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Comparative study of brand and generics of PPI available in Saudi market

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Introduction: PPI is a class of medication that is very effective in suppressing the secretion of gastric acid. It used to treat the acid-related disorders in condition like dyspepsia and PU. It works by binding to H⁺/K⁺-exchanging ATPase in gastric parietal cells, resulting in suppression of basal and stimulated acid secretion. 1st PPI discovered was Omeprazole and it is available in different dosage forms contains 10, 20 & 40 mg per tablet/capsule. Other PPI is Lansoprazole, which is available in capsules and suspensions, disintegrating tablets & IV forms and in contains 15 & 30 mg. The 3rd one is Pantoprazole, available in tablet, gastro-resistant coated table & in powder for reconstitution for injection. From 2006 to 2010, the generics share of total PPI prescriptions in the USA increased from 24% to 68% which show importance of generics. 79% of physicians in Saudi support substitution in most cases “2009”.

This study is conducted to

1. Define if the locally manufactured PPI formulations equivalent to the brand formulations.
2. Determine the prescribing patterns for brand versus generics alternatives at Saudi health institutions and the reason behind their preference is justified?

Results: Illustrating the quality control tests used to evaluate tablets physical characters such as weight variation, friability, thickness and hardness For Pantopazole. According to the results. Hardness of Pantozol was the highest and Toprazole was lowest. The weight variation for all tablets was within USP specification. For friability test Toprazole failed to pass the test. All tablets fulfill USP specification for disintegration test. After measuring the three products of both Omeprazole & Lansoprazole, results show no significant differences between them.

Conclusions:

1. All generics products of Omeprazole and Lansoprazole showed high quality in their dissolution profile and similar results to the brand product of each.
2. For Omeprazole; Omiz is reaching the maximum of 98.51% at 30 minuets which is the highest percent of drug release between the three products.
3. For Lansoprazole; Takepron is reaching the maximum of 92.7% at 60 minuets which is the highest percent of drug release between the three products.
4. Unlike the other two PPIs not all generics of pantoprazole are of equal quality in their dissolution profile. Brand **Pantozol** is reaching the maximum of 98.10% at 60 minuets which is the highest percent of drug release between the five products.
5. The majority of physicians and pharmacists prefer prescribing and dispensing brand formulation of Proton Pump Inhibitors which need increase the awareness of quality of generic products.

Recent Publications:

1. Brand Name and Generic Proton Pump Inhibitor Prescriptions in the United States: Insights from the National Ambulatory Medical Care Survey (2006–2010) Andrew J. Gawron,1,2 Joseph Feinglass,3 John E. Pandolfino,4 Bruce K. Tan,5 Michiel J. Bove,5 and Stephanie Shintani-Smith2,5
2. Gawron, A., Feinglass, J., Pandolfino, J., Tan, B., Bove, M. and Shintani-Smith, S. (2015). Brand Name and Generic Proton Pump Inhibitor Prescriptions in the United States: Insights from the National Ambulatory Medical Care Survey (2006–2010). Gastroenterology Research Andren Practice, 2015, pp.1-7

Biography

Hawra Al-Mubarak clinical pharmacy intern student graduated from Imam Abdulrahman bin Feisal university. I have received training in Alsalyah primary health care center, king Fahad specialist hospital, prince Saud bin Jalawi hospital and currently training in king Fahad hospital in Hufuf. My professional interests focus on generics substitution and bioequivalence research and quality control. I am currently completing the *in vivo* studies for my graduation project. In addition, I have interests in community services and self-development.

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