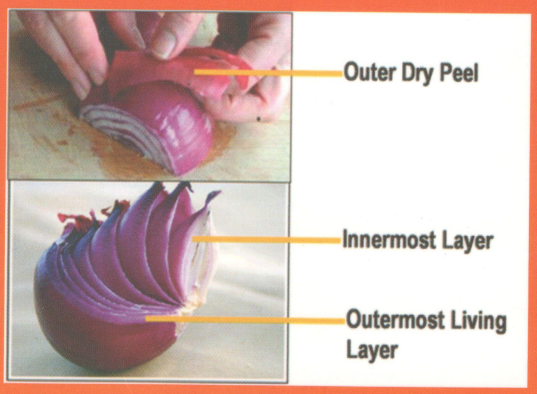
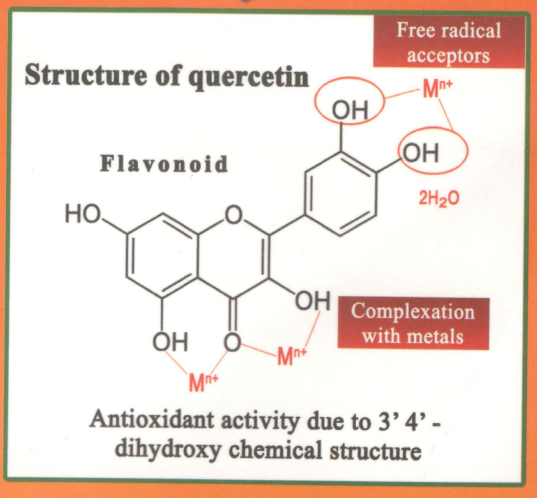


- Antihyperglycaemic
- Anticarcinogenic
- Antihypertensive
- Antithrombotic
- Antimicrobial
- Antioxidant



Antioxidant activity due to 3' 4' - dihydroxy chemical structure

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Jamia Hamdard, New Delhi

THIRD NATIONAL SEMINAR ON "CURRENT REGULATIONS ON HERBAL DRUGS AND FOOD SUPPLEMENTS"

Inaugural function from left: Bushra Parveen, Dr. Sayeed Ahmad, Dr. Arun Gupta, Professor Nadeem Siddiqui, Professor Seyed E. Hasnain, Professor R.K. Goyal, Professor S.S. Handa and Professor Vidhu Aeri

Valedictory function from left: Dr. Sayeed Ahmad, Dr. Arun Gupta, Professor Raisur Rehman, Professor S.H. Ansari and Mr. C.P. Khare

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The NIRF Rank 1 Pharmacy institute of India (**School of Pharmaceutical Education and Research, Jamia Hamdard)** organized a National Seminar on Current Regulations for Herbal Drugs and Food Supplements in collaboration with the **Society for New Age Herbals**. The seminar covered important aspects pertaining to herbal medicines and food supplements. It asserted that a good regulatory framework with stringent quality control is essential for development of quality products in herbal drugs and food supplements that can be promoted and used throughout the globe and for refurbishing public faith in herbal products. More than 750 scientists from academia and various herbal drug and food supplement industries participated in the seminar.

Several dignitaries from India and abroad including Prof Hassan Khalid (Khartoum University, Sudan), and Dr. Mohamed Alamin and Dr. A.H. Mohmed (Licensing Authority of Herbal Drugs in Sudan) attended the seminar.

INAUGURAL SESSION

Professor Vidhu Aeri, Head of the Department of Pharmacognosy and Phytochemistry, welcomed the delegates, however Professor Nadeem Siddiqui introduced the gathering about seminar. The Chief Guest of the function, Professor Ramesh K. Goyal (Vice Chancellor, DPSRU, New Delhi) highlighted the importance of the theme, whereas Professor S. S. Handa, Eminent Pharmacognosist and Ex. Director of Indian Institute of Integrative Medicine, Jammu, in his Key Note speech stressed upon the critical need to bring together scientists, industry people, policy makers and regulatory agencies to consider challenges and opportunities of the next decade and discussed new guidelines for food and phytopharmaceuticals. In his presidential remarks, Professor Seyed Ehtesham Hasnain, Vice Chancellor, Jamia Hamdard, elucidated the necessity of putting medicinal herbs to rigorous scientific testing and developing standards so as to maintain quality for global competitiveness. Dr. Sayeed Ahmad, Organizing Secretary of the seminar, thanked the participants, valuable guests, invited speakers, chief guest (Professor R.K. Goyal), Key note speaker (Professor S.S. Handa) and acknowledged the support provided by Aimil, Hamdard, ICMR, Dabur, Rex Remedies, Fermish, Agilent, Dehlvi, Nature and Nature and Liimra.

