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GMP A Vital Thread of Homoeopathy

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Abstract: ***Every consumer has the right to obtain high-quality medicines, ensuring they get their money's worth. The responsibility for quality lies with the manufacturer, who must maintain documented evidence for it. In July 1969, during its 22nd Health Assembly, WHO (World Health Organization) emphasized the significance of GMP (Good Manufacturing Practices), which has gained global acceptance and become standard practice in the pharmaceutical sector. GMP provides guidelines and standards regarding the manufacturing processes and facilities. It specifies requirements related to location, environment, infrastructure, equipment, quality control, raw materials, and procedures to guarantee consumers receive high-quality products that meet government standards. With the global rise in the use of homoeopathic medicines and the swift growth of the international market, ensuring the safety and quality of these medicines has become a significant issue for health authorities, the pharmaceutical industry, and consumers alike. The safety of homoeopathic medicines is heavily reliant on their quality.***

Keywords: Quality assurance, Standard operating procedures, Pharmaceutical industry, Quality control

1. Introduction

Good Manufacturing Practice (GMP) pertains to the quality assurance protocols that ensure medicinal products are produced and controlled consistently to adhere to the quality standards appropriate for their intended use, as outlined by the marketing authorization (MA) or product specifications. GMP includes not only the manufacturing procedures but also the quality control measures implemented throughout the production process. Building a GMP facility is insufficient; it is crucial that it function to the levels of current Good Manufacturing Practice. Standard operating procedures (SOPs) must be followed to guarantee correct manufacturing, environmental cleaning, record keeping and retention, and facility and equipment monitoring, to name a few.[1]

The standards and procedures for quality assurance of completed homoeopathic products, especially for combination or mixed homoeopathic products, are significantly more intricate than those for individual remedies like Mother tincture and Liquid Potency Medicine. Additionally, the quality of completed homoeopathic products is affected by the quality of the raw materials involved.

In October 2006, the Indian Government introduced G.M.P. regulations for all Homoeopathic manufacturers. Afterwards, it was implemented starting in November 2008. Contamination not only decreases the product's effectiveness but can also be harmful to its function in Homoeopathy due to the use of very small therapeutic doses. Being extremely clean is vital when it comes to manufacturing Homoeopathy products.[2]

It is important to highlight that neglecting to implement Good Manufacturing Practices (GMP) can result in inferior product quality or significant quality issues such as mislabeling, the presence of impurities in raw materials, and contamination. In the end, this could pose serious threats to public health, making product recalls unavoidable. Nevertheless, homeopathic manufacturing presents unique challenges that require specifically skilled personnel. The source materials (like mother tinctures), excipients, or the final homeopathic products must adhere to the quality standards outlined in official pharmacopoeias or other recognized documents. A major concern is the management of toxic substances, particularly fresh materials that are susceptible to degradation and microbial contamination, as well as homeopathic medicines derived from animal or human sources. Some of these raw materials can pose safety risks, even at the highest dilutions. The effectiveness of medicines can also be jeopardized by unintentional contamination of starting materials, excipients, or the vessels used for dilutions. Ensuring the consistency of homeopathic product quality involves not only setting appropriate specifications but also applying standard manufacturing procedures validated in accordance with GMP.[2]

Good Manufacturing Practice (GMP) guidelines are not detailed directives for product manufacturing. Instead, they consist of a set of general principles that must be adhered to during the manufacturing process. When establishing its quality program and production methods, a company has various options to meet GMP standards. It is up to the company to identify the most effective and efficient quality processes.

The Good Manufacturing Practices for Homeopathic Drugs, as outlined in Sub-Rule (2) of Rule 85E of the Drugs & Cosmetics Rules, 1945, along with the conditions specified in Schedule 'MI', aim to ensure that:

1) The raw materials utilized in drug manufacturing are genuine, meet the prescribed quality standards, and are free from contaminants;
2) The manufacturing process follows the established standards;
3) Sufficient quality control measures are in place;
4) The manufactured drugs that are released for sale meet acceptable quality standards.
5) To accomplish these goals, each licensee must develop methods and procedures to adhere to the prescribed manufacturing practices, which should be documented in a manual and maintained for reference and inspection.

