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Pharma Testing Facility: An Overview

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Abstract

The basic purpose of quality assurance in Pharmaceutical manufacturing and supply system is to have a full proof mechanism and exhibitions that every medicine receives by a patient must be safe, effective and pure of acceptable quality. To accommodate all these conditions and parameters, the candidate medicine as well as even established medicine must undergo a series of weathering to make it real perfect and fit for use. To have such medicine, there are established quality standards and set of procedure supported by analytical and instrumental techniques, using variety of physiochemical markers. Pharmaceutical quality is affected by material in use, manufacturing process, packaging and storage conditions and also on some other eco-factors leading to expiration date, decomposition and so on. To have an error free medicine, testing for its standardization require involvement of series of steps using precision instrument under control conditions, utilizing the principle of "Section and discord" such testing conditions require heavy investment, many a times, it is difficult to afford by the Pharma companies also. To cope with such situation, almost all the World Government facilitates testing activities by establishing specialized testing Centre. These Centres provide support to quality standardization, by paying certain amount. However, developing sophisticated analytical testing mechanism to evaluate and also to monitor the quality attributes of drug under examination for purity and structure, require a big list of equipment and highly skill expertise, which in general beyond the internal capacity of a Pharma company and require special attention of World governments; may be in form of establishing such facilities in government sector or outsourcing or maybe through public private partnership (PPP). Whatever procedure/initiatives may be, but it should be given urgent attention by all the country governments involved in Pharma manufacturing sector [1-3].

Keywords: Pharma testing; Medicine; Pharmaceutical manufacturing

Abbreviations: PPP: Public Private Partnership; CTM: Chinese Traditional Medicine; NIPER: National Institute of Pharmaceutical Education and Research; CDP-PS: Cluster Development Programme for Pharma Section; SPVS: Special Purpose Vehicles; PMDA: Pharmaceuticals and Medical Devices Agency; EURLS: European Union Reference Laboratories; PMDEC: Pharmaceuticals and Medical Devices Evaluation Centre

Historical Development and Status of Government Testing Facilities Worldwide

Before the beginning of the 20th Century, Pharma sector was not well organised and dominated by European and American countries, Asia was still mainly equipped with traditional medicine like CTM (Chinese Traditional Medicine), Indian Traditional medicine or

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Japanese/Korean Traditional medicine, based on herbal preparation which did not require to have a detail of ingredients, subsequently such preparation does not go through rigorous analytical weathering to ensure purity and quality. Effective Pharma quality came into existence with publication of the book 'Economic Control of Quality' in 1931 by Walter A. Shewhart. During 60"s, big quality control changes were also initiated in Japan, Korea and India. In India, no vigorous effects were made by the Government on measuring the drug testing facilities in past century but with the beginning of this millennium, much more initiatives were introduced.

Status of Government Drug Testing Facilities in India

Till a few years back, India had only five (5) Drug Testing laboratories under direct Control of the Government of India, situated in different parts of the country [4]:

a. Central Drug Laboratory, Kolkata
b. Central Drug Testing Laboratory, Mumbai
c. Central Drug Testing Laboratory, Guwahati
d. Central Indian Pharmacopoeia Laboratory, Ghaziabad
e. Central Drug Laboratory, Chandigarh

These National Centres are doing an excellent job, and are well equipped, with the modern testing facilities. But with the growing drug market, introduction of several pharma companies and enhanced production, created deficiency situation and demanded opening of new centres. As these centres were unable to cope with the growing demands, search for other alternatives arose in the form of outsourcing and PPP (Public Private Partnership). Current global analytical testing service market in experiencing a rapid growth with about 11% per year.

The CMC (Chemical Manufacturing and Control) activity in analytical testing is moving fast, with global testing services market of 2.42 $ billion in 2016 is expected to be 4.13$ billion by 2021. Such a fast growth of market, further catalyses to look beyond the current facilities by Government and others.

Future of Pharma Testing and Government Support

With many fold increase in establishment of a testing facility, high cost of instruments and ascending cost of testing due to utilization of several channel to make sure that product is one of the purest form, further increases the testing cost. In addition, precision testing also require talented person who demand more perks and salary, make the cost effective solution more serious. Fund constraints does not allow the Government to open many new centres thus PPP (Public Private Partnership) is also a good initiative, under this a number of MOU has been signed with private player and Government Institutes like NIPER (National Institute of Pharmaceutical Education and Research, Mohali, in 2016 and now, it is spread to other NIPER locate at different places in India. In India, Cluster Development Programme for Pharma Section (CDP-PS) has also been initiated by the Government to enhance quality, productivity and innovative capabilities with the following objectives:

a. Easy access to standard testing facilities and value addition
b. Strengthening the existing infrastructure
c. Reducing the cost of production
d. To help industry to meet the requirement of standards of environment norms
e. To be part of bio informatics such as regulations, IPR issue etc.

In view of the above, creation of identified infrastructure and common facilities to a special purpose vehicles (SPVS) has also been setup.

