ejpmr, 2023, 10(1), 82-85

SJIF Impact Factor 6.222

EUROPEAN JOURNAL OF PHARMACEUTICAL AND MEDICAL RESEARCH

www.ejpmr.com

Review Article

ISSN 2394-3211

EJPMR

GOVERNMENT INITIATIVES FOR PHARMACEUTICAL ANALYSIS IN INDIA

Sakshi Dixit, Prajwal Shelar*, Abhishek Patil and Shriniwas Patil

Alard College of Pharmacy, Marunje, PCMC- 411 057, Pune.

***Corresponding Author: Prajwal Shelar**

Alard College of Pharmacy, Marunje, PCMC- 411 057, Pune.

Article Received on 08/11/2022 **Article Revised on 29/11/2022** **Article Accepted on 19/12/2022**

ABSTRACT

The importance of quality control(QC) testing by an analytical laboratory cannot be overstated, as it serves as one of the "checks and balance" between the pharmacy and consumer. We are all aware that a quality preparation is vital, and the QC laboratory should play an integral part in establishing the safety and accuracy of pharmacy preparations. As the compounding practice continues to evolve as well. Analytical challenges can cover a multitude of areas ranging from lack of an appropriate reference standard for comparative analysis to complication quantitative analysis by a complex sample matrix.[1] Estimation of the profile of organic impurities is the most challenging, most interesting task. The protocol for this begins with the detection of the impurities by chromatographic methods, mainly thin-layer chromatography (TLC) and/or HPLC. The next step is to attempt identification by retention matching with available potential impurities. If this fails, the structure of the impurities must be determined by on-line or off-line coupling of chromatographic and spectroscopic techniques.[2]

KEYWORDS: (TLC) and/or HPLC.

INTRODUCTION

Significance of pharmaceutical analysis: Instrumental methods of chemical analysis have become the backbone of experimental chemistry. Before instrumental analysis, traditional methods of analysis such as titration, solvent extraction methods, and determination of content in the sample by simple methods were used. Modern medicines are to be standardized and analyzed to meet exacting standards which relate to quality, efficacy, and safety. Modern methods of analysis are exceedingly sensitive and provide precise and detailed information from small samples of material. Analytical instruments are used in several fields such as.

- Environmental testing
- Clinical Analysis
- Forensic Analysis
- Food and Beverage Analysis
- Materials Characterization and research
- Pharmaceutical Analysis
- Petrochemical testing
- Life science research

Chemical purity may be defined as an entity containing no foreign particles. To estimate the impurity present in the sample, various processes, separation techniques, and purification methods are available for attaining the level of purity.Analytical techniques are extensively used to identify and quantify potential impurities at an early stage of drug development. Pharmaceutical analysis is also an essential means of ensuring that successive batches of materials used in toxicological studies are the reasonable correlation of analytical profiles.[3] It has a relatively wide spectrum of use in the detection of the chemical constituents of natural products through spectroscopic techniques like UV-visible, FTIR; Spectrometric methods like Mass and NMR; and chromatographic methods like HPTLC, HPLC, GC, and Ion exchange chromatography; and also hyphenated techniques like GCMS, LCMS, LC-NMR. The interpretation of spectroscopic data obtained from compounds is widely used for the quantitative determination of the composition of mixtures of related compounds. It is important to establish the chemical identity of any new drug substance and quantify potential impurities at an early stage in development.

Challenges in the availability of analytical facilities

In India, considering the significance of analytical facilities, most of chemical and pharmaceutical industries have their own set up for routine analytical attempts. Most of Government initiated Public Sector Undertakings (PSUs) may also have the required set up. But, in most of the academic or educational institutes where several research attempts in different subjects are undertaken do not have substantial research infrastructure. These research projects could be formulation of drug into suitable dosage forms; synthesis of novel molecules with potent pharmacological activities; isolation of phytochemicals from natural sources; evaluation of toxicities on animal models or validation of method developed for analysis of

