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Review Article

A BRIEF REVIEW ON PROCESS ANALYTICAL TECHNOLOGY (PAT)

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ABSTRACT

Process analytical technology (PAT) has been defined as a mechanism to design, analyze and control pharmaceutical manufacturing processes through measurement of critical process parameters which affect critical quality attributes. PAT checks the quality of raw material attributes both physically and chemically (i.e. at off-line, on-line, in-line). PAT involves a shift from testing the quality of building to the quality of products by testing at several intermediate steps. PAT saves a huge amount of time and money required for sampling and analysis of products. The main goal of PAT is to provide successful tools such as multivariate data analysis and acquisition tools, modern process analyzers or analytical chemistry, endpoint process monitoring, controlling tools and continuous improvement and knowledge improvement tools. In this review attempt has been carried out to explore the concept of PAT, different tools of PAT, goals of PAT, How it Works and Its benefits.

Keywords: PAT, Pharmaceutical, Manufacturing process, Quality assurance.

INTRODUCTION

The term "Process Analytical Technology (PAT)" has been used to describe "a system for designing and controlling manufacturing through timely measurements (i.e. during processing) of critical quality and performance attributes for raw and in-process materials and also processes with the goal of ensuring final product quality into the product and manufacturing processes, as well as continuous process improvement.

Process analytical technology (PAT) has been defined by the United States Food and Drug Administration (FDA) "as a mechanism to design, analyze, and control pharmaceutical manufacturing processes through the measurement of Critical Process Parameters (CPP) which affect Critical Quality Attributes (CQA)" [1-3].

The concept actually aims at understanding the processes by defining their CPP's, and accordingly monitoring them in a timely manner (preferably in-line or on-line) and thus being more efficient in testing while at the same time reducing over-processing, enhancing consistency and minimizing rejects.

The FDA has outlined a regulatory framework for PAT implementation. With this framework–according to Hinz "the FDA tries to motivate the pharmaceutical industry to improve the production process". Because of the tight regulatory requirements and the long development time for a new drug, the production technology is "frozen" at the time of conducting phase-2 clinical trials [1, 2].

PAT allows for and encourages continuous process manufacturing improvement. It uses real-time information to reduce process variation and manufacturing capability and demands a solid understanding of the various processes involved in the operation. Simply put PAT is a real-time testing and adjustment based on the complete understanding of how the components and related processes affect the final product. This is in accordance with the fundamental principle that quality cannot be tested but is instead built into the medicinal product by design [2, 3].

PAT is a system for

- Designing, analyzing and controlling manufacturing.
- Timely measurements.
- Critical quality and performance attribute.
- Raw and in-process materials.
- And processes.

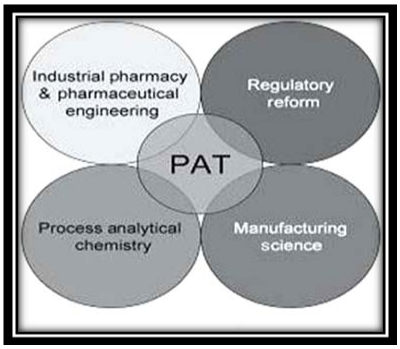

Fig. 1: Main area covered by PAT

Background

Conventional Pharmaceutical manufacturing is generally accomplished using batch processing with final laboratory testing conducted on representative samples to ensure the quality of the product. This conventional approach has been successful in providing quality pharmaceuticals to the public. The problem with this type of approach is that if at final testing product fails to pass the quality specifications [4]. The whole batch has to be discarded incurring a huge loss to the organization. Not only this, another problem is that if that particular representative sample is not up to the quality specification but the overall batch is good, in that case also the whole batch to be discarded based on the result of the sample. It may also happen that the representative samples passes the test, but the overall batch is of low quality and based on the result of the test sample, the product is released, only to be recalled later from the market. So, The Food and Drug Administration (FDA) are inviting discussions throughout the pharmaceutical industry concerning a new mode of operation, which will address these concerns. This mode of operation is known as Process Analytical Technology (PAT). Process analytical technology (PAT) is a key element of the "Pharmaceutical Current Good Manufacturing Practices (cGMPs) for the 21st Century a Risk Based Approach" initiative announced by the FDA in August 2002 to improve and modernize Pharmaceutical manufacturing [4, 5].

