19-02-2018

REPORT

One day seminar cum workshop on "Pharmaceutical Products Stability: Quality and Regulatory Perspectives"

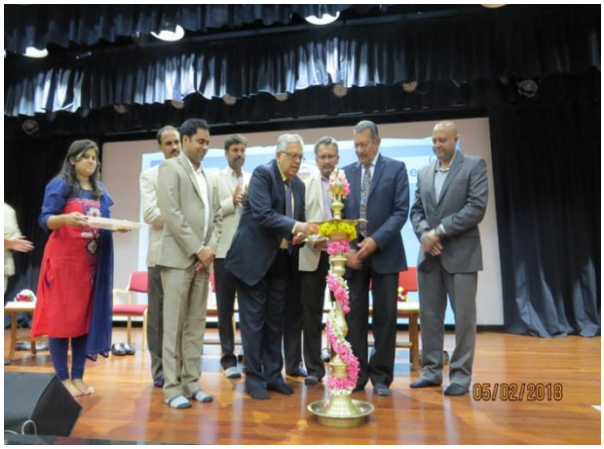
Department of Pharmaceutics, JSS College of Pharmacy in association with IncepBio, Bangalore had organized One day seminar cum workshop on 5th February, 2018 titled "Pharmaceutical Products Stability: Quality and Regulatory Perspectives" with the objective to impart concepts of stability studies of new drug substances and pharmaceutical products; provide information on Validation and Calibration of Pharmaceutical equipment, Instruments and facilities and to provide basic concepts, principles, working protocols and hands on experience of temperature and relative humidity mapping using wired and wireless loggers

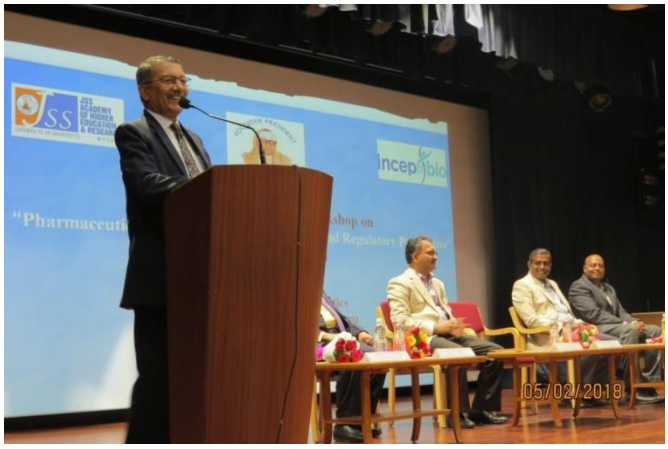
Dr. P.A. Kushalappa, Director (Academics), JSS Academy of Higher Education and Research, Mysuru inaugurated the workshop, he stressed upon the understanding the importance of stability of pharmaceutical drug products both by the prescriber, manufacturer and patient. Sri. A.G. Raghu, Santhana Gopala Consultants, Mysuru and Mr. Ambarish M. Ghali, Co-Founder and Director, IncepB Pvt. Ltd., Bangalore, Mr. Hemanth Kumar, Manager, IncepBio Pvt. Ltd., Bangalore were the guests of honour.

Dr. T M Pramod Kumar, Principal, presided the function and welcomed the guests and participants; explained the overview and objectives of the seminar and Dr. M P Venkatesh proposed a vote of thanks.

The scientific session included preliminary aspects related to stability, temperature and humidity mapping and forenoon session gave hands on training to the delegates on temperature and humidity mapping using wired and wireless data loggers.

A total of 317 delegates from different pharmacy colleges and from industries attended the seminar and all the sessions were interactive and well attended.





Mr A G Raghu explained the basic concepts related to the stability testing of new pharmaceutical products, basics of stability, determination of drug substance and product shelf life, concepts of retest period of a substance, regulatory guidelines related to carrying out a stability study like 21 CFR Part 211 Section 166, USFDA Draft Guidance – Stability Testing of Drug Substances and Drug Products , CPMP Guidance, ICH Q1A(R2), Stability

Testing of New Drug Substances and Products, WHO Technical Report No. 953 2009, Schedule M and other applicable regulations.

Mr Ambarish stressed on information related to Temperature and Relative Humidity mapping, importance of uniform temperature and humidity in the storage unit in empty and in normal storage conditions. An emphasis was made on the zones to be avoided for storage of sensitive products (temperature and humidity) and excursion limits (event of power failure and door opened conditions). A mapping validation is used on a newly operational space in order to determine whether the space will meet the needs of a product.

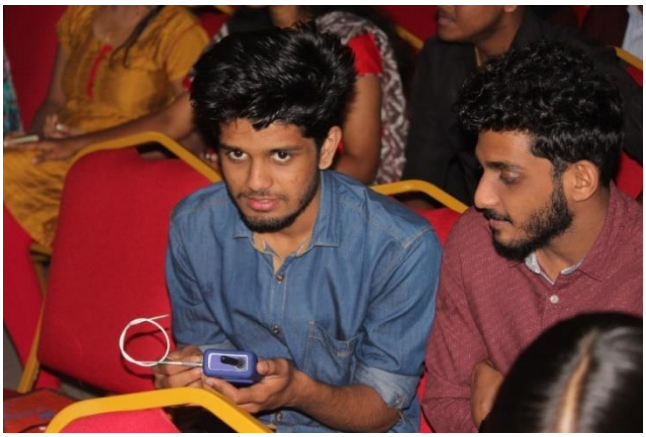
Hands-on-Training

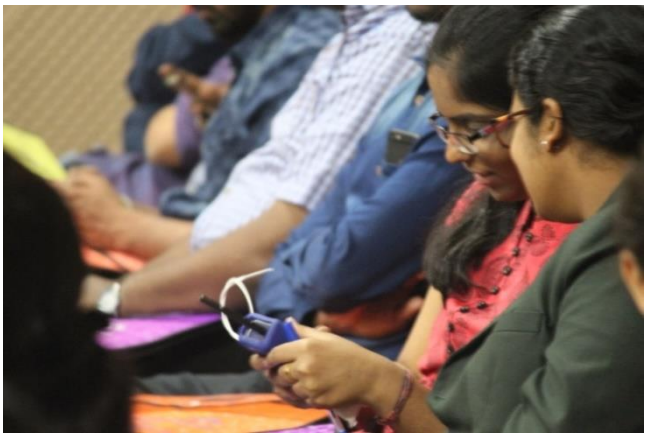
The temperature and relative humidity mapping was performed on Refrigerator (low temperature monitoring) and Hot air oven (hot temperature monitoring).

Three different loggers were used for the mapping process

1. Kaye Val probe – wireless loggers
2. Fourtec – wireless loggers
3. Brainchild – wired loggers

The influence of door opening impact on temperature fluctuations was demonstrated, the real time temperatures at different locations inside an equipment was compared with the actual temperature displayed by the equipment sensor.





Dr. D.V. Gowda, Head, Dept. of Pharmaceutics, Dr. H.V. Gangadharappa and Dr. M.P. Venkatesh, Assistant Professors coordinated the event