dosage form and bulk drug. Almost at every stage, analysis with modern technique is preferred. But due to lack of sound research infrastructure, many projects couldn't be completed in proper manner or may not be analysed precisely. So, these project undertaking researchers are advised to outsource the required analytical facility. But, private sector labs cost higher charges for the same; so again, researchers may not afford it which results in decrease in analytical runs without observing precision in results by going for multiple runs of same analysis. Also, education regulatory authority may not set compulsion to private academic institutes to have all these analytical facilities. Hence, private institutes avoid spending fund in it, ultimately which affects the performance of researchers who is affiliated to that institute and/or actually working there. Many institutes may not have skilled personnel for smooth handling of these sophisticated instruments. Considering all these constrains, Government has taken few initiatives to set analytical facilities under various schemes at Government institutes or State or Central Universities. The main motto observed is to inculcate research aptitude in young researchers so that quality research output is obtained which would help in nation building.

This review summarizes the Government initiatives for making the research facilities available and thereby inculcates and develop research aptitude in budding researchers. To achieve this goal, analytical labs have been set up which are under direct control and supervision of bodies like Department of Science and Technology (DST-GOI), Council for Scientific and Industrial Research- CSIR, Department of Biotechnology (DBT-GOI), Department of Atomic Energy (DAE-GOI)

Government initiatives

Sophisticated Analytical Instrument Facility(SAIF)

Department of Science and Technology (DST) flagship scheme Sophisticated Analytical Instrument Facilities (SAIF) Scheme was started in 1974 as Regional Sophisticated Instrumentation Centres (RSIC) which was later renamed SAIF in 2002-03.

At present, there are fifteen sophisticated analytical instrument facilities spread across the country. With time, the centers have updated and are being upgraded with the latest developments that are taking place globally.[4]

1. Indian Institute of Technology- Madras, Chennai.
https://www.iitm.ac.in/
2. Central Drug Research Institute (CDRI), Lucknow.
https://www.cdri.res.in/
3. Indian Institute of Technology- Bombay, Mumbai.
https://www.iitb.ac.in/
4. Indian Institute of Science, Bangalore.
https://iisc.ac.in/
5. Punjab University, Chandigarh.
https://puchd.ac.in/
6. All India Institute of Medical Sciences (AIIMS), New Delhi.
https://www.aiims.edu/
7. North-Eastern Hill University (NEHU), Shillong.
https://www.nehu.ac.in/
8. Gauhati University, Guwahati.
https://gauhati.ac.in/
9. SICART, Gujarat.
http://www.sicart.res.in/
10. STIC-Kochi
https://www.sticindia.com/
11. Indian Institute of Technology- Patna.
https://www.iitp.ac.in/
12. Indian Institute of Engineering Science and Technology, Shibpur.
https://www.iiests.ac.in/
13. Mahatma Gandhi University, Kottayam.
http://mgu.ac.in/
14. Karnatak University, Dharwad.
http://www.kud.ac.in/
15. Shivaji University, Kolhapur.
http://www.unishivaji.ac.in/

Central Instrumentation Facility(CIF)

Central Instrumentation Facility (CIF) is equipped with several technologically modern instruments that can be used for advanced research applications. To maximize instruments used to promote science, in line with the Government of India's directive, our CIF is open to external use both for academia and the Industry.[5]

1. IISER Bhopal
https://www.iiserb.ac.in/
2. IIT(BHU) Varanasi
https://www.iitbhu.ac.in/
3. SPPU Pune
http://www.unipune.ac.in/
4. NBRI, Lucknow
http://www.nbri.res.in/
5. Central University of Rajasthan
https://www.curaj.ac.in/
6. Lovely Professional University, Punjab.
https://www.lpu.in/
7. Rajiv Gandhi University, Arunachal Pradesh.
http://www.rgu.ac.in/
8. IICB Kolkata
http://www.iicb.res.in/
9. Pondicherry University, Pondicherry.
https://www.pondiuni.edu.in/
10. University of Science and Technology Meghalaya.
https://www.ustm.ac.in/
11. IIT Gandhinagar
https://iitgn.ac.in/

