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A Process of Quality Control

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ABSTRACT
The development of a drug product is a lengthy process involving drug discovery, laboratory testing, animal studies, clinical trials and regulatory registration. To further enhance the effectiveness and safety of the drug product after approval, many regulatory agencies such as the United States Food and Drug Administration (FDA) also require that the drug product be tested for its identity, strength, quality, purity and stability before it can be released for use. For this reason, pharmaceutical validation and process controls are important in spite of the problems that countered. Process controls include raw materials inspection, in-process controls and target so for final product. IPQC stands for in process quality control. These are checks that are carried out before the manufacturing process is completed. The function o in-process controls is monitoring and if necessary adaption of the manufacturing process in order to comply with the specifications .this may include control of equipment and environment too. In-process materials should be tested for identity, strength, quality and purity as appropriate and approved or rejected by the quality control unit during the production process. Rejected in-process materials should be identified and controlled under a quarantine system designed to prevent their use in manufacturing. Quality control is a process by which entities review the quality of all factors involved in production. ISO 9000 defines quality control as "A part of quality management focused on fulfilling quality requirements The results of measurements should provide reliable information and the laboratory should prove the correctness of measurements with documented evidence. Analysts serious responsibilities to produce correct and timely analytical results, and are fully accountable for the quality of their work. The expanding national and international trade, the responsibility of national registration authorities permitting the use o A Quality Control Manager procedures to ensure that products meet Manager Key wordscarry . able to f various chemicals required long ago reliable test methods, which were acceptable by all parties concerned. Supervises staff and oversees product development quality and efficiency standard s. The Quality Control will also work with clients to ensure the final products meet their needs and requirements

Keyword: Quality Control,ISO, Total Quality Management, QA/QA, Inspection

I. INTRODUCTION

The development of a medicine product is a lengthy process involving medicine discovery, laboratory testing, beast studies, clinical trials and nonsupervisory enrolment . To further enhance the effectiveness and safety of the medicine product after blessing, numerous nonsupervisory agencies similar as the United States Food and Drug Administration(FDA) also bear that the medicine product be tested for its identity, strength, quality, chastity and stability before it can be released for use. For this reason, pharmaceutical confirmation and process controls are important in malignancy of the problems that may been combated . Process controls include raw accoutrements examination, in- process controls and target so for final product. The purpose is to cover the on- line and off- line performance of them manufacturing process and also validate it. Indeed after the manufacturing process is validated, current good manufacturing practice also requires that a well- written procedure for process controls is established to cover it performance. The QA/ QC good practice guidance outlined then reflects practicality, adequacy, cost-effectiveness, being experience, and the eventuality for operation on a world wide base. A QA/ QC programme contributes to the objects of good practice guidance, videlicet to ameliorate translucency, thickness, community, absoluteness, and confidence in public supplies of emigrations estimates. The issues of the QA/ QC process may affect in a reassessment of force or source order query estimates. For illustration, if data quality is set up to be lower than preliminarily allowed and this situation can not be remedied in the timeframe of the current force, the query estimates ought to be re-evaluated.1- 3

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Description OF IPQC

IPQC stands for IN PROCESS QUALITY CONTROL. These are checks that are carried out before the manufacturing process is completed. The function of in- process controls is covering and if necessary adaptation of the manufacturing process in order to misbehave with the specifications. This may include control of outfit and terrain too. In-process accoutrements should be tested for identity, strength, quality and chastity as applicable and approved or rejected by the quality control unit during the product process. Rejected in- process accoutrements should be linked and controlled under a counterblockade system designed to help their use in manufacturing. Written procedure should be established and followed that describe the in process controls and tests as specified [2] – [4]

¾ Tablet or capsule weight variation.

Decomposition time.

Content uniformity and homogenecity.

Dissolution time and rate.

Clarity, Absoluteness or pH of results.

When the expression " Quality is use we generally suppose in term of an excellent product or service that fulfils Or exceeds our expression ". These exception are grounded on the intended use & the selling price**.**

Quality can be defined as –

Q = P/T

Where,

Q= Quality

P= Performance

T = Expectation[15]

Quality control (QC) is a process through which a business seeks to ensure that product quality is Maintained or improved. Quality control requires the business to create an environment in which Both management and employees strive for perfection.ISO 9000 defines quality control as "A part of Quality management focused on fulfilling quality requirements"[16,17].

