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GMP Values

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Good Manufacturing Practise (GMP) place emphasis on human safety and needs. Thus, GMP set values to ensure the products manufactured are safe and efficient to the users. The 7 values are : Safety, Identity, Strength, Purity, Efficacy, Stability, Consistency or Reproducibility

Safety

The manufacturer has to ensure that products manufactured are free from any unforeseen adverse or undesirable effects from recommended usage. Patients safety are already compromised with their illness. Users may be bed-ridden, geriatics or neonates. Thus this issue of product safety is utmost important.

Product defects may not only affect one or two consumers, but may cause a crisis as seen by some historical cases, such as the death of many children in Sri Lanka few years ago, due to Paractemol Syrup being contaminated with Diethylene Glycol.

Identity

Products should be as claimed on their labels. The products are identifiable and verifiable to the known active and quantity used. Also, every materials, components, equipment used and process must be well documented for purpose of ‘traceability’. Manufacturers must be able to identify each and every component of the drug products.

Strength

Product should deliver the accurate dose and strength of the active components throughout its shelf-life. There should be a pre-determined specifications or limits a product should contain of its active ingredients. A product with wrong strength may lead to inefficient treatment and worse, may be harmful to the users.

Purity

The needs for product safety also require that the product be free from any contamination of foreign matters and microbes. Sensitive products, such as injections, liquids and creams, should be tested for such contaminants. This value imposes manufacturers to comply rigidly to the requirements of GMP, especially pertaining to control of cross contamination.

Efficacy

A product must not only contain the desired active ingredients in its desirable quantity, it should also be able to deliver the intended desired effects of the drug product to the users. Bad formulations, deviated environmental conditions, process deviations and non-validated processes may retard the delivery and effective absorption of some active ingredients.

Stability

The challenge to manufacturer in complying to GMP further requires that the product posses not only the desired identity, strength, quality and purity, but also able to retain them for the time period of its designated shelf-life. This requires collaboration between Quality Control and R&D to develop a protocol for such measures to be taken effectively. When done, manufacturers are assured of the product stability at various conditions, throughout its shelf-life period.

Consistency/Reproducibility

Products are produced repetitively at different time period. Thus, the ability to produce a product with all the desired GMP values at a particular time is insufficient. Manufacturers must be capable of producing products with all the desired quality attributes consistently regardless of the time period or even under minor changes eg. to personnel, minor environmental deviations, minor equipment changes, etc.

End.