Council of Scientific and Industrial Research(CSIR)Institutes

The Council of Scientific & Industrial Research (CSIR), known for its cutting-edge R&D knowledge base in diverse S&T areas, is a contemporary R&D organization. CSIR covers a wide spectrum of science and technology – from oceanography, geophysics, chemicals, drugs, genomics, biotechnology, and

nanotechnology to mining, aeronautics, instrumentation, environmental engineering, and information technology. It provides significant technological intervention in many areas concerning societal efforts, which include environment, health, drinking water, food, housing, energy, and farm and non-farm sectors. Further, CSIR's role in S&T human resource development is noteworthy.[6]

1. Advance Material and Process Research Institute [CSIR-AMPRI], Bhopal.
https://ampri.res.in/
2.Central Building Research Institute [CSIR-CBRI], Roorkee.
https://cbri.res.in/
3.Center for Cellular and Molecular Biology [CSIR-CCMB], Hyderabad.
https://www.ccmb.res.in/
4. Central Electro Drug Research Institute [CSIR-CDRI], Lucknow.https://cdri.res.in/
5. Central Electro Chemical Research Institute [CSIR-CECRI], Karaikudi.https://cecri.res.in/
6. Central Electronics Engineering Research Institute [CSIR-CEERI], Pilani.https://www.ceeri.res.in/
7. Central Food Technological Research Institute [CSIR-CFTRI], Mysuru.https://cftri.res.in/
8. Central Glass and Ceramic Research Institute [CSIR-CGCRI], Kolkata.https://www.cgcri.res.in/
9. Central Institute of Medicinal and Aromatic Plants [CSIR-CIMAP], Chennai.
10. Central Institute of Mining and Fuel Research [CSIR-CIMFR], Dhanbad.https://cimfr.nic.in/
11. Central Leather Research Institute [CSIR-CLRI], Chennai.https://www.clri.org/
12. Central Mechanical Engineering Research Institute [CSIR-CMERI], Durgapur.
https://www.cmeri.res.in/
13. Central Road Research Institute [CSIR-CRRI], New Delhi.https://crridom.gov.in/
14. Central Scientific Instruments Organization [CSIR-CSIO], Chandigarh.https://www.csio.res.in/
15. Central Salt and Marine Chemicals Research Institute [CSIR-CSMCRI], Bhavnagar.https://www.csmcri.res.in/
16. Central Madras Complex [CSIR-CMC], Chennai. https://www.csircmc.res.in/
17. Fourth Paradigm Institute [CSIR-4PI], Bangalore.
https://csir4pi.res.in/
18. Extramural Research Division [CSIR-EMR], New Delhi.https://csirhrdg.res.in/
19. Institute of Genomics and Integrative Biology [CSIR-IGIB], Delhi.https://www.igib.res.in/
20. Institute Of Himalayan Bioresource Technology [CSIR-IHBT], Palampur.
https://www.ihbt.res.in/
21. Indian Institute of Chemical Biology [CSIR-IICB], Kolkata.https://www.iicb.res.in/
22. Indian Institute of Chemical Technology[CSIR-IICT], Hyderabad.https://www.csir.res.in/
23. Indian Institute of Integrative Medicine[CSIR-IIIM], J&K.https://iiim.res.in//
24. Indian Institute of Pertroleum[CSIR-IIP], Dehradun. https://www.iip.res.in/
25. Indian Institute of Toxicology Research[CSIR-IITR], Lucknow. http://iitrindia.org/
26. Institute of Minerals and Materials Technology [CSIR-IMMT], Bhubaneswar.
https://www.immt.res.in/
27. Institute of Microbial Technology [CSIR-IMTECH], Chandigarh. https://www.imtech.res.in/
28. National Aerospace Laboratories [CSIR-NAL], Bangalore. https://www.nal.res.in/
29. National Botanical Research Institute [CSIR-NBRI], Lucknow. https://nbri.res.in/
30. National Chemical Laboratory [CSIR-NCL], Pune.
https://www.ncl-india.org/
31. National Environmental Engineering Research Institute [CSIR-NEERI], Nagpur.
https://www.neeri.res.in/
32. North East Institute of Science and Technology [CSIR-NEIST], Jorhat. https://www.neist.res.in/
33. National Geophysical Research Institute [CSIR-NGRI], Hyderabad. https://www.ngri.res.in/
34. National Institute of Science Communication and Policy Research [CSIR-NISCPR], New Delhi
https://niscpr.res.in/
35. National Institute for Interdisciplinary Science and Technology [CSIR-NIIST] Thiruvananthapuram.
https://www.niist.res.in/
36. National Institute of Oceanography [CSIR-NIO], Goa. https://www.nio.org/
37. National Metallurgical Laboratory [CSIR-NML], Jamshedpur. https://www.nmlindia.org/
38. National Physical Laboratory [CSIR-NPL], New Delhi. https://www.nplindia.org/
39. Structural Engineering Research Centre [CSIR-SERC], Chennai. https://serc.res.in/
40. Unit for Research and Development of Information Products[CSIR-URDIP], Pune.
https://urdip.res.in/