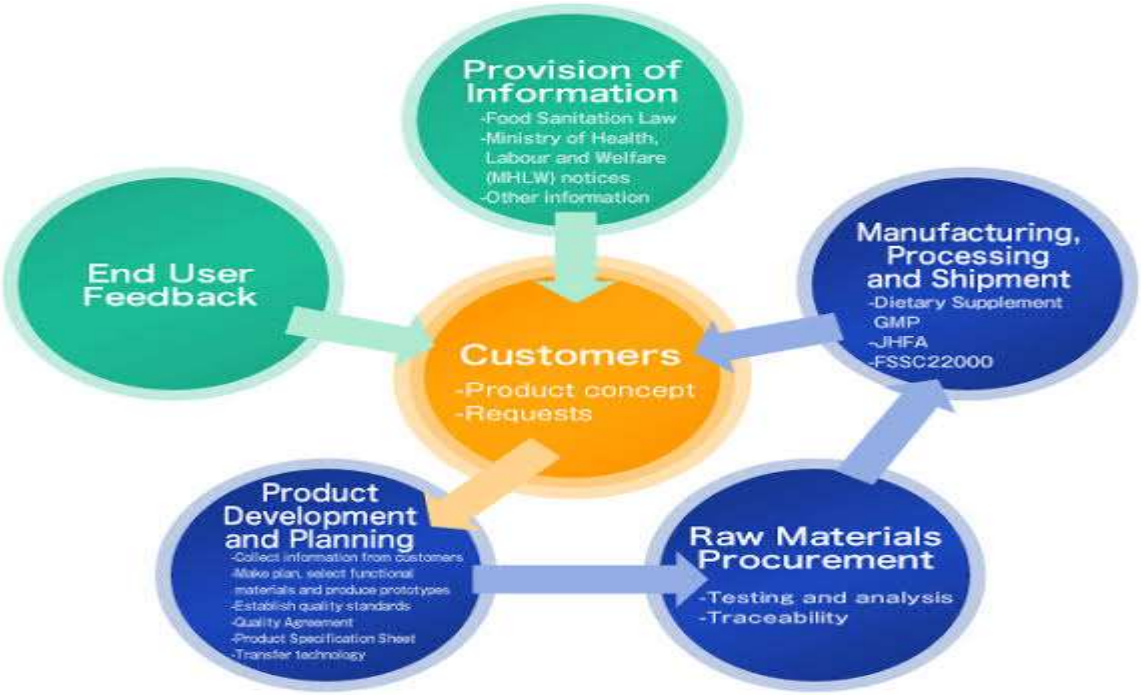

Fig. Dietary Supplements On Quality Control

In GMP, quality control deals with sampling, specifications, testing, organization, and release procedures , Which ensure that the necessary and relevant tests are conducted, and materials and products are not Released for use. Sale or supply till they are proved to be of satisfactory quality[16,18].

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PRACTICAL CONSIDERATION IN DEVELOPING QA/QC SYSTEMS

Implementing QA/QC procedures requires resources, expertise and time. In developing any QA/QC system, it in expected that judgements will need to be made on the following: Resources Allocated to QC for different source categories and the compilation process; Time allocated to Conduct the checks and reviews of emissions estimates; Availability and access to information on Activity data and emission factors, including data quality; Procedures to ensure confidentiality of Inventory and source category information, when required; Requirements for archiving Information; Frequency of QA/QC checks on different parts of the inventory; The level of QC Appropriate for each source category; Whether increased effort on QC will result improved Emissions estimates and reduced uncertainties; Whether sufficient expertise is available to Conduct the checks and reviews. In practice, the QA/QC system is only part of the inventory Development process and inventory agencies do not have unlimited resources. Quality control Requirements, improved accuracy and reduced uncertainty need to be balanced against Requirements for timeliness and cost effectiveness. A good practice system seeks to achieve that Balance and to enable continuous improvement of inventory estimates. Within the QA/QC System, good practice provides for greater effort for key source categories and for those source Categories where data and methodological changes have recently occurred, than for other source categories3It is unlikely that inventory agencies will have sufficient resources to conduct all the QA/QC procedures outlined in this review on all source categories. In addition, it is not Necessary to conduct all of these procedures every year. For example, data collection processes Conducted by national statistical agencies are not likely to change significantly from one year to The next.4 Once the inventory agency has identified what quality controls are in place, assessed The uncertainty of that data, and documented the details for future inventory reference, it is Unnecessary to revisit this aspect of the QC procedure every year. However, it is good practice to Check the validity of this information periodically as changes in sample size, methods of Collection, or frequency of data collection may occur. The optimal frequency of such checks will Depend on national circumstances. While focusing QA/QC activities on key source categories Will lead to the most significant improvements in the overall inventory estimates, it is good Practice to plan to conduct at least the general procedures. General QC Procedures on all parts of The inventory over a period of time. Some source categories may require more frequent QA/QC Than others because of their significance to the total inventory estimates, contribution to trends in Emissions over time or changes in data or characteristics of the source category, including the Level of uncertainty.5,6 For example, if technological advancements occur in an industrial source Category, it is good practice to conduct a thorough QC check of the data sources and the Compilation process to ensure that the inventory methods remain appropriate5-7. It is recognised That resource requirements will be higher in the initial stages of implementing any QA/QC System than in later years. As capacity to conduct QA/QC procedures develops in the inventory Agency and in other associated organisations, improvements in efficiency should be expected. The general procedures require no additional expertise in addition to that needed to develop the Estimates and compile the inventory and should be performed on estimates developed using Tier 1 or higher tier methods for source categories. A review of the final inventory report by a person Not involved in the compilation is also good practice, even if the inventory were compiled using Only Tier 1 methods. More extensive QC and more rigorous review processes are encouraged if Higher tier methods have been used. Availability of appropriate expertise may limit the degree of Independence of expert reviews in some cases. The QA/QC process is intended to ensure Transparency and quality.6,7