The PAT initiative was first proposed by the United States Food and Drug Administration's (FDA), Centre for Drug Evaluation and

Research (CDER) with the objective of achieving good health and cost benefits by application of modern process control and tests in Pharmaceutical manufacturing industries.

Quality-by-Design (QbD) is well-established in development and manufacture of pharmaceutical drug substance and drug product and is discussed in ICH Q8, Q9 and Q11. The outcome of QbD is a well-designed and understood quality product that consistently delivers the continuous performance. The knowledge obtained during development helps in justify the establishment of a design space, (process) control strategy and set point within the (regulatory approved) design space. Materials made within the design space will produce an acceptable product, and the changes within the design space are (regulatory) acceptable. These same principles and concepts have been applied to the development of analytical methods and termed Analytical QbD (AQbD). Analogous to process QbD, the aim of AQbD is to design a well-understood, robust method that consistently delivers the necessary performance as described in the analytical target profile (ATP) [6, 7]. One set of analytical tools used in support of Pharmaceutical development and control include in-situ analytics, chemometrics and modeling, i.e., Process Analytical Technology (PAT) tools.

PAT Goals

The goal of PAT is to understand and control the manufacturing process, which is consistent with our current drug quality system; quality cannot be tested into products; it should be built-in or should be by design [8-10].

In August 2002, recognizing the need to eliminate the hesitancy to innovate, the Food and Drug Administration (FDA) launched a new initiative entitled "Pharmaceutical CGMPs for the 21st Century: A Risk-Based Approach." This initiative has several important goals, which ultimately will help improve the public's access to quality health care services. The goals are intended to ensure that:

- The most up-to-date concepts of risk management and quality systems approaches are incorporated into the manufacture of pharmaceuticals while maintaining product quality.
- Manufacturers are encouraged to use the latest scientific advances in Pharmaceutical manufacturing and technology.
- The Agency's submission review and inspection programs operate in a coordinated and synergistic manner.
- Regulations and manufacturing standards are applied consistently by the Agency and the manufacturer.
- Management of the Agency's Risk-Based Approach encourages innovation in the pharmaceutical manufacturing sector.

Agency resources are used effectively and efficiently to address the most significant health risks. The approach is based on science and engineering principles for assessing and mitigating risk related to poor product and process quality. The desired state of Pharmaceutical manufacturing and regulation may be characterized as follows:

- Approaches recognize Product quality and performance are ensured through the design of effective and efficient manufacturing processes.
- Product and process specification are based on a mechanistic understanding of how formulation and process factors affect product performance.
- Continuous "real time" quality assurance.
- Relevant regulatory policies and procedures are tailored to accommodate most current level of scientific knowledge.
- Risk-based regulatory,

1. The level of scientific understanding of how formulation and manufacturing process factors affect product quality and performance.

2. The capability of process control strategies to prevent or mitigate the risk of producing a poor quality product.

How PAT Works–An Instant

The first step away from off-line testing would be at-line testing. This is the movement of process dedicated testing equipment to the production line to provide rapid results. One advantage is the elimination of transfer of samples involving time delays. Apart from traditional tests such as dissolution, assay, friability, hardness, and thickness, this could also include accelerated dissolution rate analysis, and near infrared (NIR) tablet analysis. One approach of process analytical chemistry is on-line testing, which either draws samples or monitors periodically. Another mode is known as in-line testing, which places probes in constant contact with the drug product. The advantage of on/in-line is better control of the process. Near infrared (NIR) is one of the techniques that have gained recent recognition as a means to add on or in-line analysis at the production level. The near-infrared light does not destroy or react with samples and is able to penetrate into and through solid samples. While NIR has gotten most of the attention, PAT is not limited to NIR but can include many other forms of monitoring, such as Raman, Mid-IR, acoustic emission signals and other imaging techniques [11].

