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A REVIEW ON GOOD MANUFACTURING PRACTICE (GMP)

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ABSTRACT

A component of quality assurance known as "good manufacturing practices" guarantees that goods are continuously produced and controlled to the quality requirements relevant to their intended use and as mandated by the marketing license. GMP rules provide minimum standards that manufacturers of food or pharmaceutical items must fulfill to ensure that their products are safe for consumers and do not pose any risks. The safety and effectiveness of medical products are dependent on the healthcare industry upholding high standards of quality. The manufacture, control and quality assurance of medicines, medical devices and other healthcare items are made easier with the support of a system of rules and regulations known as good manufacturing practices or GMPs. In order to protect patient health and uphold public confidence this research study examines the importance of GMP in the healthcare sector. The fundamental tenets of GMP are examined along with the regulatory environment and its effects on medication production, quality assurance, product safety and regulatory compliance among other facets of the healthcare industry. In addition, the paper addresses the difficulties and prospects for GMP implementation in the future highlighting the necessity of continual improvements to satisfy the changing needs of the sector.

KEYWORDS: Good Manufacturing Practices (GMP), Healthcare industry, Quality control, Product safety.

INTRODUCTION

GMP is a system for ensuring that products are consistently produced and controlled according to quality standards. It is designated to minimize the risks involved in any pharmaceutical production that cannot be eliminated through testing the final product. GMP-is intended to assure that raw materials used in the manufacture of drugs are of i.Known quality ii. Standardized quality iii. Free from contamination.[4]

A component of quality assurance known as good manufacturing practice (GMP) makes ensuring that goods are regularly manufactured and controlled to the quality standards necessary for their intended use and as stipulated by the marketing authorization. The primary goal of GMP is to reduce the hazards that are present in the production of pharmaceuticals, which can be broadly divided into two categories incorrect labeling and cross-contamination/mix-ups.[9] Above all, producers must ensure that their products do not put patients at risk by being of insufficient safety, efficacy, or quality. For this reason, risk assessment has become a crucial component of WHO quality assurance recommendations. A component of the entire system for ensuring the quality of drugs is inspections. Pharmaceutical manufacturing facilities are inspected with the intention of either enforcing compliance with Good Manufacturing Practices (GMP) or granting permission to manufacture particular pharmaceutical goods, usually in connection with an application for marketing authorization. In order to remove the risk provided by the infiltration of phony medications, another facet of pharmaceutical inspection involves keeping an eye on the quality of pharmaceutical products along the distribution chain, from the point of manufacture to the point of delivery to the receiver.[3]

Purpose The World Health Organization's "good manufacturing guidelines" are interpreted as GMP rules under the National Medicines Regulatory Authority Act No. 5 of 2015. For the purpose of regulating the manufacture of pharmaceuticals, the National Medicines Regulatory Authority (NMRA) thus accepts the WHO GMP principles along with any changes that come forth. It is anticipated that manufacturers will follow Good Manufacturing Practices in all aspects of their business. A GMP inspection or many may be required before pharmaceutical manufacturers are granted site approval in Sri Lanka to seek for marketing authorization. The NMRA is required to periodically conduct normal inspections as well as ad hoc inspections, such as when

products are licensed for commercialization in Sri Lanka. Along with all WHO GMP Guidelines, this guideline will be the primary foundation for the GMP inspection of such production facilities.[1,2]

Guidelines- GMP guidelines provide guidance for manufacturing testing and quality assurance in order to ensure that a food or drug product is safe for human consumption. GMP guidelines are not prescriptive instructions on how to manufacture products. They are series of general principles that must be observed during manufacturing-

1. Pharmaceutical manufacturing facilities must maintain clean and hygienic manufacturing area.
2. Controlled environmental conditions in order to prevent cross contamination of drug product from adulterants that may render the product unsafe for human consumption.
3. Manufacturing processes are clearly defined and controlled. All critical processes are validated to ensure consistency and compliance with specifications.
4. Any change to the manufacturing processes is evaluated. Changes that have an impact on quality of the drug are validated as necessary.
5. Instructions and procedures are written in clear and unambiguous language. (Good Documentation Practice)
6. Records are made manually or by instrument during manufacture, which demonstrate that all the steps required by the defined procedures and instructions were infact taken and the quantity and quality of food or drug was as expected. Deviations are investigated and documented
7. Records of manufacture (including distribution) that enable the complete history of a batch to be traced are retained in a comprehensible and accessible form.
8. The distribution of the food or drugs minimizes any risk to their quality.
9. A system is available for recalling any batch from sale or supply.
10. Complaints about marketed products are examined, the cause of quality defects are investigated, and appropriate measures are taken with respect to the defective products and to prevent recurrence.[4]

Application of GMP to AYUSH Medicines

(Voluntary Certification Scheme for AYUSH Products under Drug & Cosmetic ACT 1940 on 23rd June 2000) The procedures and techniques used in the manufacture and quality control of herbal medicine are often substantially different from those employed for conventional pharmaceutical products. For this reason application of GMP in the manufacture of herbal medicine is an essential tool to assure their quality.