1. **Basic requirement of Quality Control**
2. All the batches of product should be analysed approved According to the requirements of the relevant Authorizations.
3. It should be ensure that the finished product contain APIs that Comply with the qualitative & Quantitative composition of the marketing authorization are of the required purity & are enclosed in Properly labelled container[19,15].
4. Sample of starting material packaging material intermediates & Bulk finished product should be taken By personal & by method Approved by quality control department
5. Sufficient facilities, trained person & approval procedure for Sampling insection & testing of starting

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6. Material ,packaging Material ,intermediates, bulk & finished product and the test Method should be Validated [20].
7. Record should be maintained either manually or by using Recording instrument to ensure that all the Required sampling Inspection and testing procedure were conducted. If any Deviation is found it should Also be recorded & further Evaluated[21,16].
8. The result of insecption & testing of material,intermediates and Bulk & finished products should be Recorded & formally Evaluated against standards products assument should cover a Review & evalution of Relevant production documentation & an Assement or deviation from specified procedures[22].

ELEMENTS OF QA/QC SYSTEM

The following are the major elements to be considered in the development of a QA/QC system to
be implemented in tracking inventory compilation:

- An inventory agency responsible for coordinating QA/QC activities;
- A QA/QC plan;
- General QC procedures
- Source category-specific QC procedures
- QA review procedures;
- Reporting, documentation, and archiving procedures.
- For purposes of the QA/QC system, the QC approach includes all procedures in plus additiona

QUALITY CONTROL EQUIPMENTS [7,9]

Friabilator

Friabilator is the instrument which is used to detect the friability of the tablets .Friability is the Combined effects of shock and abrasions. So to resist shock and abrasions friability test is done For the tablets. In this a no. of tablets are put in the friabilator and revolves at 25rpm,dropping The tablets a distance of six inches with each revolutions .Conventional compressed tablets that Lose less than 0.5 to 1.0% of their weight are generally considered as acceptable. When capping Is considered on friability testing , the tablet should not be considered as for commercial use, Regardless of the %age of loss seen.

Dissolution test apparatus

The dissolution test is conducted to assure that drug is properly breaks into their parts in a Respective medium. Dissolution testing can be continued through three stages .

STAGE(1-3)-Six tablets are tested and are acceptable if all the tablets are not less than Monograph tolerance limit plus 5%.if the tablet fails ,an additional six tablets are tested. The Tablets are acceptable if average of the twelve tablets are greater than or equal to tolerance limit And no unit less than tolerance limit minus 15% ,if tablet still fails the test, an additional 12 Tablets are tested. The tablets are acceptable if the average of all 24 tablets is greater than or Equal to tolerance limit and if not more than 2 tablets are less than tolerance limit minus 15%.Industrial pharmacists routinely test their formulations for dissolution.7

Digital pH meter

Digital pH meter is used in pharmaceutical industries to assure the pH of the solutions which is Needed for the preparation of the drug, pH is very important to make assure the stability of the Product. Solutions stability investigation usually commence with probing experiments to confirm Decay at the extremes of pH for an e.g 0.1N HCL,Water, and0.1N NaOH).These intentionally Degraded samples may be used to confirm assay specificity as well as to provide estimates for Maximum rates of degradation. This initial experiment should be followed by the generation of a Complete pH rate profile to identify the pH of maximum stability. Aqueous buffers are used to Produce solutions over a wide range of ph values with constant levels of drug ,cosolvent and Ionic strength. Since most solution pharmaceuticals are intended for parenterals routes of Administration ,this initial ph Rte study should be conducted at a constant ionic strength that is Compatible with physiologic media. Ionic strength of an isotonic 0.9% NaCl solution is 0.15.8

