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Supergenerics: Esomeprazole minitablets as a model

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Esomeprazole is the S-isomer of omeprazole. It is a proton pump inhibitor that suppresses gastric acid secretion by specific inhibition of (H⁺/K⁺) ATPase in gastric parietal cell. It is marketed by Astrazeneca Co., under the brand name Nexium® 20 mg and 40 mg as gastro-resistant film coated pellets compressed to tablets (MUPS). Generic products are identical drugs with the brand name drug and are interchangeable with them, and they are therapeutically equivalent. US FDA and other similar authorities do not recognize the term "Supergenerics". These products are also referred as 'added value generics, new therapeutic entities or hybrids'. These products differ from the original product in formulation or method of delivery. Moreover, these products could be an improved formulation of a known product. A pharmaceutical product developed and manufactured with less excipients and unit operation while maintaining the product therapeutic performance compared to the originator could be considered as an improved therapeutic entity as it reduces the overall cost for manufacturing that could lead to reduced healthcare spending. In this study, enteric coated mini-tablets of ESM were prepared. Bioequivalence studies both under fed and fasting conditions were carried out for the mini-tablets 40 mg versus Nexium 40 mg MUPS. The results for fasting conditions were within acceptable limits, while fed conditions results were not (higher extent of absorption which means less *in vivo* degradation than Nexium). The argument of this presentation: Do we accept or reject, particularly when it has no negative effect on the therapeutic efficacy?

Biography

Derar Omari has completed his PhD from Cairo University and MSc from Jordan University of Science and Technology. As an Assistant Professor in Faculty of Pharmacy, Yarmouk University, he is teaching Industrial Pharmacy, Pharmaceutics and Physical Pharmacy. He published many papers in reputed journals.

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