



Generic Drugs

By

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Generics

- All prescriptions must be filled generically if a generic exists, unless written “DAW”
- Patent life
- Abbreviated New Drug Application (ANDA)
- Therapeutic equivalence
 - Pharmaceutically equivalent
 - Bioequivalent

Generic Drugs

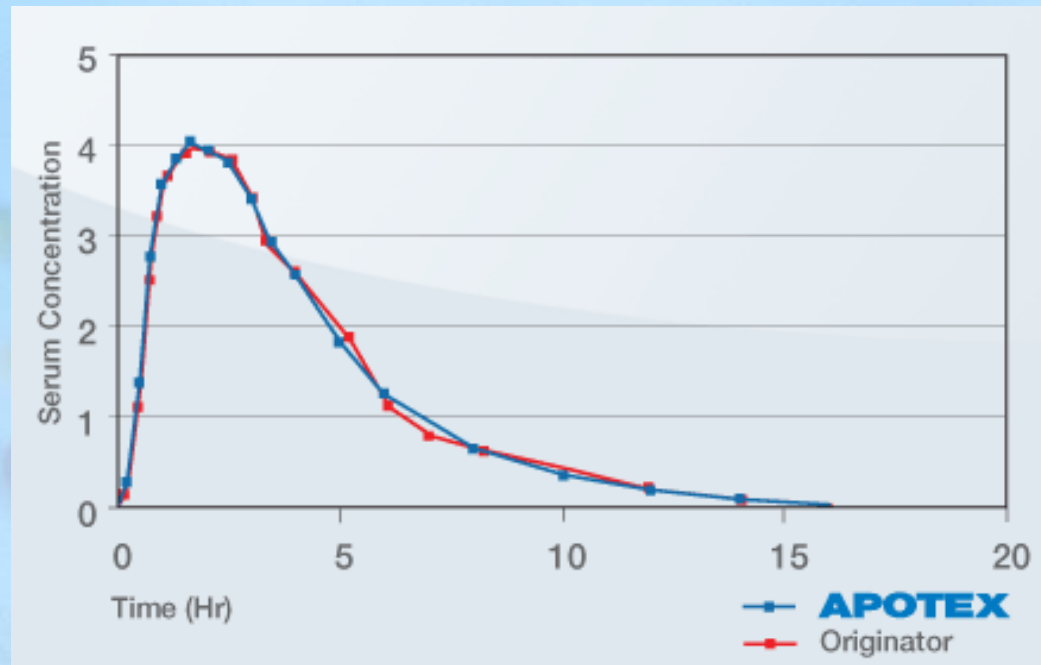
- **Pharmaceutically equivalent**

- Same active ingredient and strength/ concentration
- Same dosage form
- Same route of administration

- **Bioequivalence**

- Same rate and extent of absorption
 - Time to peak
 - Peak concentration
 - Area under the curve
- Small study
- Can differ by -20% to $+25\%$

Bioequivalence



Bioequivalence

- **A rated products**

- Bioequivalent & therapeutically equivalent
- “AB”-further in-vivo or in-vitro studies to verify bioequivalence
- Can substitute for one another
 - AA conventional dosage form
 - AN aerosolization
 - AO Injectables/oil
 - AP Injectable soln
 - AT Topical Product

- **B rated products**

- Cannot substitute/ not bioequivalent
- BC Ext-rel dosage forms
- BD Active ingredient w/ bioequivalency issue
- BE Delayed release PO dosage form
- BN aerosolization
- BR supps or enema meant for systemic abs
- BS product with drug standard deficiency

Generic Drugs

- **Prograf®
(tacrolimus)**
 - 5 generics
 - Sandoz; AB rated
- **Cellcept®
(mycophenolate)**
 - 10-11 generics
 - Sandoz
 - AB rated
 - 250mg, 500mg
- **Neoral®
(cyclosporine)**
 - Gengraf (Abbott)
 - IVAX
 - Pliva
- **Rapamune®
(sirolimus)**
 - Multiple patents

Questions??