Moisture analyzer

A moisture analyzer indicating by its name as to analyze moisture in a drug content. The formula Which is used to detect moisture is as follows:

% moisture content(M.C) = (wt. of water in sample/wt. of dry sample)*100

Drying of solids

The moisture content in a solid can be expressed on a wet-weight or dry weight basis .On a wet Weight basis, the water content of a material is calculated as a %age of the weight of the Wet solid ,whereas on the dry weight basis, the water is

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expressed as a %age of the weight of the Dry solid. In pharmacy loss on drying is commonly referred as L.O.D, is an expression of Moisture content on a wet weight basis which is calculated as follows:8

Process viscometer

This instrument is capable for performing the rheologic studies of most pharmaceutical Preparations such as semi-solid preparations or formulations :pastes, ointments and creams.

Digital refractometer

Digital refractometer is used for those product which are sensitive to light refraction so it is Simply used to check the refraction spectrum of drug product.7

Leak test apparatus

A leak test apparatus is used for checking the crimping of the valve which must be available to Prevent defective containers due to leakage. For metal containers, this is accomplished by Measuring the "crimp" dimensions and ensuring that they meet specifications. Final testing of the Efficiency of the valve closure is accomplished by passing the filled containers through the water Bath. Periodic checks are made of the temperature of the water bath, these results are recorded.

Quality Control Tools

There are many approaches to quality control. The type you use depends on your specific product and Should be determined before any quality control inspection begins. There are seven primary quality Control tools which include:

- ✓ Checklists. At its most basic, quality control requires you to check off a list of items that areImperative to manufacture and sell your product.
- ✓ Fishbone diagram. This visual is helpful for determining what causes a specific problem, be it Materials, machines, methods or manpower.
- ✓ Control chart. This helps you see how processes historically change using controls. The chart Helps you find and correct problems as they happen, predict a range of outcomes and analyze Variations [19,23].
- ✓ Stratification. Instead of looking at all factors together, stratification separates data so you can Identify patterns and specific problem areas.
- ✓ Pareto chart. This type of bar chart provides a visual analysis of problems and causes so you can Focus on the most significant issues.
- ✓ Histogram. A common graph that uses bars to identifies frequency distributions that indicate how Often defects occur [20,24].
- ✓ Scatter Diagram. Plotting information along two axes on this graph can help visually identify Relationships between variables.
- ✓ A quality control inspector uses one or more of the available tools or methods to do a complete
- ✓ Analysis of a product or service to determine where improvements can be made. An inspector
- ✓ Typically gets training to know what method to use and how to properly use it [25]

IPQC TESTS FOR VARIOUS DOSAGE FORMS:[7-11]

Tablets:

A. Drug contents determination.
B. Moisture contents of granules.
C. Assay of active ingredients.
D. Weight variation of uncoated tablets.
E. Hardness test.
F. Disintegration test.

Drug Content Determination

A physically sound tablet may not produce the desired effects. To evaluate a tablet potential for Efficiacy, the amount of drug per tablet needs to be monitored from tablet to tablet and batch to Batch, and a measure of the tablets ability to release the drug needs to be ascertained.

Moisture Content of granules

Granules should possess sufficient strength to withstand normal handling and mixing processes Without breaking down and producing large amounts of fine powder. On the other hand, some Size reduction during compaction into tablets is desirable to expose the areas of clean surface Necessary for optimum bonding to take place so moisture content is the very important factor for Producing god pharmaceutical product.

Assay of active ingredient

In a tablet an active ingredient is present which is called active pharmaceutical ingredient (A.P.I).So to prepare the tablet assay has to be done to produce good finished product.

Hardness test

The monitoring of tablet hardness is especially important for drug products that possess real or Potential bioavailability problems that are sensitive to altered dissolution release profiles as a Function of the compressive force employed .One of the earliest testers to evaluate tablet Hardness was the Monsanto hardness tester to evaluate tablet hardness tester.