PAT Tools

There are many current and new tools available that enable scientific, risk managed pharmaceutical development, manufacture, and quality assurance. These tools when used within a system can provide effective and efficient means for acquiring information to facilitate understanding of process develop risk-mitigation strategies, achieve continuous improvement, and share information and knowledge. In the PAT framework, these tools can be categorized according to following:

1. Multivariate data acquisition and analysis tools

From a physical, chemical, or biological perspective, pharmaceutical products and processes and processes are complex multi-factorial systems. There are many different development strategies that can be used to identify optimal formulation and process conditions for these systems. The knowledge acquired in these development strategies that can be used to identify optimal formulation and process condition for those systems. The knowledge acquired in these development programs are the foundation for product and process design. Some manufacturers use multivariate mathematical approaches, such as the statistical design of experiments, response surface methodologies, process simulation, and pattern recognition tools, in conjunction with knowledge management systems. The applicability and reliability of knowledge in the form of mathematical relationships and models can be assessed by statistical evaluation of model predictions. Methodological experiments (e. g., factorial design experiments) based on statistical principles of orthogonality, reference distribution and randomization provide effective means for identifying and studying the effect and interaction of product and process variables. Traditional one-factor-at-a-time experiments do not effectively address interactions between product and process variables. Interactions essentially are the inability of the one factor to produce the same effect on the response at different levels of another factor. Experiments conducted during product and process development can serve as building blocks of knowledge to grow to accommodate to a higher degree of complexity throughout the life-cycle of a product. Information from such structured experiments support the development of a knowledge system for a particular product and its processes. This information, along with information along with other development projects, cans the4n become part of an overall institutional knowledge base. As this institutional knowledge base grows in coverage (range of variables and scenarios) and data density, it can be mined to determine useful patterns for future development projects. These experimental databases can also support the development of process simulation models, which can contribute to continuous learning and help to reduce overall development time [12].

Modern process analyzers or process analytical chemistry tools

Process analytical chemistry as a discipline has grown significantly during the past several decades, due to an increasing appreciation for the value of collecting process data during production. From the simple process measurement such as pH, temperature and pressure, modern tool that measure chemical composition and physical

attributes have evolved. These modern process analysis tools provide non-destructive measurements that contain information related to both physical and chemical attributes of tae material being processed. These measurements can be performed in the following manner:

- Offline in a laboratory
- At line in the production area, during production close to the manufacturing process
- Online where measurement system is connected to the process via a diverted sample stream; the sample may be returned to the process stream after measurement
- In line where process stream may be disturbed (e. g. probe insertion), and measurement done in real time
- Non-invasive, when the sensor is not in contact with the material (e. g., Raman spectroscopy through a window)in the processor, the process stream is not disturbed

Many of these recent innovations make real-time control and quality assurance during manufacturing feasible. However, multivariate mathematical approaches are often necessary to extract this information from complex signatures and to correlate these results to a primary method of analysis.

Process and endpoint monitoring and control tools

Following steps can be included for design and optimization of drug formulations and manufacturing process within the PAT framework:

1. Identify and measure critical material and process attributes relating to product quality

2. Design a process measurement system to allow real-time or near real time (e. g., on-, in-or at-line)monitoring of all critical attributes

3. Design process controls that provide adjustments to ensure control of all critical attributes.

4. Develop mathematical relationship between product quality attributes and

5. Measurement of critical material and process attributes.

6. Therefore, it is important to emphasize that a strong link between product design and process development is essential to ensure effective control of all critical quality attributes. Process monitoring and control strategies framework, a process endpoint need not be a fixed time, but can be the achievement of the desired material attribute. This, however, does not mean that process time is not considered. A range of acceptable process times (process window) is likely to be achieved during the manufacturing phase and should be evaluated; considerations for addressing significant deviations from acceptable process time should be developed. Process end points intended for use in real-time release should be considered more critical than those that are only used for in process control.

4. Continuous improvement and knowledge management tools

Continuous learning through data collection and analysis over the life cycle of a product is important. Data can contribute to justifying a proposal for post-approval changes including the introduction of new technologies. Approaches and information technology system that support knowledge acquisition from such databases are valuable for the manufacturers and can also facilitate scientific communication with the regulatory agency.

