



Generic-A Great Claim

A generic drug is the same as brand name drug



In Dosage

The way it is taken

The way it should be used



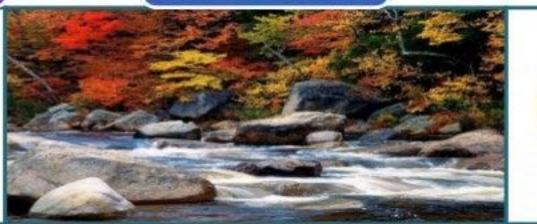
The way it works



In Quality



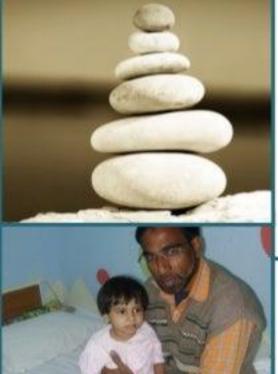












Generic-Perception or Reality

Our drugs are equal quality

Give me Tylenol instead of Panadol

We do not compromise on quality and put in 100% API

More than 50% drugs are fake

We & our kids use the same drugs, we manufacture











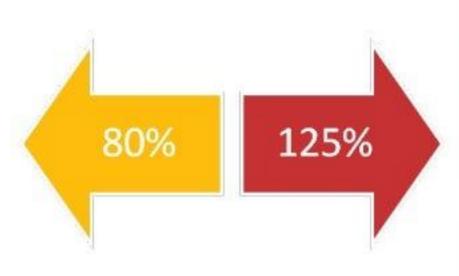


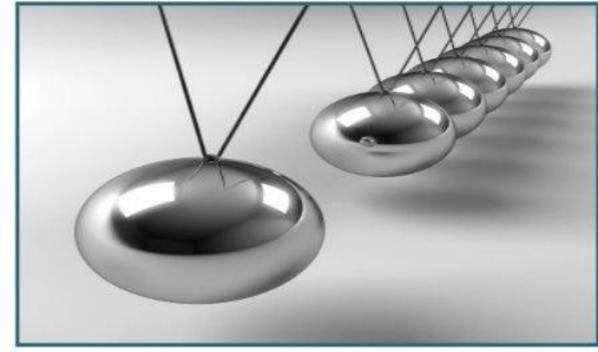


Great Challenge with Generics

Manufacturing & Quality Control

Product Characteristic & Label Therapeutic Equivalency













Dosage Form Change Over ???

Reference drug is in tablet form

 Can we manufacture injection instead of tablet?

Let's think

 Is there need of any clinical study to go for injection?

Do you think

 Has clinical studies nothing to do with dosage form?

Open for discussion. If you have any reference of any developed country, it will be added knowledge.













Overage

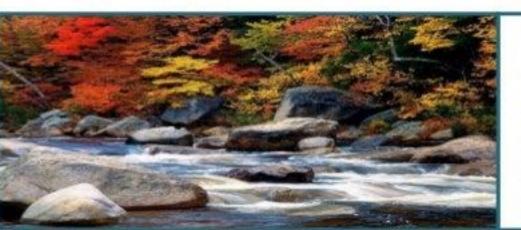
Ergotamine Tartarate

Thyroxine

ACE Inhibitors

Tobramycin













Overage

Generally, use of overage is discouraged. An overage in the drug product, whether it appears in the final product or not, should be **JUSTIFIED** considering the safety and efficacy of the product. Important aspects are

Amount of overage

Reason of overage

Justification for the amount of overage









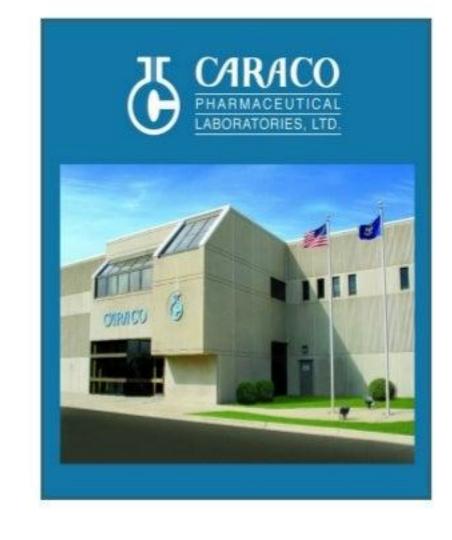
Caraco Pharmaceuticals, a







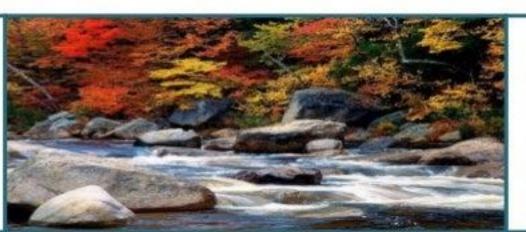










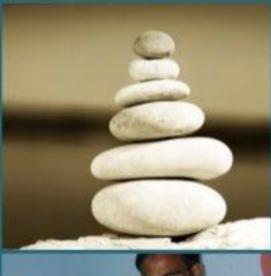


Stability











Dissolution Failure

Metoprolol Succinate Tabs ER Recall due to dissolution 2009 Ethex (KV Pharmaceuticals) 2014 Wockhardt & Ranbaxy

Tropol XL (Sandoz) approved in 1992

Recalled due to dissolution

Therapeutic failure reported in 2007

What do you think?