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Disintegration test

A generally accepted maximum is that drug to be readily available to the body, it must be in Solution. For most tablets, the first important step towards solution is break down of the tablet Into smaller particles or granules, a process known as disintegration .The U.S.P device to test Disintegration uses 6 glass tubes that are 3 inches long, open at the top, and held against a 10 Mesh screen at the bottom end of the basket rack assembly To test for disintegration time, one tablet is placed in each tube , and the basket rack is positioned in a 1-L beaker of water ,simulated gastric fluid and at 37°-+2°c ,such that tablet remains 2.5cm below the surface of the liquid on their upward movement and descend not closer than 2.5cm from the bottom of thebeaker. A standard motor driven device is used to move the basket assembly containing the tablets up and down through distance of 5 to 6cm at a frequency of 28 to 32 cycles per minute.

I.P.Q.C TEST FOR SYRUPS AND SUSPENSION[9-11]

- Drug contents determination.
- Assay of active ingredients.
- pH.
- Weight per ml.
- particle size

Drug content determination

Determination of drug content in suspension and syrups are important because their concentration has to be sufficient itself that it produce thepharmacological action. A suspension is much prescribed to pediatrics so their concentration has to be sufficient not to less not to large.

Assay of active ingredient

Active ingredient means pure drug present in the product .An assay of active ingredient must be done because it is the only which is responsible for pharmacological action and in syrups and suspension a small and fine particles are included in syrups and suspension

pH of the product

pH affects the stability of the product so before filling and after filling of suspension and syrups pH has to be checked out for consistency of the product.

Particle size

In suspension and syrups a solute particles is dispersed in a suitable solvent so particle size becomes the I important factor for the suitability of the product and all the particles has to be of same size and shape for proper dispersing in the solvent.

I.P.Q.C TEST FOR SEMI- SOLIDS [11-12]

a) Drug contents determination.
b) Assay of active ingredients.
c) Uniformity and homogeneity test.
d) Viscosity and specific gravity test.
e) Filling test.

Drug content determination

As all have discussed earlier drug content becomes important factor for active pharmaceutical Product. Drug content has to be of very suitable ratio that it can give the pharmacological action.

Homogenecity test

The semi-solid preparations require further treatment are transferred or pumped to the proper Homogenizer, the selection of which is governed by the degree and rate of shear stress required.

Viscosity and Specific gravity test

Once the desired semi-solid preparation have been chosen, a consistency that provides the Desired stability and has appropriate flow characterstics must be attained. For emulsion it is Routinely observed that the building up of viscosity in a freshly prepared emulsion requires some Time. The is recommended, therefore that newly formulation emulsion be allowed to rest Undisturbed for 24 to 48 hours before it is determined whether its rheology properties Correspond to those that are required. The viscosity of emulsions responds to changes in Composition in accordance with the following generalizations.

- There is a linear relationship between emulsion viscosity and viscosity of continous phase.
- The greater the volume of the internal phase, the greater is the apparent viscosity.
- To control emulsion viscosity, three interacting effects must be balanced by the formulator.
- The viscosity of o/w and w/o emulsions can be increased by the reducing the particle size of The dispersed phase.
- Emulsion stability is improved by a reduction in particle in particle size.
- Flocculation or clumping which tends to structure the internal phase ,can be stabilizing Effect, it increases the viscosity .

I.P.Q.C TEST FOR INJECTABLES [6-8]

- Drug contents determination.
- Clarity test.
- pH.

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- Pyrogen test.
- Stability test.
- Leakage test.
- Check up of particulate matters.

Pyrogen test

The presence of pyrogenic substance in parentrals is determined by a qualitative biologic test Based on the fever response of the rabbits. Rabbits are used as test animal because they show aphysiologic response to pyrogens similar to that of human beings. If a pyrogenic substance is Injected into the vein of a rabbit, an elevation of temperature occurs in a period of three hours.

Sterility test

All products labelled "sterile" must pass through sterility test, having been subjected to an Effective process of sterilization. The traditional concept of sterilization is the absolute condition Of total elimination of all the microorganisms. With a terminal methods of sterilization of a Parenteral product, particularly steam under pressure, a probability of no more than one sterile Unit in a million is readily achievable. The term aseptic indicates a controlled process in which The level of microbial contamination is reduced to the degree that microorganisms can be Excluded from a product during processing. It describes apparently sterile state.