TECHNICAL SESSIONS

The technical session, comprising of 10 plenary lectures, had a balanced representation of industry, academics and the government agencies. Dr. J.L.N. Sastry (Dabur), Dr. Neeraj Tandon (ICMR), Professor S.K. Moulick (AIIMS), Dr. Khalid Khan (Fermish), Dr. Arun Gupta (Dabur), Dr. Santosh Joshi (Hamdard), Dr. N. Srikanth (CCRAS), Dr. N.B. Brindavanam (Dabur) and Dr. Aman Gupta (Amway) were the invited speakers.

TECHNICAL SESSION 1

Chaired by Professor Hasan Khalid (Professor University of Khartoum, Sudan), Professor R.K. Khar (Ex. Professor Jamia Hamdard), Dr. Khalid Mehmood Siddiqui (Ex. Deputy Director General, CCRUM)

Lecture 1: Necessity for the correction of AYUSH drug regulations

Dr. J.L.N. Sastry, Dabur India Ltd.

Dr. Sastry highlighted important aspects of Drugs and Cosmetics Act which require revision from the AYUSH perspective. He also shared that the rules for AYUSH drugs under Drugs and Cosmetics Act does not contain any provision for collection of samples from physicians, thus makes the physicians immune from any penalty. He further highlighted that for effective enforcement of quality related regulations to the ASU drugs, there is urgent need to create a central drug testing laboratory for AYUSH medicines.

The schedules of the regulations need urgent revision since, the therapeutic index of many companies have become the schedule. There is also need to revise the list of books mentioned in the schedule. To ensure the quality of drugs, Good Agricultural Cultivation Practices should also be covered in the regulation.

Lecture 2: Quality Control of Unani herbal medicines in India

Dr. Santosh Joshi, Hamdard Laboratories

Highlighted the quality challenges related to botanical raw materials like crop-to-crop variation due to natural challenges and processing conditions. Mixing of various grades of raw material, *e.g.,* incase of saffron also leads to quality issues in the final formulation.

Labelling issue: Preservatives are not mentioned on the label of herbal extracts which leads to quality issues, *e.g.,* detention of the consignment in the export country ports due to presence of starch (preservative, not mentioned on the label). Another issue is substitution in the formula due to non availability of a particular medicinal plant and incorrect and unsystematic storage of raw materials.

Lecture 3:Biodiversity Act, 2002 and its implications for biopharmaceutical sector

Dr. N. B. Brindavanam, Dabur India Ltd.

The speaker discussed the implications of Biodiversity Act, 2002 from the perspective of recognition of sovereign rights on the biological resources including for the purpose of commercial gains. The act is based on three pillars of "Conservation, Sustainable Use and Commercial use with equitable sharing."

As per the Act, it is obligatory to seek prior approval from National Biodiversity Authority for access Bioresource/traditional knowledge for all activities centered around commercial use. The benefit sharing (monetary and non-monetary) mechanism (GSR-827) has also been defined in the act with Bioresource Management Committee, State Biodiversity Board and National Biodiversity Authority including free access for purely local use.

Impact: The Biodiversity Act, 2002 has no impact on research. The patent application may also be file without hinderance, however, the benefit sharing process must be agree upon before filing patent. However, it should be kept in mind that the National Biodiversity Authority keeps ecological health above human health.

TECHNICAL SESSION 2

Chaired by Professor S.K. Gouswami (Dean and Professor School of Life Sciences, J.N.U.), Professor Mohd Ali (Ex. Professor Jamia Hamdard), Dr. T.K. Mukherjee (Ex. Editor, IJEB, NISCAIR)

Lecture 4: Clinical trial of a herbal medicine in heart failure patients in a tertiary care hospital

Professor S. K. Maulik, All India Institute of Medical Sciences

Professor Maulik presented the preclinical and clinical research work on use of Arjuna bark aqueous extract in heart failure. He concluded that though, encouraging results were obtained in preclinical studies, the extract did not show any benefit as an add on therapy to the baseline treatment with modern drugs. He also reported that Arjuna bark did not show any interaction with commonly used cardiovascular medicines like diuretics and digoxin, *etc*. Further, the extract was found to have no effect on CYP2D6 enzyme (metabolises ACE inhibitors and Beta blockers).

However, studies need to be carried out on the effect of Arjuna bark extract *per se* treatment in heart failure patients. It is noteworthy to mention that despite Arjuna bark being used as an aqueous extract in Unani system of medicine, ICMR considered it as a new drug (and not AYUSH drug) and asked for conduct of preclinical toxicity studies.

Lecture 5: Current Regulation on Food Supplements

Dr. Aman Gupta, Amway

Dr. Aman Gupta deliberated upon the Food Standards and Safety Regulation, 2016. He highlighted the issue of overlapping definitions of various drug and food agencies in India. He informed that the approval guidelines are for non-specific foods and food ingredients. For the formulation containing combination of approved products requires further approval.

