Important Areas of Good Manufacturing Practice (GMP)

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Out comes:

1. What is GMP?
2. Why GMP is important?
3. List importance areas of (GMP)
4. Conclusion
5. References

What is GMP?

Is that part of quality assurance which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorization or product specification.

Why GMP is important?

1

A poor-quality medicine may contain toxic substances that have been unintentionally added.

2

A medicine that contains little or none of the claimed ingredient will not have the intended therapeutic effect.

Important areas of (GMP)

Good manufacturing practice is concerned with both production and quality control.

The basic requirements of GMP are that:

1. **All manufacturing processes are clearly defined, systematically reviewed in the light of experience and shown to be capable of consistently manufacturing medicinal products of the required quality that complying with their specifications.**

2 **Critical steps of manufacturing processes and significant changes to the process are validated.**

3 **All necessary facilities for GMP are provided.**

4

Appropriately qualified and trained person.

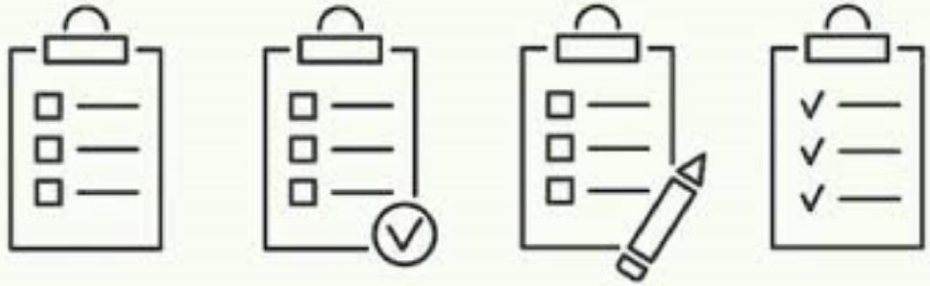
5

Adequate premises and spaces.

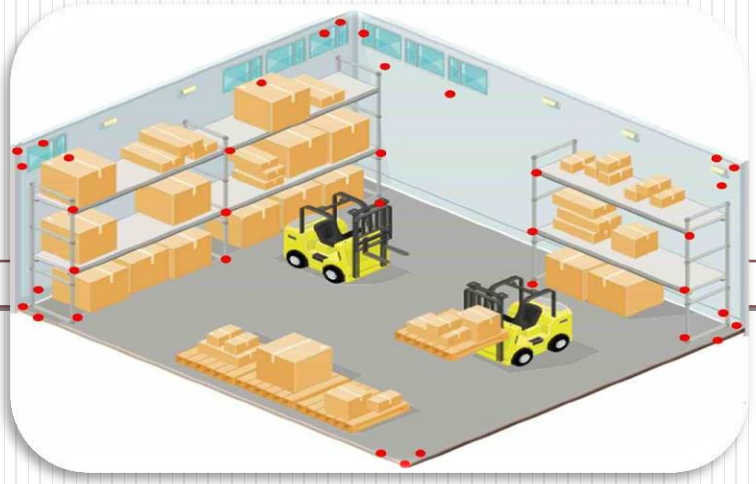
6 **Suitable equipment and services.**

7 **Correct materials, containers, and labels.**

8 Approved procedures and instructions.



9 **Suitable storage and transport.**



10 **Instructions and procedures are written in an instructional form in clear and unambiguous language, specifically applicable to the facilities provided.**

11

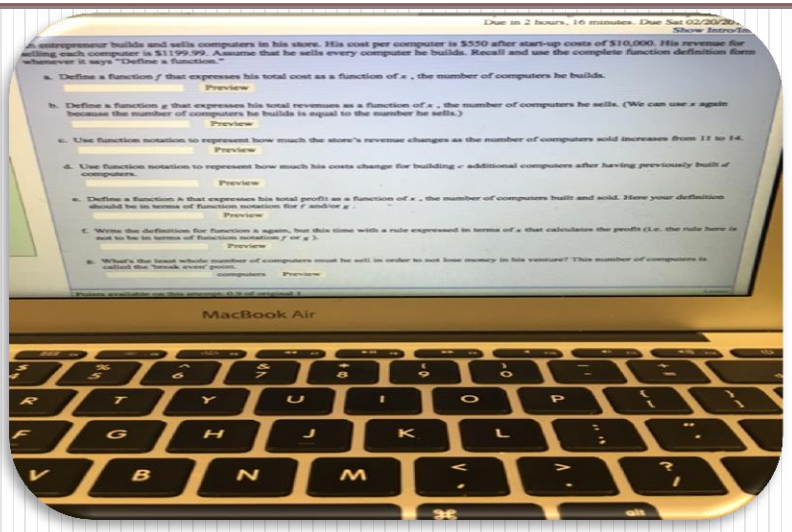
Operators are trained to carry out procedures correctly.

12

The distribution of the products minimizes any risk to their quality.

13

Records are made, manually and/or by recording instruments, during manufacture which demonstrate that all the steps required by the defined procedures and instructions were in fact taken and that the quantity and quality of the product was as expected.



14 **A system is available to recall any batch of product, from sale or supply.**

15 **Complaints about marketed products are examined, the causes of quality defects investigated, and appropriate measures taken in respect of the defective products and to prevent reoccurrence.**

Conclusion:

1- Pharmaceutical industry is regulated by GMPs.

2- Good manufacturing practices must be followed.

3- GMPs ensure drug products are safe, pure, and effective.

Reference

Rules and Guidance for Pharmaceutical Manufacturers and Distributors 2007. Chapter 2.

THANK YOU FOR YOUR ATTENTION