Leaking test

Ampules are intended to provide hermetically sealed container for a single dose of a product, Thereby completely barring any interchange between the contents of the sealed ampule and its Environment. Should capillary pores or tiny cracks be present, microorganisms or other Dangerous contaminants may enter the ampule or the contents may leak to the outside and spoil The appearance of the package. Changes in temperature during storage cause expansion and Contraction of the ampule and contents, thereby accentuating interchange if an opening exists. Leakers usually detected by producing a negative pressure with an incompletely sealed ampule, Usually in a vacuum chamber, while the ampule is entirely submerged in a deeply coloured dye Solution ,usually 0.5 to 0.1% methylene blue. Subsuequent atmospheric pressure then causes dye To penetrate an opening, being visible after the ampule has been washed externally to clear it of Dye. The vacuum (27 inches Hg or more) should be sharply released after30 min. Only a tiny Drop of dye may penetrate a small opening. Vials and bottles are not subjected to such a leaker Test because the rubber closure is not rigid; however, bottles are often sealed while a vacuum is Being pulled so that the bottle remains evacuated during its shelf life.

Clarity test

Clarity is the relative term, the meaning of which is markedly affected by the subjective Evaluation of the observer. Unquailingly a clean solution having a high polish conveys to the Observer that the product is of exceptional quality and purity .It is practically impossible, However, to prepare a lot of a sterile product so that every unit of that lot is perfectly free from visible particulate matter, that is , from particles that are 30 to 40 micrometre and larger in size. Consequently it is the responsibility of the quality control department to detect and discard individual containers of a product that the ultimate user would consider to be unclean. This clarity test is performed in industry by visual inspection machine by the light baffles against reflection into the eyes, and views against a black and white background, with the contents set in motion with a swirling action

Stability

To enhance the assurance of successful manufacturing operations, all process steps must be carefully reduced to writing after being shown to be effective. These process steps are often called standard operating procedures(SOPs).No extemporaneous changes are permitted to be made in these procedures; any change must go through the same approval steps as the original written SOP. Further external records must be kept to give assurance at the end of the production process that all steps have been performed as prescribed. Such in-process control is essential to assuring the quality of the product, since these assurances are even more significant than those from product release testing.

History of Quality control

The history of quality control is undoubtedly as old as industry itself . During the middle age Quality was to A large extent controlled by the long period of training required by the guild this training pride in workers For quality of a product. Until early 19^{th} century ,the factory system ,with started in great Britain in the mid 1950s & grew into the industrial revolution in early 1800s.

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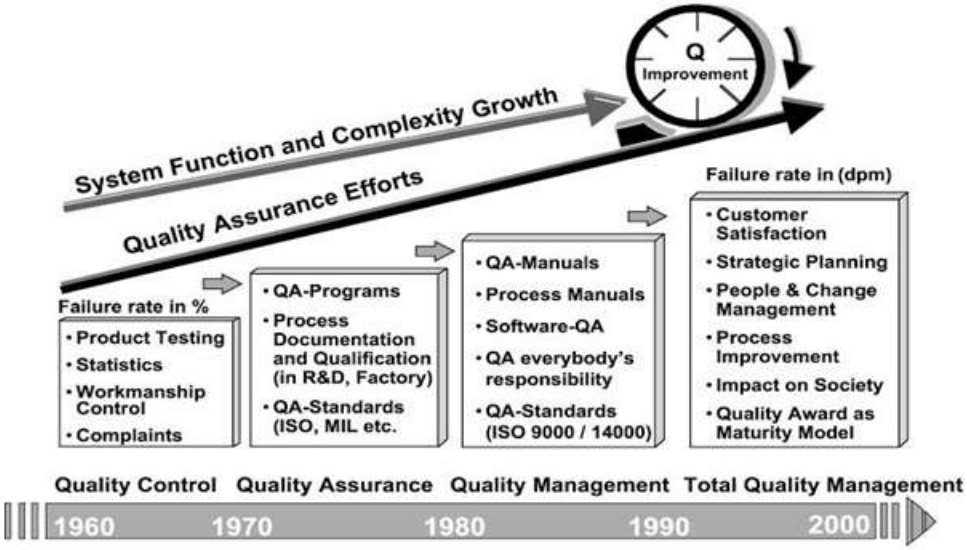
American quality practices involved in the 1800s As their was shaped by changes [25,27].



Evolution from quality control to Total Quality

The simplest form of quality control was a sketch of the desired item. If the sketch did not match the item, It was rejected, in a simple Go/no go procedure. However, manufacturers soon found it was difficult and Costly to make parts be exactly like their depiction; hence around 1840 tolerance limits were introduced, Where in a design would function if its parts were measured to be within the limits. Quality was thus Precisely defined using devices such as plug gauges and ring gauges. However, this did not address the Problem of defective items; recycling or disposing of the waste adds to the cost of production, as does Trying to reduce the defect rate. Various methods have been proposed to prioritize quality control issues And determine whether to leave them unaddressed or use quality assurance techniques to improve and Stabilize production [28].In 1924, W.A Shewhart of bell telephone Laboratories developed a statistical chart for the control of Product variable .This chart is considered to be the beginning of statistical quality control of product . IN 1946 the American society of quality control was formed .Walter Shewhart began to focus on controlling Process in the Mid 1920 ,making quality relevant not only for the finished product but for the process that Created it.In 1960, the first quality control circle as formed for the purpose of quality improvement. Simple Statical technique were learned & applied by japans & other workers [29].