Manufacturing processes are distinctly outlined and regulated. All key processes undergo validation to guarantee consistency and adherence to specifications. Manufacturing operations are monitored, and any alterations to the process are assessed. Modifications that could affect the drug's quality are validated where necessary. Guidelines and procedures are articulated in straightforward and clear language. Personnel are trained to execute and document procedures accurately. Records are generated either manually or through instruments during production that confirm that all necessary steps in the defined procedures and instructions were followed, and that the drug's quantity and quality met expectations. Investigations and documentation occur for any deviations. Records of production (including distribution) are maintained in a clear and accessible manner, allowing for the complete tracing of a batch's history. A mechanism is in place to retrieve any batch of drug from sale or distribution. Complaints regarding marketed drugs are assessed, the root causes of quality issues are explored, and suitable actions are taken concerning the defective products and to avert future occurrences.[3]

Good manufacturing practice (GMP) guidelines include the following aspects:

- Production procedures,
- Facilities,
- Staff,
- Packaging and labeling.

Hygiene: A pharmaceutical production facility must ensure that the manufacturing area remains clean and sanitary.

Environmental conditions must be controlled to avoid cross-contamination of drug products from other substances or foreign particles that could make the drug unsafe for human use.

The manufacturing processes are clearly outlined and regulated. All critical operations are validated to guarantee consistency and adherence to specifications.

Procedures and instructions are articulated in straightforward and unambiguous terms.

Operators receive training to execute and document the procedures.

Records are maintained, either manually or via instruments, during production to verify that all necessary steps outlined in the procedures and instructions were completed and that the drug's quality and quantity met expectations. Investigations and documentation of deviations are required.

Records of manufacturing and distribution that enable complete traceability of a batch are maintained in a readily accessible format.

The risk to the quality of the drugs is minimized through their distribution.

A system is in place to recall any batch of drugs that is sold or supplied. Investigations are conducted into the sources of quality defects, complaints about marketed medications are assessed, and suitable measures are implemented to rectify the defective products and prevent future occurrences.

Date of Expiry

Homoeopathic medicine expiration dates vary depending on the type of medication.

a) Attenuation (dilution) and liquid potency
b) Mother tinctures and solutions
c) Trituration, solid potency, and biochemical/cell salts
d) Preparing combination liquids
e) Combination tablets.
f) Externally applied ointment or cream g. Eye/ear drops.

Potency and attenuation of liquids

1) Since liquid potency medications typically contain higher concentrations of ethanol (80–90%), they do not need an expiration date; that is, the date is not applicable (N/A).
2) Mother tincture: The strength of ethyl alcohol in mother tinctures varies based on the herbs, minerals, and chemicals used. As a result, the product's expiration date can be determined following a stability test or by comparing it to imported homoeopathic mother tinctures and solutions that are registered in the USA and Europe.
3) Since more than 95% lactose is used in the manufacturing of Biochemic and Homeopathic tablets, the expiration date of Biochemic and Biochemic combination medications can be determined by a stability test, the self-life of the lactose used (certificate of analysis), or by consulting imported European and USA-registered Homeopathic medicines.
4) Ointment/Cream: Products must have an expiration date, which can be determined by a stability test or by referring to imported homoeopathic ointments, creams, etc. that are registered in the USA and Europe.
5) Eye/Ear Drops (sterile production): These products need to have an expiration date, which can be determined by a stability test or by comparing them to imported homoeopathic eye/ear drops that are registered in the USA and Europe.[4]

2. Conclusions

Without a doubt, the safety and efficacy of homeopathic medications are greatly enhanced by Good Manufacturing Practices (GMP). However, manufacturers must make investments to meet GMP standards, which can be especially difficult for small scale producers in emerging countries. Higher production costs as a result of GMP implementation may raise the final product's price. The availability of these medications may be impacted by this cost increase.The authorities of National health therefore take this effect into account and take the necessary steps to support and encourage manufacturers to improve their GMP compliance. According to the experiences of different nations, giving manufacturers a grace period to enhance their GMP is a good example.

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