GOEL INSTITUTE OF PHARMACY AND SCIENCS LUCKNOW

Topic = Scall up and post approval changes & Platform Technology

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SUPAC

S = Scall
U = Up and
P = Post
A = Approval
C = Changes

The scall up process & the changes made after approval in the composition, manufacturing process, manufacturing equipment & change of site are known as scall up & post approval changes.

FDA & American of pharmaceutical scientist provided the scientific bundaries for the scall up & post approval changes required for immediate release product called SUPAC.

It provides guidlines for approval changes in the following.

- Component
- Composition
- Site of manufacturing
- Process & equipment

Scall - up = Increase in size i.e. from pilot plant to manufacturing Scall.

Post Approval changes =

Making changes in already approved & validated process.

Scientific Rationale

- The expedite the process of post approval changes of drug product.
- FDA can assume their safety & effectiveness
- Lower the regulatory burden for industry.
- The FDA has issued various guidline for SUPAC changes designated as.

A> SUPAC - IR = Immediate release of solid dosage form.

B> SUPAC - MR : Modified release of solid oral dosage form

C> SUPAC - SS : Non - sterile dosage forms creams, emulsion.

- **SUPAC Guidlines define -**

(1) Level of chemistry, manufacturing & control change.

Recommended chemistry, manufacturing & control tests for each level of change.

Recommended in vitro dissolution & release tests for each level of change.

Recommended documentation that should support the changes for new drug application & abbreviated new drug application

Level of changes =
- Minor change
- Moderate change
- Major change

Filling =
- Annual report
- changes being affected supplement
- Prior Approval supplement

Tests =
- Application / compendial tests
- In vitro dissolution / release
- In vivo dissolution / release.

Need for SUPAC Guidline

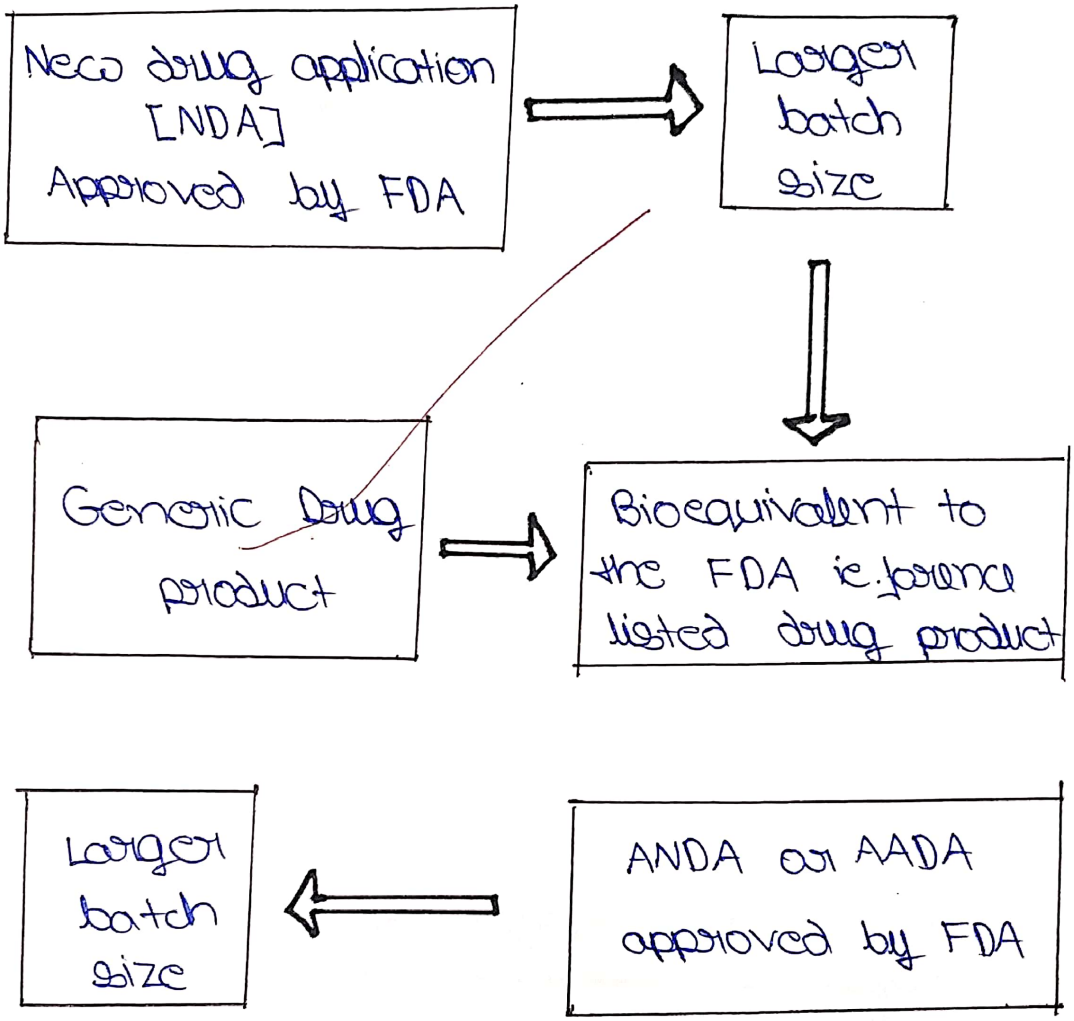
The expediate the process of post approval changes of drug product.

FDA can assume their safety & effective

Lower the regulatory burden for industry.

The FDA has issued various guidance for SUPAC designated as

- SUPAC - IR
- SUPAC - MR
- SUPAC - SS



Advantage =

Members of the production & quality control division can readily observe scale up runs.

excipients & drugs, stored by the quality control division can be divin from the more suspicious area provided to production division.

- Access engineering department personnel is provided with production personnel in the manufacturing area, installation, maintenance & repair.

Disadvantage =

The frequency of direct interaction of the formulated with the production to manufacturing area will be reduced.

Any problem in manufacturing will be directed towards it can pilot plant personnels.

Introduction of Platform Technology

- Platform technologies are considered a valuable tall to improve efficiency & quality in drug development.
- The basic idea is that a plat form in combination with a risk based.

to leverage prior knowledge, for a systemic method given new molecule.

- The technology has distinct & differentiating competetive advantages.
- It can significantly improve the bio-availibility of complex molecules due to its size & adhesive system.
- It is also flexible, encapsulating a broad range of active principles & its system can be adjusted to achieved properties.
- In addition, the technology is vestill with key features such as:

(i) chemical stability & solubility of the active molecule.

(ii) High drug loading can be achieve.

(iii) High encapsulation efficiency.

(iv) Developed industrial process & scalability

(v) Stable, simple & solvent free technology

(vi) Reformulation of drug near potent expiration.