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QA/QC in the Pharmaceutical Science: A Review

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ABSTRACT: Quality Assurance in pharmaceutical supply system is to help ensure that each medicine reaching a patient is safe ,effective and of acceptable quality.A comprehensive quality assurance program includes both technical and managerial activities. Quality control is an essential operation of the pharmaceutical industry. It may also perform the statistical evaluation of the test results to show that the process is reproducible. It analyzes the product complaints to learn how effective its test program has been in preventing rejectable product from reaching the market place.
KEYWORDS: Quality control,Quality Assurance,IPQC.

I. INTRODUCTION

[1] Quality Control and quality assurance and good manufacturing practices are the prime consideration for the manufacturing distribution and marketing of the Pharmaceutical products for the ensuring of its identity,strength, purity pharmacological safety and efficacy and effectivity. The term Quality Assurance and quality control and good manufacturing practices are define in most of the international regulatory documents including WHO,USFDA,MHRA,TGA,MCC,etc. The quality of the product of Pharmaceutical manufacturer depends on the fact that up to which satisfactory level of QA ,QC and GMP system has been adopted in the process of manufacturing ,distribution and marketing of products during its total shelf life. The main objective of this review is to demonstrate the basic difference among the quality Assurance and quality Control and good manufacturing practices and emphasize their necessity for the Pharmaceutical product.

[2,3] The QA/QC good practice guidance outlined here reflects practicality, acceptability, cost-effectiveness, existing experience, and the potential for application on a world wide basis. A QA/QC programme contributes to the objectives of good practice guidance, namely to improve transparency, consistency, comparability, completeness, and confidence in national inventories of emissions estimates. The outcomes of the QA/QC process may result in a reassessment of inventory or source category uncertainty estimates. For example, if data quality is found to be lower than previously thought and this situation cannot be rectified in the timeframe of the current inventory, the uncertainty estimates ought to be re-evaluated.

Figure 1 :Composition of Good Manufacturing Practices

II. WHO DEFINITION OF QUALITY ASSURANCE[4]

• Quality Assurance is a wide-ranging concept covering all the matter is that individually or collectively influence the quality of product it is the sum total of the organised arrangements made with the object of ensuring that Pharmaceutical products are of the expected quality required for their intended use.

• Quality Assurance therefore, Incorporates GMP (good manufacturing practices), GLP (good

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laboratory practice) ,and original product design and development.

• QA = GMP + QC + Product design & Development + Quality Goal Activities.

2.1.FUNCTION OF QUALITY ASSURANCE SYSTEM AS PER GUIDELINES OF WHO [5]

• designing and developing the medicinal product as per the requirement of GMP and other associated codes such as Good Laboratory Practice(GLP) and Good Clinical Practice (GCP).

• Specifying production and control operations clearly in written form and adopting the GMP requirements.

• Specifying managerial / key personnel responsibilities clearly in a job descriptions.

• Making necessary arrangements for the manufacture supply and use of the correct starting and packing materials.

• Carrying out the necessary controls on the starting materials,intermediate and bulb product and other in process control, calibrations and validations.

• Correct processing of finished product and checking the quality according to the define procedures.

• Ensuring that the Pharmaceutical products are not sold or supplied before the authorised person have certified that each production batch has been produced and control in accordance with the requirements of the marketing authorisation and any other regulation relevant to the production, control and release of products.

• Making satisfactory arrangements to ensure that medicinal products are stored distributed and subsequently handled in such a way that quality is maintained throughout their shelf life.

• Establishing a procedure for self inspection and quality audit which appraises the effectiveness and applicability of the quality assurance system.

[6]Article will focus on some of the Pharmaceutical Quality Systems in relation to QA of manufactured medicines. The eight pillars of PQS constitute a good foundation for discussion.

Figure:2 Eight Qualiy Systems Contribute to the high quality of the finished pharmaceutical products

2.1.1. Quality by design

[7] ICH Q8 defines design space from the concept that quality cannot be tested into product but has to be built in by design.

2.1.2. Quality risk management

[8] All products and all processes have an inherent element of risk. organization that is intending to apply an effective quality risk management approach, a clear definition of whatis considered ''risk'' should be agreed upon because of the too many stakeholders in the pharmaceutical industry and their corresponding diverse interests. Risk management plans should be used to identify risk.Quality Risk Management is defined as a method for the assessment, control, communication and review of risks tothe quality of the drug (medicinal) product through the product lifecycle where decisions can occur at any point in the process.

