GENERIC DRUGS

Dr. SHASHI KIRAN MISRA

ASST. PROFESSOR

SCHOOL OF PHARMACEUTICAL SCIENCES

GENERIC DRUGS

- 1. A generic drug is a pharmaceutical drug that contains the same chemical substance as a drug that was originally protected by chemical patents
- 2. A generic drug is a pharmaceutical drug which is equivalent to a brand-name product in dosage, route of administration, strength, quality, Kinetics, and its intended use.
- 3. It may also refer to any drug which is marketed under its chemical name without advertising
- 4. For getting the approval to market the generic drug an abbreviated new drug application termed as ANDA is to be submitted by the drug companies

The abbreviated new drug application (ANDA) submitted by drug companies must show the generic medicine is the same as the brand- name version in the following ways:

- **The active ingredient in the generic medicine is the same as in the brand-name drug/innovator drug.**
- **The generic medicine has the same strength, use indications, form (such as a tablet or an injectable), and route of administration (such as oral or topical).**
- **The inactive ingredients of the generic medicine are acceptable.**
- **The generic medicine is manufactured under the same strict standards as the brand-name medicine.**

A generic drug application submitted to FDA for approval must show that:

- The manufacturer is capable of making the drug correctly.
- The manufacturer is capable of making the drug consistently.
- The “active ingredient” is the same as that of the brand.
- The right amount of the active ingredient gets to the place in the body where it has effect.
- The "inactive" ingredients of the drug are safe.
- The drug does not break down over time.

IMPORTANCE

- Generic drug manufacturers do not have to spend extra money for drug discovery and preclinical and clinical trials.
- Generics are available at a lower cost; they provide an opportunity for savings in drug expenditure in a country
- According to the FDA, generic drugs can cost an estimated 85 percent less than the medicines they are designed to copy.

- Patients can easily find generic counterparts: Patients do not require investigating extreme to discover choices to many popular brand name drugs.

-Stay with the course with generics: Patients are three times
more likely to dump branded prescriptions compared to
their generic choices, and oftentimes this neglect is directly linked to high copy.

What are the Basic Generic Drug Requirements?

- .Same active ingredient(s)
- Same route of administration
- Same dosage form
- Same strength
- Same conditions of use
- Inactive ingredients already approved in a similar NDA

Brand Name Drug vs. Generic Drug

(NDA) Requirements

1. Labeling
2. Pharm/Tox
3. Chemistry
4. Manufacturing
5. Controls
6. Microbiology
7. Inspection
8. Testing
9. Animal Studies
10. Clinical Studies
11. Bioavailability

(ANDA) Requirements

1. Labeling
2. Pharm/Tox
3. Chemistry
4. Manufacturing
5. Controls
6. Microbiology
7. Inspection
8. Testing
9. Bioequivalence

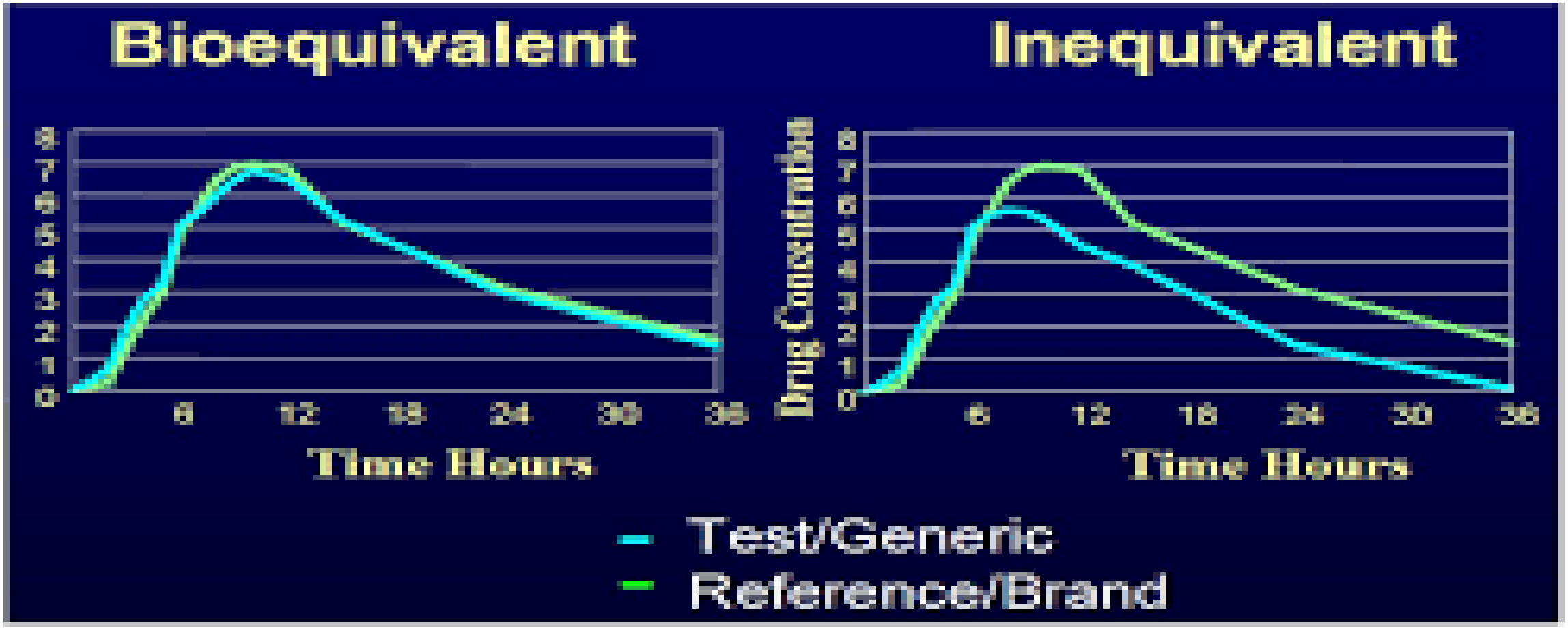
What is Bioequivalence?