Lecture 6: Drug Development and Regulatory aspects in ASU system: Scope and Challenges

Dr. S. Srikanth, Central Council for Research in Ayurvedic Sciences

Discussed the issues of overlapping regulations on food supplements, ethical doses of herbal extracts and drug interaction studies. He outlined that the drug interaction studies being carried out by CCRAS are indicative studies and do not provide absolute guarantee of no interaction with any drug.

He also discussed that the clinical trials esp. the add on trial are challenged by the demarcations of the medical systems, in case more than one medical system is involved. He also informed that the new guidelines on research on ASU drugs are currently in draft state and opinions are being sought.

TECHNICAL SESSION 3

Chaired by Dr. Gyan Singh (Ex. Editor, NISCAIR), Professor Mohd Husain (HOD, Biotechnology, Jamia Millia Islamia), Dr. Kshipra Mishra (Additional Director, DIPAS, DRDO)

Lecture 7: Phytopharmaceuticals : A new regulation in India

Dr. Neeraj Tandon, Indian Council for Medical Research.

Dr. Tandon informed that as per USFDA data, there are more than 50,000 ADRs due to botanicals and herbal drugs. CDSCO had issued phytopharmaceutical guidelines in 2013. Now a new appendix has been added in the schedule Y (Appendix 1B) outlining the process for new drug application of phytopharmaceuticals. As per this guideline, a comprehensive procedure for drug development research has been defined on the phytopharmaceuticals (mainly for, but not limited, to single herb products) in line with drug development process of pharmaceuticals including quality, safety, efficacy and drug interaction studies. The products approved under the new appendix, though being herbal products, can be prescribed by the practitioners of modern system of medicine.

Lecture 8: Current regulations on modern herbal medicine

Dr. Khalid Khan, Fermish Clinical Technologies

Dr. Khan outlined the regulations for herbal medicines in light of recent USFDA guidance for botanicals.

Lecture 9: Clinical research on herbal medicines: Indian perspective

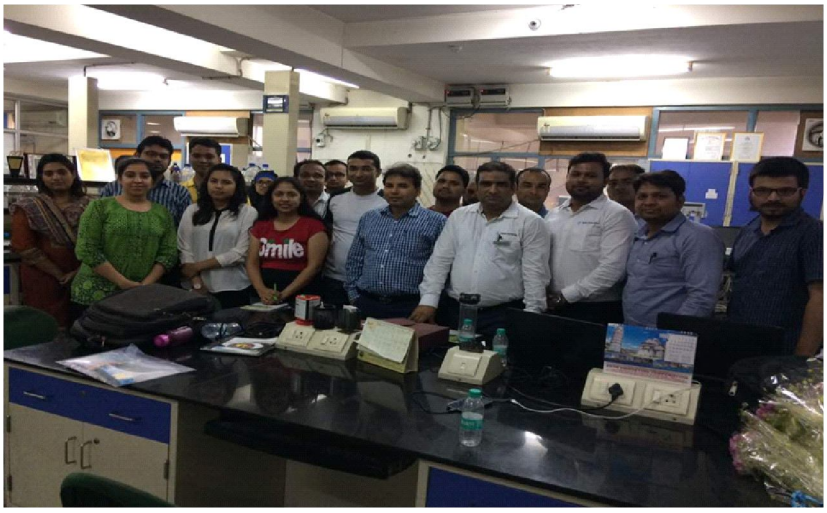
Dr. Arun Gupta, Dabur India Ltd.

Dr. Gupta presented the aspects of clinical trial on herbal medicines with special reference to AYUSH systems. He highlighted the challenges and solutions for conduct of clinical trials from the point of view of blinding, control, randomization *etc*. He also outlined the details of regulatory aspects including registration of clinical trials and audio visual recording of informed consent.

Valedictory session

The valedictory function was addressed by Professor Raisur Rahman (Advisor, Unani AYUSH), Mr. C.P. Khare was guest of Honour. Dr. Arun Gupta (Co-ordinator) and President Society for New Age Herbals concluded the seminar after felicitation to sponsors and awardees of best paper by Dr. Sayeed Ahmad (Organizing Secretary).

GC-MS Metabolomics Workshop on 17th May 2017



GCMS workshop was attended by more than 65 delegates from JamiaHamdard and outside members, which was sponsored by Agilent Technologies.

The first Lecture was on Basics of GCMS by Indrajit Sen (Agilent technologies) followed by second Lecture on LC-QTOF Mass- spectrometer: A workhorse for metabolomics applications by SaurabhNagpal (Agilent technologies). Further, Demo on GCMS analysis of metabolites by Indrajit Sen &SaurabhNagpal (Agilent technologies) in Bioactive Natural Product Laboratory.