Strategy for implementation

The Agency understands that to enable successful implementation of PAT, flexibility, coordination, and communication with manufacturers is critical. The Agency believes that current regulations are sufficiently broad to accommodate these strategies [5]. Regulations can effectively support innovation when clear, effective, and meaningful communication exists between the Agency and industry, for example, in the form of meetings or informal communications.

The first component of the PAT framework described above addresses many of the uncertainties with respect to innovation and outlines broad principles for addressing anticipated scientific and technical issues. This framework should assist a manufacturer in proposing and adopting innovative manufacturing and quality assurance. The Agency encourages such proposals and has developed a regulatory strategy to consider such proposals. The Agency's regulatory strategy includes the following:

- A PAT team approach for CMC review and CGMP inspections.
- Joint training and certification of PAT review, inspection and compliance staff.
- Scientific and technical support for the PAT review, inspection and compliance staff.

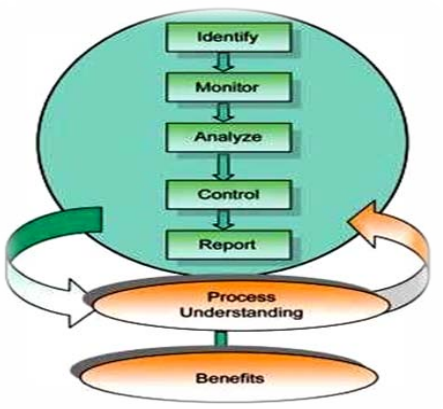

Fig. 2: Proposed steps to a PAT implementation

The recommendations provided in this guidance.

1. **Identify**

This step includes the process of identifying an opportunity that would benefit from the PAT approach, as well as identifying the critical quality attributes that need to be monitored and controlled in the process.

2. Monitor

The next step after identifying the critical quality attributes would be to monitor them. Monitoring is usually achieved using on-line instruments. Recent advances in on-line analytical instrumentation have encouraged more online monitoring of parameters of interest. The simple premise is that we cannot control something we cannot monitor. The monitoring step allows us to collect data for the CQA of interest and evaluate the effect of adjusting the CQA on the overall process efficacy.

2. **Analyze**

The analysis step ensures that once we have identified our critical quality points and monitored them, we employ statistical analysis to determine how the critical quality attribute is related to the overall process efficacy. This step includes the development, verification, and validation of any statistical models that could define the process. Experimental studies, engineering test plans, and retrospective data analysis are methods that we employ to analyze the CQA relationship to the overall process [4, 13].

3. **Control**

After we have analyzed the relationship between the CQA and overall process efficacy and developed any statistical models, the next step in the PAT effort would be to control the process to ensure that the CQA is within specified limits at all times. This is the most critical step of the PAT roadmap that essentially ensures that "real-time" quality assurance is met. Report The reporting element

encompasses any tools that aid in assuring that the process was in fact in control throughout the processing period. Reporting tools serve two purposes-they allow for data to be reported in a fashion that aids in developing process understanding, and they allow for any exceptions from the "ideal state" to be documented in the final release records [5, 13].

In the current manufacturing process the variability present in the raw material is checked at the end of the process when the final product testing is done. The process variables which are incorporated in the process are optimized and set during development. According to fig 3 it shows that process variables are controlled as closely as possible during production process only no changes can be made at other stages.

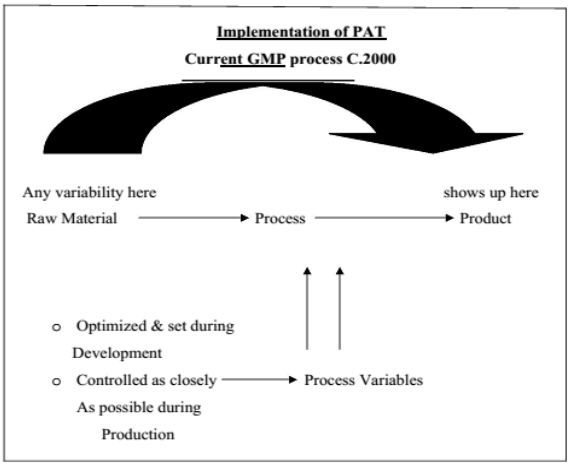

Fig. 3: Current GMP process

Combination of feed forward and feedback control of CPP's provides even greater control of critical quality attributes. Quality is built into the pharmaceutical products during the process itself with help of PAT.