Requirements

1. The AYUSH products shall be processed from suitable quality raw materials as per method of production and composition defined in API/UP/SP/HP

2. The raw materials used shall comply with requirements for raw materials specified in the API/UP/SP/HP 3. The finished AYUSH products should comply with the requirements specified in API/UP/SP/HP 4. AYUSH products shall be processed, handled, packaged under hygienic conditions adhering to the GMP guidelines as detailed below

(a) Personal hygiene should be maintained.
(b) Premises must be located, designed, constructed, adapted and maintained to suit the operations to be carried out. Sanitary measures should be adopted.
(c) Ancillary areas- Each and every area in the premises should be properly designated and separate, e.g., rest room, refreshment rooms, changing rooms, toilets should not communicate directly with production and storage areas. Animal houses should be well isolated from other areas with separate entrance and air handling facilities.
(d) Storage areas should be designed or adapted to ensure good storage conditions. Separation and segregation of materials should be maintained
(e) Weighing areas should be separate or part of the storage or production area
(f) Production area-Premises should preferably be laid out in such a way as to allow the production to take place in areas connected in a logical order corresponding to the sequence of the operations and to the requisite cleanliness levels.
(g) Quality control areas- Quality control laboratories should be designed to suit the Operations to be carried out in them.
(h) Equipment-Equipments must be located, designed, maintained, constructed & adopted to suit the operation to be carried out.
(i) Materials- All materials and finished products should be quarantined immediately after receipt or processing until they are released for use or distribution. Water used should comply with WHO guidelines for drinking water quality.
(j) Starting materials-Starting materials should be purchased only form approved s pliers and where possible directly from the producer.
(k) Labels-* Designated name of the product *Batch no *Status of content *Analytical report no. on label of approved material.
(l) Packaging materials-The purchase, handling and control of primary and printed packaging materials should be as for starting materials.
(m) Intermediated or Bulk products-These products should be kept under appropriate are conditions.
(n) Finished products - These should be held in quarantine until their final release.
(o) Rejected recovered reprocessed & reworked materials- These should be clearly marked as such and stored separately in restricted areas. They should

be either returned to sup- plier or reprocessed or destroyed.
(p) Waste materials- should be disposed off safely and in a sanitary manner at regular and frequent intervals.
(q) Batch processing and packaging records should be maintained.
(r) Packing-The products shall be packed in clean, hygienic bottles/containers made of materials suitable for the respective dosage forms.
(s) Labeling-Name of AYUSH product

List of active ingredients with quantity
Dosage form
Batch no. assigned by the manufacturer
Expiry date in an uncoded form
Directions for use & warnings and precautions
Name & address of the manufacturer or the company.[4]

Principles of GMP Good Manufacturing Practices (GMP) Fundamentals of GMP Healthcare product manufacturing, packing, labeling, and testing are governed by a system of rules and guidelines known as good manufacturing practices, or GMPs. GMP guarantees that goods are continuously produced and managed in compliance with defined quality standards. Reducing risks of product contamination, errors, and deviations that may endanger patients or lower the quality of the product is the main goal of GMP.

The following are the main tenets of GMP
Manufacturers need to set up and keep up strong quality management systems.
a. Quality Management Systems: A strong quality management system that covers all facets of production, quality assurance, and documentation must be established and maintained by manufacturers. This comprises quality policies, a thorough quality assurance program, and standard operating procedures (SOPs).[6]
b. Personnel: It is imperative that individuals participating in industrial processes receive sufficient training, certification, and continuous education. GMP places a strong emphasis on the requirement for qualified and skilled employees who follow guidelines and uphold moral principles.
c. Facilities and Equipment: According to GMP, producers must have facilities and machinery that are suitable and that are built, designed, and maintained to guarantee the integrity, safety, and quality of their products. This entails appropriate storage settings, regulated atmospheres, and consistently calibrated apparatus.[7]
d. Materials Management: The need of appropriate control and traceability of components, raw materials, and packaging materials used in the manufacturing process is emphasized by GMP. This covers thorough paperwork, suitable storage settings, and suitable supplier qualification.[8]
e. Documentation and Record-Keeping: GMP places a strong emphasis on the necessity of thorough and accurate documentation at every stage of the production process. Records for quality control, production instructions, standard operating procedures, and batch records are all included in this. To provide efficient quality control and guarantee traceability, all actions need to be thoroughly documented.
f. Quality Control and Testing Strong quality control mechanisms, including as testing protocols, sampling schedules, and requirements for raw materials, intermediate products, and final products, must be put into place in order to comply with GMP regulations. Assuring product quality and adherence to set standards requires analytical testing and validation.

