Good Manufacturing Practices

(PHAR 533)

Fifth Grade – Spring Semester

Faculty of Pharmacy
Pharmacy Department
Tishk International University

Lecture 1

Introduction to GMP

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Outlines

- History of GMP
- GMP Definition
- Key Principles of GMP
- Standard Operating Procedures (SOPs)
- Documentation
- Personnel
- Facilities
- GMP Objectives
- Class Activity

Learning Outcomes

At the end of this chapter, you will be able to:

- Understand basic GMP concepts.
- List and explain the key principles of GMP.


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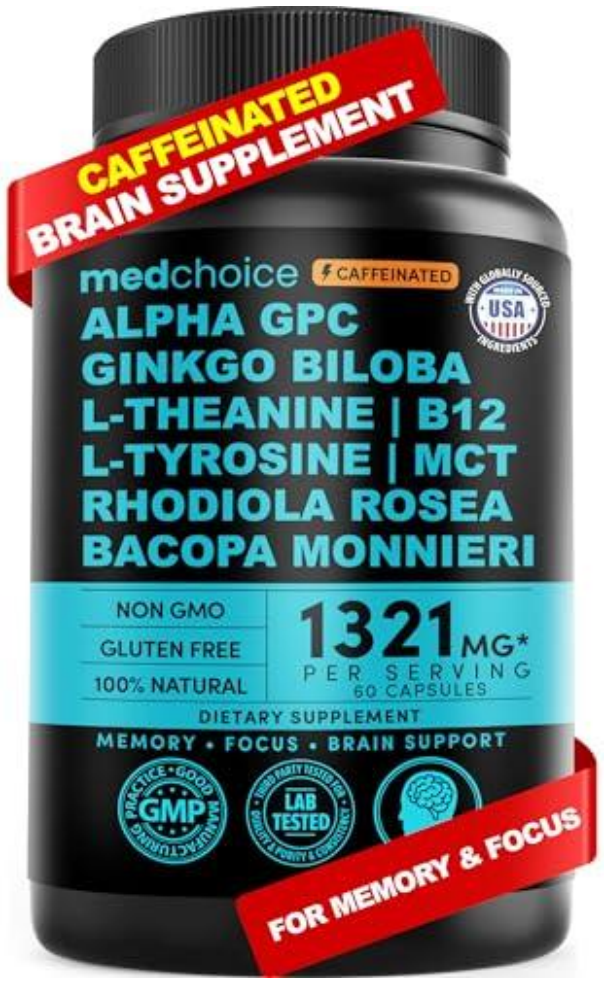
Made with
Organic Ingredients
GMP
Dietary Supplement I Vegetarian Capsules
Available in pack of 60/90/120/200


CAFFEINATED
BRAIN SUPPLEMENT
medchoice
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USA
ALPHA GPC
GINKGO BILOBA
L-THEANINE | B12
L-TYROSINE | MCT
RHODIOLA ROSEA
BACOPA MONNIERI
NON GMO
GLUTEN FREE
100% NATURAL
1321 MG*
PER SERVING
60 CAPSULES
DIETARY SUPPLEMENT
MEMORY • FOCUS • BRAIN SUPPORT
GMP
LAB TESTED
FOR MEMORY & FOCUS


GOOD MANUFACTURING PRACTICE
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History of GMP

Medicines directly affect human health, and any defect in their quality can lead to serious consequences.

Poor manufacturing practices may result in contaminated products, incorrect dosage, reduced efficacy, or toxicity.

Good Manufacturing Practices (GMP) principles were developed after serious incidents where unsafe medicines caused harm to patients. These events highlighted that **testing alone was not enough** and that **strict control of manufacturing processes** was necessary to ensure safety and quality.

GMP are exist to prevent these problems before they occur and to ensure public trust in medicines.

The main goal of GMP is patient safety

GMP Definition

Fundamental quality system used in the pharmaceutical industry to ensure that medicines are consistently produced and controlled according to required quality standards.

- Set of guidelines and principles that ensure pharmaceutical products are safe, effective, and of high quality.
- Regulates how medicines are manufactured, processed, packed, labeled, and stored.
- Focuses on **controlling every step** of production to prevent errors, contamination, mix-ups, and deviations that could affect product quality.

Key Principles of GMP

GMP is built on several key principles that work together to minimize variability and errors, including:

1. Well-defined procedures
2. Proper documentation
3. Trained personnel
4. Suitable facilities

1- Standard Operating Procedures (SOPs)

Standard Operating Procedures are written instructions that describe how tasks should be performed.

SOPs ensure that activities are carried out consistently, regardless of who performs them, and help maintain compliance with GMP requirements.

Without SOPs, processes rely on memory and personal habits, which leads to variability

2- Documentation

Documentation is a cornerstone of GMP

Written records provide evidence that processes were performed correctly.

Accurate documentation ensures traceability, accountability, and the ability to investigate deviations when problems occur.

3- Personnel

Human error is a major source of quality problems.

GMP requires that personnel be:

1. Adequately trained
2. Qualified
3. Aware of their responsibilities

4- Facilities

Facilities must be designed and maintained to support clean and orderly manufacturing.

This helps to **prevent** cross-contamination and mix-ups between products

GMP Objectives

The **main objectives of GMP** are:

1. Batch-to-batch consistency.

Every batch of medicine must be manufactured in the same way and meet the same quality standards.

2. Preventing errors rather than detecting them after production.

By controlling processes and environments, GMP reduces the chance of mistakes, contamination, and deviations before they affect the product.

Class Activity

Work in groups (**6 students**)

You have **15 minutes** to draw a simple **poster** that explains one topic from the following list:

- GMP in One Picture
- From Raw Material to Finished Product
- If It Isn’t Written, It Didn’t Happen (the importance of documentation)
- Sources of Contamination

Use keywords, arrows, and drawings (not long text)

References

Bunn, G. P. (Ed.). (2015). *Good manufacturing practices for pharmaceuticals* (7th ed.). John Wiley & Sons.