In the current manufacturing process the variability present in the raw material is checked at the end of the process when the final product testing is done. The process variables which are incorporated in the process are optimized and set during development [14].

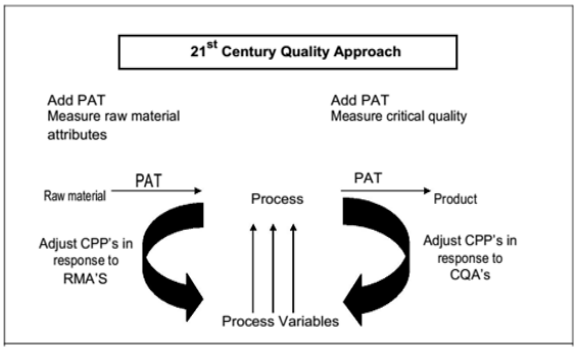

Fig. 4: 21st Century quality approach

Steps involved for implementation of PAT:

Step 1

Adjust the critical process parameters in response to raw material analysis.

The various critical parameters adjusted are

- **Chemical attributes**: identity, purity.
- **Mechanical attributes**: particle size, particle shape, inter and intra particulate bonding.

Step 2

Adjust the critical process parameters in response to critical quality attributes like content uniformity, moisture content, dissolution rate, etc**.** Adjust the critical process parameters in response to critical quality attributes like content uniformity, moisture content, dissolution rate, etc. The feed forward and backward control is the degree of flexibility in process conditions (time) should be applied to manage differences in physical attributes of material being processed.

So fig. 4 helps us in knowing that an approach can be justified and established with differences in physical attributes and process end points are used to control the process.

Benefits of PAT

- Cost reduction in manufacturing.
- Immediate action if quality is not met.
- Better and more stable products.
- Computerized data obtained will be of easier regulatory adherence

Benefits category	Specific PAT benefits
Reduced operating costs	Increased Operating efficiencies, improved cycle time, Decreased operating costs, continuous processing, Real-Time monitoring, Feed-Back controls & Result, inventory reduction, increased capacity utilization, attain production schedule, Reduced reprocessing expenses
Quality improvements	Increased quality, increased regulatory compliance, increased product uniformity, Process finger printing, increased process understanding, Quality designed into process, use of scientific, risk-based approach, Recall prevention, No sampling requirements, Critical process control provided, Rapid identification of counterfeits, substances.
Positive regulatory impact	Moderate regulator burden on FDA, improved scientific basis for regulatory functions.
Increased occupational safety	Decreased occupation exposure to toxic substances
Minimize environmental impact	Reduced environmental impact, Minimize waste generation during manufacturing
Positive research & discovery impact	Reduced product development life cycle/time to market.

Applications

Chemometrics

Chemo metrics is the intersection of chemistry and the mathematics of large matrices of data. Chemo metrics is complex and requires the use of computers and software to perform the necessary computations. These techniques reduce large amounts of data into a few recognizable components without any loss of data.

Two chemo metric techniques that have been found to be useful are Principal Component Analysis (PCA) and Partial Least Squares Regression (PLS). These techniques are recognized for their ability to eliminate noise, identify latent variables, and extrapolate missing data [1, 2].

➢ **Bio PAT**

Bio PAT as process analytical technologies applied throughout

development, scale-up and commercial scale bioprocess-based production of drug substances (including manufacturing of intermediates, APIs and the final drug products. In this report, we will focus on what PAT means in practice for the biotechnological manufacture of pharmaceuticals [18].

The aim of this study is to:

- Get a technological insight of the status of the Process Analytical Technology (PAT) Initiative with regards to pharmaceutical bioprocesses
- Study the regulatory framework and future activities in Europe and the USA
- Survey the needs for monitoring bioprocesses for pharmaceutical production
- Survey the monitoring methods and technologies available
- Find key players for collaboration in Finland and globally (both research and industrial)
- Find key ongoing projects.