Department of Biotechnology (DBT) Institutes

The main vision is to attain new heights in biotechnology research shaping biotechnology into a premier precision tool of the future for the creation of wealth and ensuring social justice – especially for the welfare of the poor. The department provides services in the areas of research, infrastructure, generation of human resources, popularization of biotechnology, promotion of industries, creation of centers of excellence, and implementation of biosafety guidelines for genetically modified organisms and biotechnology-based products.[7]

1. Center of Innovative and Applied Bioprocessing, Mohali.
http://www.ciab.res.in/
2. Center for DNA Fingerprinting and Diagnostics, Hyderabad.
http://www.cdfd.org.in/
3. National Institutes of Animal Biotechnology, Hyderabad.

https://www.niab.res.in/
4. National Institute of Biomedical Genomics, Kalyan. https://www.nibmg.ac.in/
5. National Centre of Cell Science, Pune. http://www.nccs.res.in/
6. National Brain Research Centre (NBRC), Gurgaon. http://www.nbrc.ac.in/
7. National Institutes of Immunology (NII), New Delhi. http://www.nii.res.in/
8. Regional Center for Biotechnology, Faridabad. http://www.rcb.res.in/
9. Institute for Stem Cell Biology and Regenerative Medicine (inStem), Bangalore. https://www.instem.res.in/
10. Institute of Bioresources and Sustainable Development (IBSD), Imphal.https://www.ibsd.gov.in/
11. Institute of Life Sciences (ILS), Bhubaneshwar. https://www.ils.res.in/
12. National Agri-Food Biotechnology Institute (NABI), Mohali. https://www.indiascienceandtechnology.gov.in/
13. National Institute of Plant Genome Research (NIPGR), Delhi. http://www.nipgr.ac.in/
14. Rajiv Gandhi Centre for Biotechnology (RGCB), Thiruvananthapuram.http://rgcb.res.in/
15. Translational Health Science and Technology Institute (THSTI), Haryana.http://www.thsti.res.in/

CONCLUSION

Analytical instrumentation is the essential column to build/grow up various sectors such as pharmaceutical industries, food industries, research and development institutions, etc. Hence, government has taken initiative for promoting all analytical instrumental facilities required in these sectors. These facilities help to overcome challenges facing by a researcher/student.

ACKNOWLEDGEMENT

We, the authors of this article are thankful to Managerial Board, Alard Charitable Trust's Alard College of Pharmacy, Marunje for providing internet and library facilities for carrying out literature survey.

REFERENCE

1. Kupiec, T.C., 2006. Challenges facing an analytical laboratory. *International Journal of Pharmaceutical Compounding*, *10*(6): 479.
2. Görög, S., 2006. The importance and the challenges of impurity profiling in modern pharmaceutical analysis. *TrAC Trends in Analytical Chemistry*, *25*(8): 755-757.
3. Beckett A.H. and Stenlake J.B., Practical Pharmaceutical Chemistry, Fourth edition, Part one, 1-15.
4. https://dst.gov.in/scientific-programmes/scientific-engineering-research/sophisticated-analytical-instrument-facilities-saifs
5. http://cifniperr.org/
6. https://www.csir.res.in/
7. https://dbtindia.gov.in/