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- Histogram. A common graph that uses bars to identifies frequency distributions that indicate how Often defects occur [6,10].
- Scatter Diagram. Plotting information along two axes on this graph can help visually identify Relationships between variables.
- A quality control inspector uses one or more of the available tools or methods to do a complete Analysis of a product or service to determine

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where improvements can be made. An inspector Typically gets training to know what method to use and how to properly use it [11].

Importance of Quality Control

Quality control is not the responsibility of any one person or functional area. It is everyone's Job. It Includes the assemblylene worker, the typist, the purchasing person & CEO of the company. The Responsibility for quality start when marketing Determines the customers Quality ,requirements& Continues until the product is received by a satisfied customer.Quality is critical to satisfying your customers and retaining their loyalty so they continue to buy from you In the future. Quality products make an important contribution to long-term revenue and profitability. They also enable you to charge and maintain higher prices [21,30].Consumers always get quality products of standard specifications to their utmost satisfaction. It is a well known fact that some variations are bound to exist in the nature of production in spite of careful planning. The magnitude of variations depends upon the production process, namely, machines, materials, Operations, etc. The techniques of quality control help in the study of these variations in quality of the Product and serves as a useful tool for the solution of many manufacturing problems which cannot be Solved so well by any other method.Thus, quality control is an important technique in the hands of management to maintain the quality of the Product [31].

Benefits of Quality Control

Consumer satisfaction

It's the consumers that benefit the most from the improved quality of the products. In other words, They get the best product from their desired company.

1. Reduction of production cost

If the production and operations go through inspection, the cost of the production comes down Significantly. Aside from this, quality control also keeps tabs on wastage and the production of low quality products. So, the cost of production can be cut down significantly.

2. Resource utilization

Quality control makes sure that the available resources are utilized to their fullest. Again this Ensures that the all types of inefficiencies and wastage is brought under control.

3. Reduced inspection cost

Another benefit of control over quality is that the cost of inspection can be reduced greatly

4. Increased goodwill

If quality products are made, customers are satisfied. As a result, the goodwill of the company goes Up. As a result, the company can get financed more easily.

5. Price fixation

With quality control measures, companies can make products that have the same level of quality. As a result, the company can solve the common problem: price fixation. These are a few common Benefits of quality control that a company or firm can enjoy. Hopefully, now you have a betterUnderstanding of the importance of quality [27,31,32]

Disadvantage of quality control

A major problem is that individuals are not necessarily encouraged to take responsibility for the quality of Their own work. Rejected product is expensive for a firm as it has incurred the full costs of production but Cannot be sold as the manufacturer does not want its name associated with substandard product. Some Rejected product can be re-worked, but in many industries it has to be scrapped – either way rejects incur More costs, A quality control approach can be highly effective at preventing defective products from Reaching the customer. However, if defect levels are very high, the company's profitability will suffer Unless steps are taken to tackle the root causes of the failures [32,33].

II. CONCLUSION

Monitoring chemical processes for the formation of an API is the first step to ensuring quality in Pharmaceutical manufacturing. Having reliable and reproducible methods will enable the Production plant to guarantee the consistency of drugs batch after batch. Furthermore, it may Simplify the characterization of such processes and their chemical profile. Through the years, Vast publications and general information have been presented to pharmaceutical industry Specialists about the validation of analytical methods. Federal and international regulatory groups Have published various guidelines to shed light on analytical method validation. No such Emphasis has been given, or guidelines described, however, the validation of in- process control Methods. This article intends to establish a starting point for discussions about the validation of In- process

methods. So in this, in- process methods quality control and validation are dealed With several of criteria that are discussed in this review.