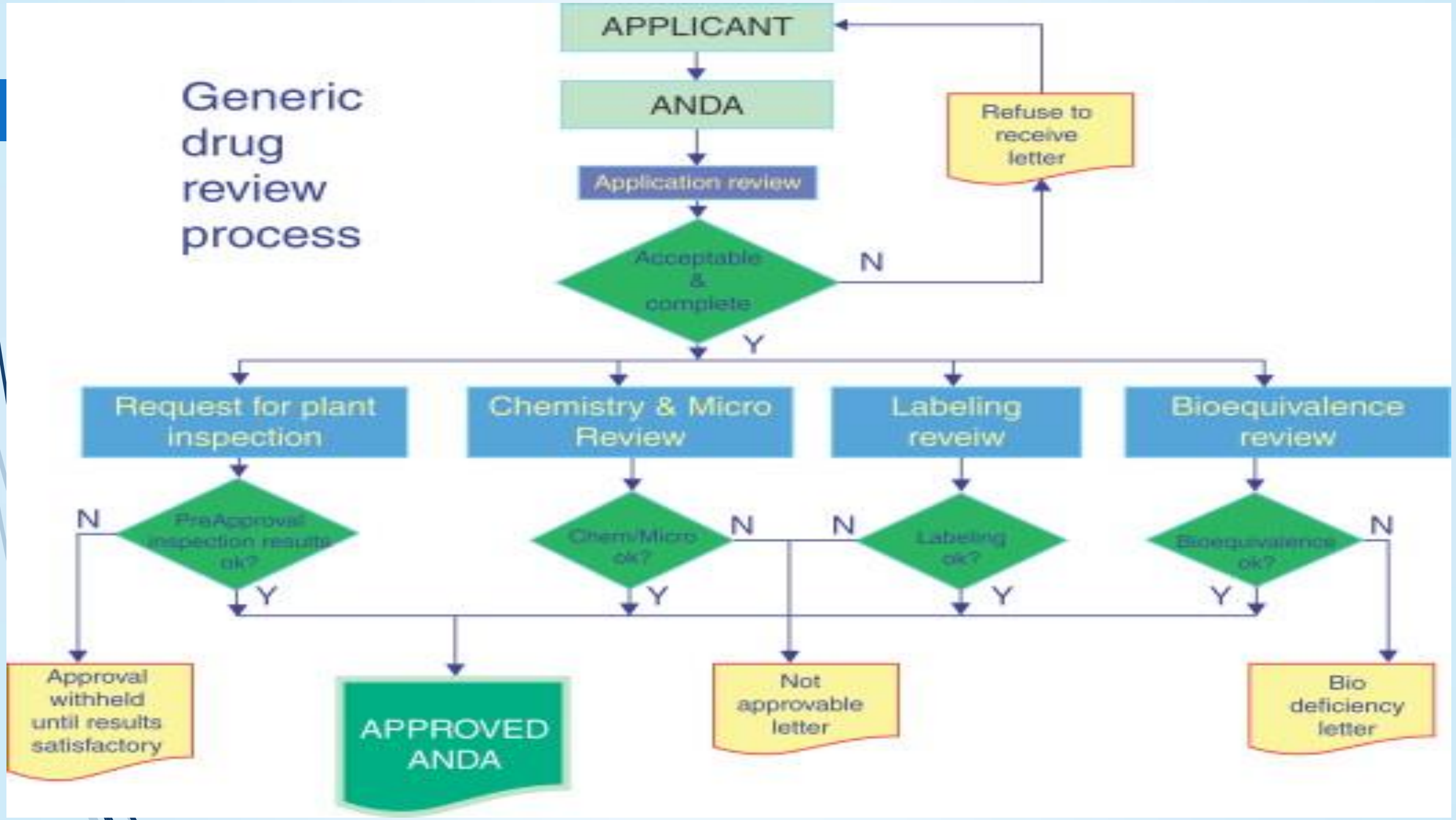
- DEFINITION:The **property wherein two drugs with identical active ingredients or two different dosage forms of the same drug possess similar bioavailability and produce the same effect at the site of physiological activity**.
- A generic drug is considered to be bioequivalent to the brand name drug if:

- The rate and extent of absorption do not show a significant difference from the listed drug, or

- The extent of absorption does not show a significant difference and any difference in rate is intentional or not medically significant

What is Bioequivalence?




Generic drug review process
APPLICANT
ANDA
Application review
Acceptable & complete
N
Refuse to receive letter
Y
Request for plant inspection
Chemistry & Micro Review
Labeling reveiw
Bioequivalence review
N
PreApproval inspection results ok?
Y
N
Chem/Micro ok?
Y
N
Labeling ok?
Y
N
Bioequivalence ok?
Y
Approval withheld until results satisfactory
APPROVED ANDA
Not approvable letter
Bio deficiency letter