Pharmaceutical quality is an area where Hatch-Waxman Amendments have had a favorable impact on the development of both brand and generic products.

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Drug Product Quality

TIME

Multiple Manufacturers ⟷ ANDA Approval →

SUPAC Formulation(s) ⟷ Supplements →

Further Development Formulation(s) ⟷ NDA Approval →

Clinical Trial Formulation(s) ⟷ Safety and Efficacy

Development Formulation(s) ⟷ Pharmacokinetics (PK)

AAPS J. 10:289-299. 2008.

The notion and availability of generics has brought about a public interest in and public discourse of pharmaceutical product quality. Questions include:

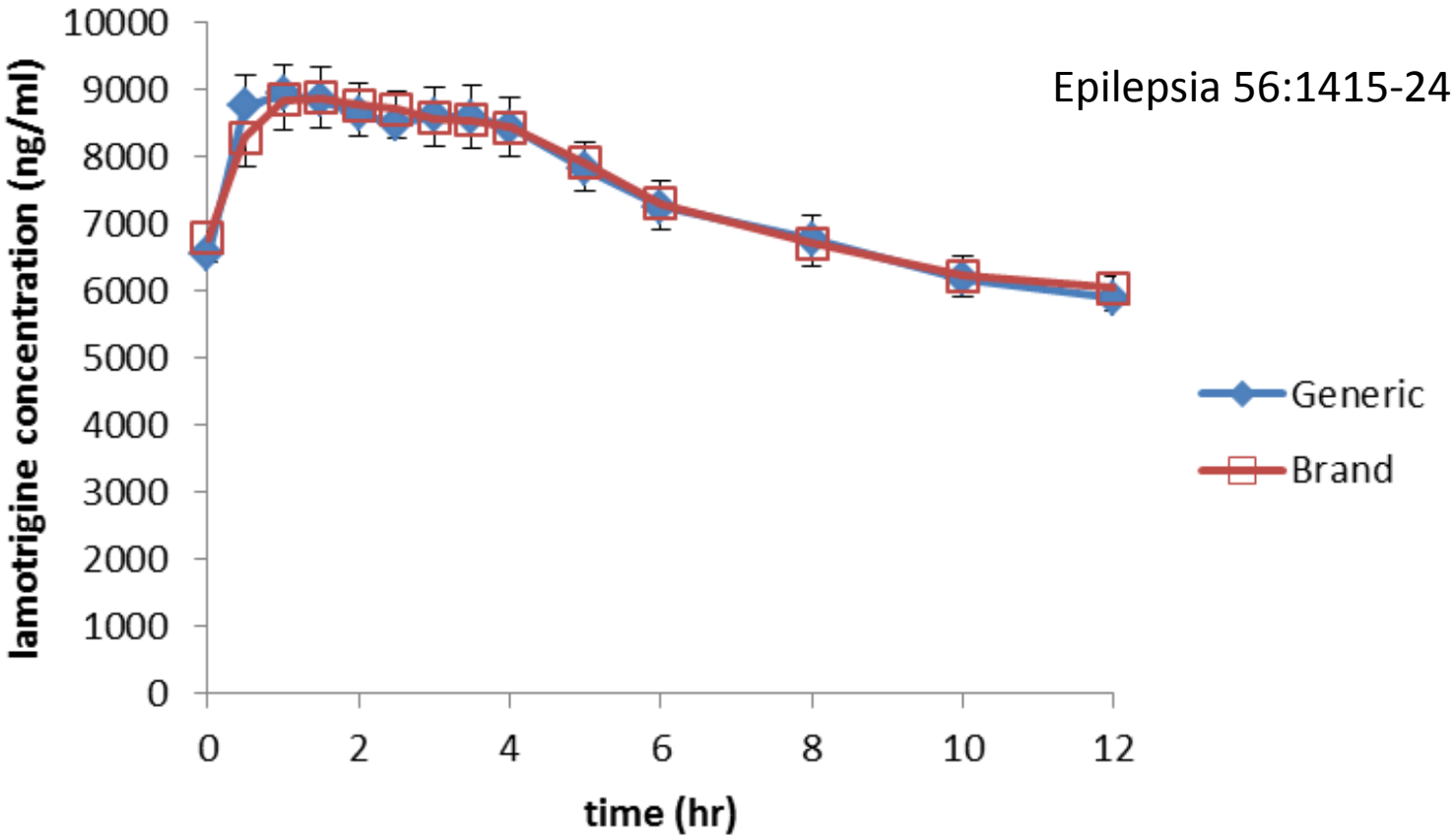
- Who, where, and how is medication made?
- What non-drug ingredients go into the medication and what is their impact?
- What quality control tests are used and what do they assure?
- What is the bioequivalence standard and is it good?
- Is it the same product made last month?
- Is the drug a narrow therapeutic index drug?

Common Excipients with No Impact on Bioequivalence

- Sodium Lauryl Sulfate
- Corn Starch
- Sodium Starch Glycolate
- Colloidal Silicon Dioxide
- Dibasic Calcium Phosphate
- Crospovidone
- Lactose
- Povidone
- Stearic Acid
- Pregelatinized Starch
- Croscarmellose Sodium
- Magnesium Stearate

J. Pharm. Sci. 105:996-1005. 2016.
Mol. Pharmaceutics. 7: 1539–1544. 2010.

Average profiles



Epilepsia 56:1415-24. 2015.

Cmax 90% CI: (98.8%, 104.5%) with mean ratio = 101.6%
AUC 90% CI: (97.2%, 101.6%) with mean ratio = 99.4%
Cmin 90% CI: (93.4%, 101.0%) with mean ratio = 97.1%

Summary

- Hatch-Waxman Amendments have had a favorable impact on the development of both brand and generic products through public interest in and public discourse of pharmaceutical product quality.