Moreover, the aim of this study is to analyze the situation in Bio PAT and propose actions, build up a consortium for future actions and also to find funding possibilities.

➢ **Crystallization**

Crystallization at production scale is typically a poorly understood unit operation, with the little implementation of the first principles aspect of crystallization in its design, optimization, and control. Problems with production crystallizers include the following: (1) inconsistencies of batch-o-batch in terms of the size and number of crystals produced and (2) the purity profile (residual impurities in crystals, or wrong polymorph or chiral purity). This can have a significant impact both on product quality and downstream process unit operations including filtration, drying, milling, and product formulation. This contribution reviews typical problems encountered in production crystallization, with case studies, advice, and strategies to understand and avoid these problems through the use of in situ crystallization characterization tools.

Case study and application of process analytical technology (PAT) towards bioprocessing: Use of ultra-performance liquid chromatography (UPLC) for making real-time pooling decisions for process chromatography [1, 5].

The biopharmaceutical community is interested in using Process Analytical Technology (PAT) for continuous real-time quality assurance. PAT has the potential to improve operational control and compliance. The operational definition of PAT is as "a system for designing, analyzing, and controlling manufacturing through timely measurements (i.e., during processing) of critical quality and performance attributes of raw and in-process materials and processes, with the goal of ensuring final product quality."

A desired goal of the PAT framework is to design and develop well-understood processes that will consistently ensure a predefined quality at the end of the manufacturing process. A process is generally considered well understood when,

1) All critical sources of variability are identified and explained;

(2) Variability is managed by the process and

(3) Product quality attributes can be accurately and reliably predicted over the ranges of acceptance criteria established for materials used, process parameters, manufacturing, environmental, and other conditions.

Table 1: Benefits associated with implementing PAT in Pharmaceutical industry [6, 9]

Application	Process analyzer	Observation
Analysis of organic content of waste water	NMR Spectroscopy	Less time & cost effective method
Raw material identification and quality control	Near infrared (NIR) Spectroscopy	Fast &cost effective method
Simultaneous monitoring of solute concentration and polymorphic state of crystal	Raman Spectroscopy & Attenuated total reflectance(ATR) and FTIR	Know how the rate of addition of reactant affects the Polymorphic state of crystal
Catalysis reaction involving conversion of acetone to Methyl isobutyl ketone (MIBK)	In-line NIR	Affects Productivity, selectivity, and yield of MIBK

Table 2: PAT application in chemical industry

Application	Process analyzer	Observation
Analysis of organic content of waste water	NMR Spectroscopy	Less time & cost effective method
Raw material identification and quality control	Near infrared (NIR) Spectroscopy	Fast &cost effective method
Simultaneous monitoring of solute concentration and polymorphic state of crystal	Raman Spectroscopy & Attenuated total reflectance(ATR) and FTIR	Know how the rate of addition of reactant affects the Polymorphic state of crystal
Catalysis reaction involving conversion of acetone to Methyl isobutyl ketone (MIBK)	In-line NIR	Affects Productivity, selectivity, and yield of MIBK

Table 3: PAT application in pharmaceutical industry [6, 9]

PAT	Process	Attribute analyzed	On/in/off-line
NIR spectroscopy-Transmission	Compression	Quantification of active ingredient	Off-line
Temperature sensor & increase	Granulation	Granulation end point	In line
NIR spectroscopy-Reflectance	Raw material	Identification	Off-line
NIR spectroscopy-Reflectance	Packing line	Identification	on-line
NIR spectroscopy-Reflectance	granulation	Wet granulation end point	On-line
NIR spectroscopy-Reflectance	Packing component identification	Identification of blister PVC-films	Off-line
NIR spectroscopy-Reflectance	Compression–tablets & capsules	Content uniformity & assay	Off-line
NIR spectroscopy-Reflectance	Powder	Moister content	Off-line
Image probe (CCD camera & high energy XE lighting system)	High shear granulation	Partical size & shape	In line
FT-IR with ATR probe	Pharmaceutical salt formation process	End point monitoring	In line
Raman spectroscopy	Compression	Analysis of API in tablets	Offline

