PHARMACEUTICAL TECHNOLOGY

FORMULATION AND DEVELOPMENT

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Formulation and Development

. Pharmaceutical technology essentially discusses principles and methods employed in the manufacturing process used by the industry

Pharmacy ----- Ethical Products & Galenical products.

Ethical products are usually the result of large scale manufacturing while Galenical products can be prepared in small industries too.

Objectives of Development

1. Frequent events are advertisement in journals or in popular media about announcement of new product.
2. This event is not an chance event of a manufacturer but is end-product of long and complex sequence of events embracing all branches of pharmaceutical sciences.
3. Objective of development – Translate an idea of a new preparation into a successful product for routine manufacture and commercial marketing.
4. Idea --- Evolution of satisfactory formula for the product to enhance specific therapeutic action of the medicine ----- Combine with correct packaging to ensure stabilityfor several years despite transport and storage in tropical conditions.
5. Every company has a section mainly meant for search and development of new drugs.

6. Pharmaceutical chemists seek new materials or modify structure of existing substances of known action keeping in mind of recent literature of relationship between molecular structure and therapeutic activity.
7. After identification of such compounds they are screened for pharmacological activity. While many may appear to be pharmacologically attractive careful selection of even one would depend on its activity and acceptable levels of toxicity or less collateral damage.
8. After preliminary encouraging results of a material it is returned to chemists for further information --- chemical properties, isolation of purified forms, or or confirmation of synthesis (mode of synthesis) --- so that manufacture of proposed medicament is a practical and economic possibility.

9. Once the stage is reached regarding mode of synthesis etc. then comes the pharmaceutical stage --- formulation of stable preparation, evolution of suitable packaging method and investigation of problems to develop from lab bench to manufacturing scale.
10. Next pharmaceutical engineer design and constructs the plant for the manufacture of the product or in cooperation with pharmaceutist adapts the process to existing equipment in the factory. Thus all branches of pharmacy have to come together for the launch and marketing of product.

Stages of Development

1. Search of Literature --- Reference books, abstrats, journals ---- Investigation of markets ----- Consumer demand ---- Need of the hour.
2. Theoretical Formulation ---- Preliminary formulation is devised --- Consideration is given to suitable presentation of medicament, in a form appropriate for method of administration -- aim of formulation should include stablility, acceptable elegance of presentation and economy of materials and processing.
3. Practical formulation -- During practical formulation all the gaps in theoretical formulations are worked out and components and proportions of the formula are confirmed by lab experiments.
4. Packaging --- Along with theoretical formulation attention is given to a packaging method proposed and this is also confirmed by laboratory experiments along with practical formulation. This will be tested in detail.

5. Small Scale Preparation --- Early preparations will 50 – 100 gm and then next stage is probably several kilograms. Use is made of small scale plant rather than hand methods and product is used for further trials.
6. Clinical or Field Trials -- Samples of small scale preps are used in clinical practice and clinical reports obtained and can be used for amendment or modification of optional formulation.
7. Storage Tests ---- Samples before clinical trials are stored in laboratory under controlled conditions of temperature and humidity while utilizing various packaging methods. Based on results changes will be made in packaging.
8. Process Development – (Large Scale) - Small scale formula evolved, tested but rarely suitable for scaling up to large quantities. Many problems will be faced selection of equipment, control of processing times, speed etc. Trials need to be done on a pilot plant intermediate between lab and small scale.
9. Manufacturing Directions --- Plant work is usually carried out by unskilled or semi – skilled labour under qualified supervision. Thus it is necessary to draw up a complete specification of product with accurate manufacturing directions and to devise suitable process testing in cooperation with analytical laboratories.