REFERENCES

[1]. Chow S. Pharmaceutical Validation and Process Controls in Drug Development. Drug Inf J 1997;31: 1195-201.
[2]. Committee on Specifications for Pharmaceutical Preparations. Good Manufacturing Practices For Pharmaceutical Products.WHO Technical Report Seriesno.82.geneva: World Health Organization, 1992, pp 14-79.
[3]. , M.(1922) overview of compaction data analysis techniques. Drug Dev.Ind. Pharm, 18:767-810.
[4]. Hiestand, E.N.,Wells,j.e.,Poet,C.B. and Ochs, J.F(1977) Physical processes of Tabletting,J.Pharm.science.66:510-519.
[5]. Dureli.A.J.Lin,Y.H(1986) stress and displacements on boundaries of circular rings Diametrically loaded .J. Appl.Mech.53:213-219.
[6]. Podzeck,f and Newton ,J.M. (2003) The implications of the determinations of the mechanical Strength of powder compacts containing a pre-formed hole. Powder Technol.132:10-15.
[7]. Seitz,J.A. andFlessland, G.M. (1965) Evaluation of physical properties of compressed Tablets,1:tablets hardness and friability.J Pharm.Science.,54:1353-1357.
[8]. Upadrashta, S.M., Katikaneni, P.r. and Nussela, N.O . (1922) Chitosan as a tablet Binder.Drug Dev .Ind.Pharm.,18:1701-1708.
[9]. Fell,J.T.and Newton,J.M(1970) Determination of the tablet strength by diametrical-Compression test. J.Pharm.Sci .,59:688-691.
[10]. Odeku.O.A and Itiola O.A(2003)Evaluation of the effects of khaya gum on the mechanical And release properties of paracetamol tablet formulation. Drug Dev.Ind.Pharm.,29,311-320.
[11]. Chapman GM, Amer G, Boyce C, Brower G, GreenC, Hall WE, Harpaz D, Millender B. Proposed Validation Standard VS1:Non-aseptic Pharmaceutical Processes. J Val Technol 2000;6:502-20.
[12]. Le Blane DA. Establishing scientifically justified acceptance criteria for cleaning validation Of finished drug product. Pharm Technol 1998;23(10): 136-48.
[13]. Nash RA. Process Validation of a 17-Year retrospective study of solid dosage forms. Drug Dev Ind Pharm 1966; 22 (1): 25-34.
[14]. Jenkins KM, Vanderwielen AJ. Cleaning Validation:An Overall Perspective. Pharm Technol 1994;18(4): 60-74.
[15]. Textiles committee, Integrated Skill Development Training Program: Conducted At Metal handicrafts service Centre; Quality control.
[16]. Dr. Derming to the Pacific Basin Foundation On September 8, 1981: Production and Operation Management Page no. 131- 170.
[17]. Arpad Ambrus: Hungarian Food Safety Office, Budapest: Chapter- 5, Quality Assurance Page no. 31.
[18]. Co- Chairs, Editors and Experts, Quality Assurance and Quality Control: Chapter-8: IPCC Good Practice Guidance and Uncertainty Management in national greenhouse gas inventories.
[19]. en.m.wikipedia.org> wiki> Quality Control.
[20]. Wadsworth Hm, Stephens K.S Godfrey A.B modern methods Second edition ,John Wiley & sonsInc.
[21]. Yu tao , wang G. Research of on-line process Quality control system Sep 2008.
[22]. Eugeno L Grant ,Statistical Quality control , MC Graw-Hill Jaunary 1996.
[23]. Judi H.M, Jenal R. & Genase D. Quality control Implementation in manufacturing companies motivating factors & challenges 2011.
[24]. William B. Stiles , Quality control in qualitative research ; clinical psychology review , Vol 13,1993.
[25]. Salvi .S.S, kerkar S.S. , Qualitative Assurance & Quality Control for project effectiveness in construction & Management , Vol. 9 ,(2) ,2002.
[26]. Leong T.K & zakuan N , Review of quality management system research in management Industry , Int J. Productivity & Quality Management , Vol. 13 (1),2014.
[27]. Neyestani B , Seven Basic Tools of Quality control : The Appropriate Techniques for solving Quality Problems in the organizations , 2017.

[28]. Quality assurance of pharmaceutical ; A compendium of Guidelines , Vol. 2 , By WHO.
[29]. Sarker dipak kumar, quality system and control for pharmaceutical , wiley.
[30]. Teasdale Andrew ,Elder David and Nims Raymond W., ICH Quality Guideline : An implementation guide , wiley.
[31]. Besterfield D.H ., Quality Control ; Seventh Edition pearson Education, 2006.
[32]. Bruce S. , A Brief history of Quality control : 10 Jul 2015 ;Manufacturing & QC Blog.
[33]. Bloom L. , Type of quality control ; Biz fluent , 2018 ; Tools & Techniques for measuring Quality.
[34]. Arachchi S.M chong S.C. , Madhushani A.G.I, Quality Assurance & Quality Control in ERP System Implementation ; American Scientific Research J. For Eng. , Tech & Sci