Near infrared

The particle size of a powdered granulation blend or powdered pharmaceutical raw material is important in that it impacts physical properties such as powder flow, dissolution rate, compressibility, and tablet hardness. Monitoring particle size and control of the manufacturing process prevents over-processing of the product. According to the literature, the most common process analyzer to be used in the determination of particle size of milled roller compacted powder, granulation, liquids and raw material is NIR the NIR Process analyzer have been evaluated on–line, in line and off line result of this evaluation compare favourably to those of traditional methods such as sieve analysis, digital microscopy and particle size instrumentation. The sheep and spatial distribution of particles influence physical properties such as powder flow and filterability. Clark used NIR microscopy off-line to determine spatial distribution and cluster size of ingredients in granulation and compressed pharmaceutical products. Clarke concluded that NIR microscopy was a useful tool in the determination of particle shape, particle distribution and cluster size of chemical components of the sample

Raman spectroscopy

Raman spectroscopy is suitable for quantitative analysis of pharmaceutical product because of the relationship between signal intensity and API concentration. Raman spectroscopy has been evaluated for identification and quantification of active ingredients in granulation, compression, drug pellet and both off-line and at-line use Raman spectroscopy has also been used to monitor hydration states of API as a method.

CCD camera

Wotan *et al.* assessed particle size in a high share granulator in line through the use of an image prob. The imaging probe was combined with a fuzzy logic control system to control granulation growth in the high shear granulator, preventing excessive granule growth. The system was capable of accurate and reliably producing granules material and operating conditions. Lateen *et al.* assessed particle size growth in a fluidized-bed granulation process using a monochromatic CCD camera. At line analysis of granulation samples growth and granulation, end points for the fluidized bed granulation process. The conclusion was that the imaging approach used provided a rapid evolution of granule particle size [12].

X-ray diffraction

on-line application of x-ray powder diffraction was evaluated by devise *et al.* for use in monitoring the transformation of the flufenamic acid. The on-line process analyzer was successful in monitoring the polymorphic transformation of the flufenamic acid. The results of this evaluation suggest that X-ray powder diffraction m may be used as an on-line process analyzer to monitor granulation process and parameters such as granulation end time.

FT-IR process analyzer

Process analyzers have been evaluated for API synthesis. Watson *et al.* evaluated in-line FT-IR process analyzer for the conversion of Buspirone hydroxylation to 6-hydroxylbuspiron. They recommended the use of the in-line FT-IR process analyzer to monitor and control the synthesis process since in this process ensures API quality and predicted the batch reprocessing. Lin *et al.* demonstrated the ability to real time monitor a pharmaceutical salt formation process FT-IR coupled with an ATR probe, a task which cannot be accomplished with traditional analytical instrumentation Such as titration and HPLC. FT-IR ATR permitted differentiation between mono and bi-salts allowing for real-time determination of synthesis endpoint. Other benefits were improved quality monitoring, higher yields, and end of the method transfer between laboratories and FT-IR instruments, all of which contribute to improved efficiency (15, 16, 19).

Light-induced fluorescence

LIF technology is selective for fluorescent material within drug formulation. LIF measures the emission wavelength as a result of wavelength excitation. LIF technology is nondestructive.

PAT tool for the analysis of powder mixing kinetics, blend homogeneity and tablet active ingredient content. Lai and Cooney proposed that LIF would be especially useful within the pharmaceutical industry because 60% of the 200 main active ingredients fluoresce; benefits of online LIF analysis in blending include real-time blend kinetic results and reductions in errors due to thief sampling

CONCLUSION

The use of process analytical technology can provide huge benefits to the pharmaceutical industry by increasing product quality while delivering superior asset utilization and financial value. PAT provides better knowledge of raw materials by characterizing it both physically and chemically understanding of manufacturing parameters all which is having the impact on the finished product quality. Combining together all of these results in a more robust process, better product, better process control and huge time saving which ultimately result in a good saving along with creation of a unique brand image for the organization.

CONFLICT OF INTERESTS

Declare none

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