To facilitate such activities, a number of Governments certified Test facilities have been recognised. To name a few:

i. International Institute of Bio Technology and Toxicology, Papappai, Tamil Nadu dealing all types of physical-chemical testing.
ii. GLP laboratory, Thane equipped with Toxicity and clinical testing.
iii. Jai Research Foundation, Valsad with all testing facilities.
iv. Torrent Research Centre, Gandhi Nagar; good Pharma testing.
v. Sun Pharma Advance Research, Vadodora excellent Pharma testing.
vi. Toxicology Centre, Shri Ram Institute of Industrial Research, New Delhi, dealing Pharma testing.
vii. Dabur Research Foundation, Delhi with modern Pharma testing.

Testing Facilities in other Asian Countries

Since long, Japan is the oldest established competitor with Europe and America for drug manufacturing. Now, India is also one of the senior players in this sector. In Japan, Pharmaceuticals and Medical Devices Agency (PMDA), a Government Agency is taking care of testing facilities and other related problem, PMDA was established in 2004 by merging Pharmaceuticals and Medical Devices Evaluation Centre of the National Institute of Health Sciences

(PMDEC), the organization for Pharmaceutical Safety and Research (OPSR/KIKO) and Japan Association for the Advancement of Medical Equipment (JAAME), now PMDA is part of Ministry of Health, Labour and Welfare (MHLW).In Korea, Government supported testing facilities are available in research Institutes and Universities, China is also developing efficient testing facilities through its research network and academic institution [5].

Testing facilities in Europe

European testing sciences is governed by European Commission Science of Knowledge Services, which is part of a series of such establishment established under European Union known as European Union Reference Laboratories (EURLS). These laboratories besides Pharma testing, also take care of food, feed and animal health and also doing analytical services for food contact materials, feed additives, genetically modified food and feed. These laboratories are well recognised centre for high quality testing has established reference materials, materials, proficiency testing schemes and trained staff.

Testing facilities in USA

USA is the pioneer of advance pharma testing facility. The moderation of Pharma testing started in the early 19th century with the introduction of modern analytical instruments and technique. Food and Drug Administration (FDA), is the sole Controlling agency of the Government, which has a Quality Agreement Guidance. FDA has a Contract Research Organization (CROS) doing good testing services. Recently, FDA has released a new guidance, "Request for Quality metrics" which has more wings and better analysis guiding assistance [6].

Constraints for effective testing

The use of precision instruments and highly skilled professionals makes testing reasonably costly. Such cost effective factors give push to prices also, leading to derail social welfare. According to recent available data, the Companies' shortage of skilled staff has gone up to 64%. Besides this with the introduction of everyday new instruments and techniques, testing costs keep on moving, affecting company functionary. To ease the situation, the Government has to participate in a big way to avoid the liquidation of Pharma Companies.

Attributor to Pharma testing

The two limiting factors for better pharma testing are instruments and skilled personals. Availability of skilled personnel requires extensive research and also to cope with demanding salary. The next most important is instrument and procedure of handling, however procedure is taken care by the staff. The equipment specified in the analytical methods should be confirmed and it should be in a good working order. In general, the following procedures are performed for various testing parameter [7].

Analytical Methods for Pharma testing

a. HPLC
b. GC
c. Titration
d. Acid – base
e. Aqueous mixtures
f. Indicator
g. Potentiometeric
h. Non-aqueous
i. Potentiometeric
j. Redox (iodometry etc)
k. Complexometry
l. UV – Visible spectrophotometry
m. Microbiological Assay
n. IR/IMR/Colorimetric
o. Fluorimetry, Atomic absorption, spectroscopy, polarography, gravimetry etc.

In general, following instruments are used for Pharma analytical testing:

i. Flow Injection Analyzer
ii. Dissolution Tester
iii. Disintegration Tester
iv. Density Meter
v. Liquid Chromatography with High Resolution Mass Spectrometer (LC-HRMS)
vi. Liquid Chromatography with Tandem Mass Spectrometer and Electron Transfer Dissociation (LC-MS/MS ETD)
vii. High Performance Liquid Chromatography with various detectors
viii. Gas Chromatography with various detectors
ix. Fourier Transform Infrared spectrometer
x. UV Spectrophotometer
xi. Fluorescence Spectrophotometer
xii. Capillary Electrophoresis System

Conclusion

Effective and genuine testing is the guarantee of zero defect products. It is the responsibility of Pharmaceutical manufacturers to have optimum product quality and it is also professional, social and legal responsibility of the manufacturer to provide error free medicine to patent. Currently several new countries and laboratories are becoming active player in this subject [8,9]. Yet well established are Charles River laboratories (US), WUXI

Pharma Tech (China) and European Scientific SE (Luxembourg). To have competitive edge, Government laboratories have to be modernised; it is true that many Governments are not able to cope in such situation. PPP model may be encouraged and out sourcing with stick monitoring can also serve the purpose effective testing. There will be no better end to this article than these words; we are living in a world of brutal disruption with so many ill happening in such situation if we have defective/error medicine think of what will be our fate? We have to decide by our self.

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