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Diploma in Pharmacy 2nd Year Pharmacy Law & Ethics

Chapter 8 : FSSAI (Food Safety and Standards Authority of India)
Act and Rules

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| FSSAI (Food Safety and Standards Authority of | 3 |
| India) Act and Rules | |
| Brief overview and aspects related to | |
| manufacture, storage, sale, and labelling of Food | |
| Supplements | |



PHARMACY LAW & ETHICS

Chapter 8

FSSAI (Food Safety and Standards Authority of India) Act and Rules

- → Fssai (Food Safety and Standards Authority of India) was established in 2008 under the Ministry of Health and Family Welfare.
- → It was made to set down science based standards for articles of foods and to regulate their manufacturing , storage , sale and import.
- → To ensure that availability of safe and wholesome(good) food and food supplements for consumers.
- → This act aims to establish a single reference point for all matters relating to food safety and standards.

Role and Functions of FSSAI

- ✓ It provides standards and guidelines of food safety.
- ✓ Fssai and State Food Safety Suthorities grant licence and certificate and guidelines for manufacturing, storage, sale and labelling of food articles.
- ✓ It collect data regarding contamination in foods from all parts of the country.
- ✓ It conducts training programs for persons involves in food businesses.
- ✓ It promote general awareness about food safety.
- ✓ It specify limits for additives, contamination, pesticides, heavy metals etc. in foods.

Manufacture of Food Supplements

- → The manufacture of food supplements is a regulated industry, with strict standards in place to ensure the safety and quality of these products for human consumption. The regulations vary from country to country, but in general, the following are some of the key aspects of food supplement manufacturing
- 1. **Good Manufacturing Practices (GMP) :** Food supplement manufacturers must comply with Good Manufacturing Practices (GMP) standards, which lay down guidelines for the production, control, and storage of food supplements to ensure their safety and quality.
- 2. **Raw Material Sourcing :** Food supplement manufacturers must source high-quality raw materials from reputable suppliers and ensure that the materials meet the required standards for purity, potency, and quality.
- 3. **Production Processes :** Food supplement manufacturers must follow strict production processes to ensure that the supplements are made in a clean and hygienic environment and are free from contamination and deterioration.



- 4. **Testing and Quality Control :** The manufacture of food supplements must be accompanied by regular testing and quality control measures to ensure that the finished product meets the required standards for safety and quality.
- 5. **Packaging and Labeling :** The packaging and labeling of food supplements must comply with the regulations set by the relevant authorities, including the use of appropriate warning and caution statements, if necessary

Storage of Food Supplements

- ♦ The aisles (space between rows) should be clear and not used for temporary material storage.
- ♦ Pallets should be placed in a systematic manner.
- ♦ Appropriate distance should be maintained between pallets for ventilation.
- ♦ All materials and products should be correctly tagged with their identification or lot number.
- The product should be stored in such way that loading of material should be convenient.
- Proper stoke rotation should be maintained like first in , first out.

Sale of Food Supplement

- A Licence is required for a food business operator (FBO) who wants to manufacture or sell food supplements.
- Powder ,capsule , tablets and syrup are forms of food supplements.
- Plants or serials or fruits in their natural state are not considered as food supplement. as well as their juices also.
- food supplements must be formulated according to the established medical principles
- hormones, steroids and psychotropic substances are prohibited to be used in the food supplements.

Labelling of Food Supplements

- ⇒ Every pre packaged product shall be labelled with the following information
 - The food name
 - Ingredients list
 - Information of nutrients present in it
 - Declaration of Veg. or Non-Veg.
 - Declaration of food additives used
 - Manufacturers name and complete address
 - Total quantity
 - Identification of the Lot or batch number
 - Manufacturing or packaging date
 - Expiry date best before
 - Imported food's country of origin



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