Figure 3:Process of quality risk management

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2.1.3. Corrective action and preventive actions

[9] The organization should focus on correcting and preventing problems. Preventing problems is generally cheaper than fixing them after they occur. The organization should also start thinking about problems as opportunities to improve ‘‘Root cause analysis’’ is a process by which the manufacturer can identify causes and preventive actions.

2.1.4. Six Sigma

[10] Six Sigma Projects are based on the DMAIC model.The DMAIC model is the generic model of six sigma methodology. It is an acronym that stands for; Define, Measure, Analyze, Improve and Control. Sometimes this model includes recognize as an awareness item to the model. Each of the components addresses a different aspect of the overall improvement and breakthrough strategy.

2.1.5. Total quality management

[11] Total quality management (TQM) is a concept rather than a technique. It is a philosophy that stresses a systematic, integrated, and consistent perspective that would involve everyone and everything in the organization. TQM is widely known for improving quality and other performancessuch as productivity, profit, market share, and competitive edge of organizations of various types.

III. WHO DEFINITION OF QUALITY CONTROL[12]

• Quality control is essential part of the GMP which is concerned with sampling, specifications ,and testing as well as with the organisation ,documentation, and release procedures which ensures that the necessary and relevant test are carried out, and that material are not released for the use ,nor products release for sale or supply until their quality has been judged to be satisfactory.

• Quality control is not confine to the laboratory operations only but must be involved at all the stages and in all the decision concerning the quality of the products for the achievement of the quality objectives.

• QC= Testing + Assessment.

• Basic requirements for quality control:

i)Adequate facilities trained personal and approved procedures must be available for the sampling inspection and testing of the starting materials, packaging materials, and intermediate, bulk and finished products,and for a monitoring envirnonmental conditions for GMP purposes.

ii)Sampling of starting materials,packaging materials, intermediate products,bulk products and finished products must be taken by the methods and personal approved by the quality control department.

iii)The test methods must be validated.

iv)Records must be made demonstrating that all the required Sampling, inspecting, and testing procedures have actually been carried out and that any deviation have been fully recorded and investigated.

3.1.Quality Control Equipment [13,14,15]

3.1.1. 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.

Figure 4:Roche friabilator

3.1.2.Dissolution test apparatus

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

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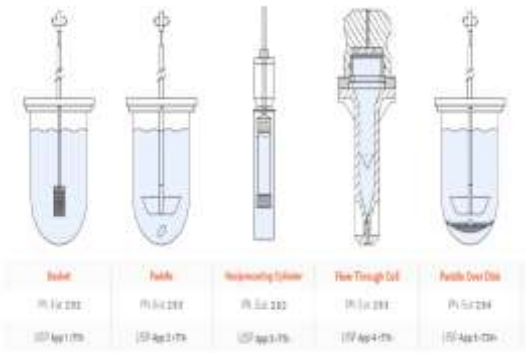
Figure 5:Dissolution test apparatus according to USP



3.1.3.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.

Figure 6:Digital pH meter

3.2.IPQC TESTS FOR VARIOUS DOSAGE FORMS[13,15,16]

Tablets:

a)Drug contents determination.
b)Moisture contents of granules
c)Assay of active ingreadients
d)weight variation of uncoated tablet
e)Hardness test
f)Disintegration test.

Syrups and Suspension

a) drug content determination
b) assay of active ingredients
c) weight per ml
d) particle size

Semisolids

a) Drug contents determination
b) Assay of active ingreadients
c) uniformity and homogeneity test
d) viscosity and specific gravity test
e) filling test

injectables

a) Drug contents determination
b) clarity test
c) pH
d) pyrogen test
e) stability test
f) leakage test
d)check up of particulate matters

IV. CONCLUSION:

When it comes to our focus,we understand that quality control is a product-oriented process.when it comes to quality assurance,it is a process oriented practice.

When quality control makes sure the end product meets the quality requirements,quality assurance makes sure that the process of manufacturing the product does adhere to standard.

Therefore,quality assurance can be idntified as a proactive process,while quality control can be noted as a reactive process.

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