CHAPTER:6
MANUFACTURE OF PHARMACEUTICAL PREPARATIONS (NON-STERILE)

BY

Mrs. K.SHAILAJA., M. PHARM.,

LECTURER

DEPTOF PHARMACY PRACTICE,

SRM COLLEGE OF PHARMACY

INTRODUCTION

- Type of the products manufactured vary from hospitals to hospital. For example: there may be 80% galanicals, 75% non commercials , hospitals 40% topical sterile , 33%eye ear drops and 30% small volume parenterals within a hospital. Some other products manufactured in hospital ma include surgical irritation fluids, special diagnostic fluids and large volume parenterals.
- Large number of hospitals go for manufacturing because of the following reasons :

1. There exist a close relation ship between doctors and pharmacists in hospital.
2. Commercially available products are not often suited for the treatment of certain unusual illness which a physician with a hospital practice is expected to cope with.
3. Because of pharmacist physician relation ship in the hospital, doctors fell at ease in requesting the pharmacist to prepare a special pharmaceutical preparation either for clinical experimental use.

PLANNING FOR MANUFACTURE OF PHARMACEUTICAL PREPARATIONS

- An early stage in the design procedure is to consider the basic facilities required for the products and add to these are the necessary support system such as storage area

- These basic facilities will generally be most expensive and should have life expectancy in both practical and technologic terms if this period is relevant for the function

- The space available for the unit must be fixed and this limits both the range and number of products manufactured

- During various stage of development, consultation is required with the FDA code and technical support. It is at this stage the feasibility patterns will emerge and management services will assist in decision making exercises.

- The balance between capital and current costs is carefully considered in relation with life expectancy of unit

- “Cross paths” and back tracking must be avoided whenever possible and it is important to the adverse situation when designing sterile product facilities which must be clearly segregated in to various categories of environment control.

MATERIALS REQUIREMENT

- Once the hospital pharmacist has determined what products be intends to manufacture and what volume and quantity he must next arrange for the procurement of necessary supplies.

- The first step in this direction is to take each formulae and determine the quantity of chemical or other material which will be required to produce the annual supply

- The second step is to enter these quantity on a summary sheet because the same drug, chemical or container may be required by many different formulas.

MANUFACTURING CAPACITY

Two important considerations in any bulk compounding programme are:

- Whether or not the pharmacist has the kind of equipment necessary to produce the drug as per formulae

- Whether or not the manufacturing capacity is enough to produce the desired quantity

- Time is the costliest factor in any manufacturing program, it is necessary that the pharmacist utilizes the maximum capacity of his equipment.

MANUFACTURING EQUIPMENTS AND ITS SOURCES

- The kind and size of manufacturing equipment required in hospital pharmacy will vary from institution to institution

- Modern technology has developed equipment to meet every production need. The available manufacturing capacity can handle amounts that are considered to be of practical volume or quantity for a small or medium sized hospital

- In addition the larger hospitals have automatic and semi automatic heavy duty production equipment which may be useful in handling large volume in minimum duration of time.

MANUFACTURING STAFF

- . The manufacturing section of pharmacy must be supervised by a technically competent, legally qualified pharmacist

- In addition he must be supported with ancillary person who can be trained to carry on such non technical pursuits as bottling, filtering,labelling etc

OPERATING COSTS

- The operating costs was shown to consist of direct costs only direct label and cost of material. Operating cost should include both direct and indirect costs.

- The terminology “over head costs” is usually used interchangeably with “indirect costs” and purpose of this section is intended to include such items as the cost of supervisory personnel, space rental, insurance equipment depreciation, maintenance, house keeping etc.

- The indirect costs should be compared with direct costs for the purpose of calculating ratio of overhead expenses. The direct and indirect costs should not increase indirect proportion.

MANUFACTURE OF OINMENTS, LIQUID AND CREAMS.

- The products are required to be free from viable organisms and can be subjected to a terminal heat sterilization process in its final container. Hence the facilities required will be less expensive and sophisticated.

- Some products require bulk manufacture in clean environment followed by sterilization by membrane filtration and aseptic filling in to previously sterilized containers.

- Hospitals may not indulge in complication and expensive process of manufacturing but will be mainly concerned with the dispensing of such products in small quantities to meet individual prescriptions

- Before a new batch is started the bulk manufacture or filling area should be inspected by an expert to confirm that the area should be thoroughly cleaned in the access zone prior to admission to the area has been cleared of all items remaining from previous batch.

- Final product containers such asccollapsible tubes, glass bottles and jars will require pre treatment prior to use in filtering zone. This pre treatment area is the best if adjacent to the filling zone, and the facilities provided should be similar in principle to those provided for the washing of sterile fluid bottles.

- After washing it is necessary to dry the containers and seals in a drying oven possibly designed as double ende facility leading into filling zone. If products are to be sterilized by dry heat in their final containers. A second oven should be provided for the purpose of steam, cooling etc.

- The receiving vessel in aseptic area should be equipped with the necessary blending and homogenizing devices so that the product does not become exposed to the aseptic environment.

MANUFACTURE OF TABLETS, CAPSULES,GRANULES AND POWDERS.

- The table ting process can be split into five stages

1. Dispensing
2. granulation
3. Dry blending
4. Compression
5. Coating

1.Dispensing involves use of a central dispensary for all use in the pharmacy. Dust extraction points will be required at each weighing station so that fine powders can be removed at source.

2. Granulation involves blending of dispensed materials after any preliminary treatment according to the batch document. The dry mass moistened with the granulation fluid and a suitable mass is then passed through sieve. Resultant moist granules are dried up .

During this process suitable blenders and operator’s skill affect not only physical characteristics but also physiological effects are interferd. After moist granulation they using small fluid bed dryer of tray dryer.

3.After granules have cooled and hardened ,final dry blending or potent drugs , lubricants are made to correctly stored and label the granules.

4. Table ting machine should be stripped down for cleaning after each batch and tools examined polished must be necessary. During compression various physical test including hardness, thickness, weight variation must be provided adjacent to machine. The containers should be decided in such a way that the product is protected from the atmosphere, including light facilities should be available for each container to be sealed and labelled properly to the products status.

5. The best can be expected in hospital pharmacy is chloroform soluble coating polymer with the required physical properties and dusting the product at the end of each application with talcum powder. Final product may not have an appearance comparable to industrial scale but reliable product having their required properties and ft for intended use can be made some products which are already dispensed in the form f powders or granules can be prepared in same facilities where tablets are being made.

THANK YOU