Formulation had not been properly validated (FDA 2008)

What should we learn?

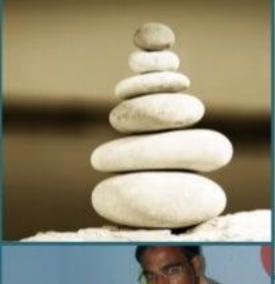














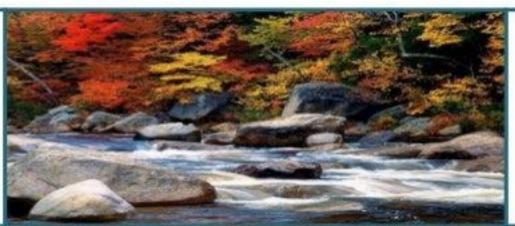
ADHD

- Mallinckrodt
- Methyl Phenidate HCl tab
- 18, 27, 36, 54 mg dose

Failure

 Fasting & fed had two different behavior in extended release

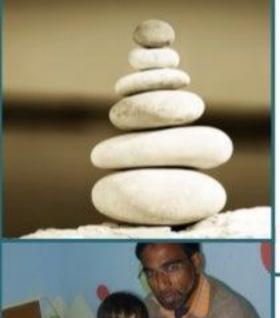












Bupripion HCl tab

 Study on low dose and waiver on high dose

Failure

 Desired kinetics was not achieved

Teva

 FDA asked to stop distribution in sep 2012















В

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Bupripion (Wellbutrin) IR Tab of SKB 1985



Based on evidence demonstrating BE with low strength

In 2006, Generic version Mfg by Impax/Teva were approved 85 post marketing reports from Jan-Jun 2007

Experienced undesirable effects

Increased side effects, Decreased therapeutic effect

Re-switched on brand

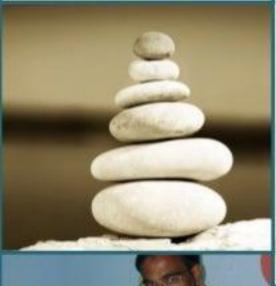














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Temporal relationship under question



Conducted study

Withdrawal of Teva drug in Mar 2013 against Sep 2012 FDA advice

U

Also generic of Actavis withdraw their version

A new challenge

General rule will not work always

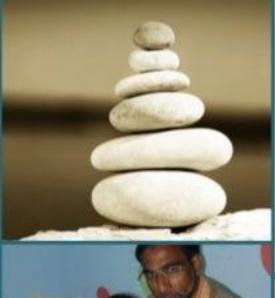
Its life, please care











Production Scale up



- Apotex Canada
- HTZ capsule 12.5 mg failed upon scale up in assay.





- Failure was limited to some batches
- Root cause was not identified even after a year.





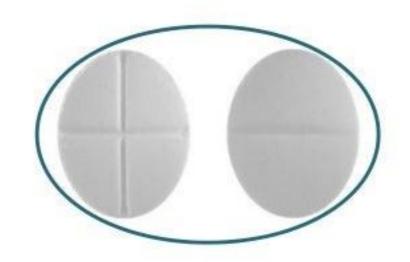








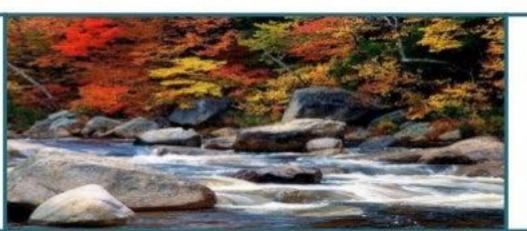
Tablet Scoring





Scoring is not a cosmetic issue but important









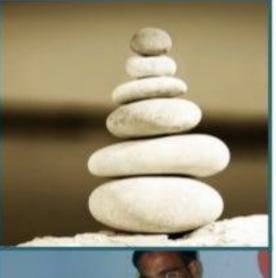
Supplier Qualification















Process



Product











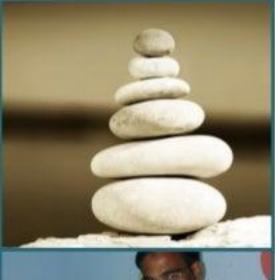
Supplier Qualification











Can a drug product manufactured from a non-compliant API ensure safety???

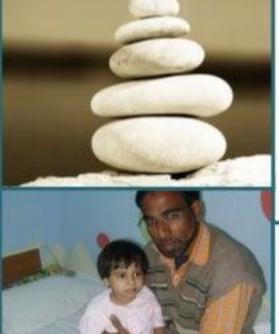












Analytical Method









