

## CHAPTER – 2 Community Pharmacy

### Topic: SOP and GMP

#### 2.1

#### Pharmaceutical Standard Operating Procedure (SOPs)

Pharmaceutical Standard Operating Procedure (SOP) is a tested, verified, approved, and documented way of executing operations that form the pharmaceutical industry's basis. It provides step-by-step guidance for the personnel to perform a specific process.

For **example**, pharmaceutical finished products are sterilized according to the approved SOP, i.e., sterilization time and temperature for every product type are defined in the SOP.

- ❖ The ultimate purpose of SOP is to streamline the Pharmaceutical Quality Management System (QMS) that contributes to the overall product quality, and safety.
- ❖ Some examples of day-to-day operations that involve SOPs include, but are not limited to:
  - SOP for orientation of the new employee.
  - SOP for preventive maintenance of a packaging machine.
  - SOP for batch manufacturing in the production department.
  - SOP for operating process machinery such as blister machine, filling machine, and labeling machine.
- ❖ It provides step-by-step guidance for the personnel to perform a specific process.
- ❖ SOPs are constantly updated in response to changing process requirements or due to the latest trends.
- ❖ It helps increase the efficiency of a pharmaceutical process in the most beneficial, effective, and proven way.
- ❖ They inspect whether the process or procedure has its SOP and whether the process is executed according to the SOP.
- ❖ They can issue a warning or non-conformance if there is no SOP or there is a deviation between executed process and the approved SOP

#### 2.2

#### Good Pharmacy Practice

- ❖ Good Manufacturing Practices (GMPs) are the set of production standards that have been embraced by regulators, retailers and consumers in the food and drug industries.
- ❖ GMPs provide a basic assurance that a product was produced under industry-standard conditions. Some of the areas addressed in GMPs include:

- Building & facility conditions
  - Equipment design and maintenance
  - Employee practices
  - Sanitation conditions
  - Raw ingredient sourcing
  - Maintaining strong production controls
  - Records and reports
- ❖ All practicing pharmacists are obliged to ensure that the service they provide to every patient is of appropriate quality. Good Pharmacy Practice is a means of clarifying and meeting that obligation.
  - ❖ The vital element is the commitment of the profession, throughout the world, to promote excellence in practice for the benefit of those served.
  - ❖ The public and other professions will judge the profession on how its members translate that commitment into the practice they observe in the community and hospital settings.
  - ❖ The necessary base of pharmaceutical sciences there must be ads emphasis on the action and uses of medicines, there should be a reasonable introduction in the pre-initial qualification course to the relevant elements of the social and behave sciences and, at all stages, the development and improvement of communication should be given due emphasis.