DISCUSSION

The pharmaceutical business relies heavily on Good Manufacturing Practices (GMP) to guarantee the efficacy, safety, and quality of its healthcare goods. For manufacturers to comply with legal obligations, safeguard patient safety, and uphold public confidence, they must follow GMP criteria. In the healthcare sector, good manufacturing practices (GMP) are critical for a number of reasons, including regulatory compliance, product safety, quality control, and drug manufacture. GMP compliance guarantees that medications are manufactured in regulated environments with strict quality control procedures in place to reduce risks and guarantee constant product quality. Additionally, it aids in avoiding contamination, mistakes, and deviations that can jeopardize patient safety and the efficacy of the product.

As a crucial component of GMP, quality control includes a number of activities including testing and sampling, process monitoring, batch record review, equipment calibration and validation, stability testing, and inquiries into results that do not meet specifications. By taking these steps, healthcare products are guaranteed to fulfill regulatory requirements and certain quality qualities. Adverse event reporting, raw material control, employee hygiene and training, and facility design are all subject to strict GMP compliance standards. Product recalls and other appropriate corrective measures must be implemented by manufacturers as necessary, along with reliable methods for monitoring and reporting adverse incidents. Regulatory bodies are essential in guaranteeing GMP adherence by conducting audits and inspections. In addition to being required by law, following GMP requirements demonstrates a commitment to making trustworthy and safe medical products. Regulatory measures resulting from non-compliance can affect a manufacturer's market access and reputation. Developing regulatory environments, intricate supply chains, technological advancements, data integrity, and staff growth and training are some of the obstacles to GMP compliance. To overcome these obstacles, a sustained commitment must be made, along with investments in technology and training, industry collaboration, and proactive risk management. The healthcare sector's GMP compliance in the future will be influenced by

technological improvements, data integrity, risk-based strategies, harmonization across borders, and a robust quality culture. Manufacturers must adopt these trends, modify their procedures, and consistently enhance their quality systems in order to satisfy changing legal mandates and guarantee patient safety.

CONCLUSION

GMP is a testing and production procedure that aids in guaranteeing a well-built product. Pharmaceutical businesses are required by law in many nations to adhere to GMP protocols, and these countries have also established their own GMP rules that are in keeping with their legal frameworks. The fundamental principles behind each of these standards are essentially consistent with the end objectives of protecting patient health and manufacturing high-quality medications. Only with meticulous planning, QA system development and GMP application in practice can the quality objective be met. Extensive attention to detail and a thorough understanding of the many GMP components which should be integrated from the beginning of product development and manufacturing facilities to production are necessary for the effective implementation of GMP.

REFERENCES

1. WHO good manufacturing practices for pharmaceutical products: main principles, World Health Organization, 2014. (WHO Technical Report Series, No. 986)
2. Good manufacturing practices for pharmaceutical products: main principles. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fifth report. Geneva, World Health Organization, 2011. (WHO Technical Report Series, No. 961)
3. EudraLex – Volume 4. Good manufacturing practice (GMP) Guidelines. European Commission. (http://ec.europa.eu/health/documents/eudralex/vol-4/ index_en.htm).
4. Pharmaceutical Inspection Convention, Pharmaceutical Inspection Co-operation Scheme (PIC/S). In: Guide to good manufacturing practice for medicinal products. Geneva, PIC/S Secretariat, July 2018. (PE 009-14)
5. Dr. Bilal Ahmad Wani & Dr.Shaheen Ahmad mir *Basics of Research Methodology and Medical Statistics For Ayuvedic Scholars*, *Ayurved Sasnskrit Hindi Pustak Bhandar Jaipur* Part A Chp-12 Clinical research, 2021; 202-203.
6. International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use. ICH Q7 guideline: Good manufacturing practice guide for active pharmaceutical ingredients. Retrieved from https://database.ich.org/sites/default/files/Q7_Guideline.pdf, 2016.
7. International Society for Pharmaceutical Engineering. Good manufacturing practice (GMP) guidance. Retrieved from https://ispe.org/initiatives/regulatoryresources/gmp/good-manufacturing-practice-gmp-guidance, 2019.
8. World Health Organization. WHO good manufacturing practices: water for pharmaceutical use. Retrieved from https://apps.who.int/iris/handle/10665/154881, 2015.
9. Good manufacturing practices for pharmaceutical products, Part one. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations. Thirty-second report. Geneva, World Health Organization, 1992. (WHO Technical Report Series, No. 823), Annex 1; and in: Quality assurance of pharmaceuticals. A compendium of guidelines and related materials. Vol. 2, 2nd updated edition. Good manufacturing practices and Inspection. Geneva, World Health Organization, 2007.