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Pharmaceutical evaluation of omeprazole enteric coated capsules available in Saudi Arabia market

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INTRODUCTION

Increasing the number of omeprazole containing products in the market, raises questions of its efficacy and generic substitution. Hence, the omeprazole generic products in the local market need to be assess for in vitro drug release based on the pharmacopeia.

OBJECTIVES

Our main objective of the present study was to evaluate the dissolution performance of different brands of omeprazole enteric coated capsules available in the Saudi Arabian market.

METHODS

The dissolution of omeprazole products was performed as per the USP monograph in 0.1 N hydrochloric acid (120 minute) and then pH 6.8 phosphate buffer (30 minute) maintained at 37°C and 100 rpm using Sotax dissolution apparatus 2 system. Omeprazole release from each product (in the dissolution samples) was determined by UV spectrophotometer (UV-1800, Shimadzu, Tyoto, Japan) at a wavelength of 305 nm (2).

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RESULTS

The in-vitro dissolution studies showed that four products (OME-1, OME-2, OME-3 and OME-4) met the requirement and release less than 15% of the drug in the 0.1 N hydrochloric acid media at 120 minutes, while product (OME-5) exhibited slightly more drug release in the acid stage than the pharmacopeial specification (15%). While, all the investigated products released more than 75% of the drug in 30 minutes in phosphate buffer, pH 6.8.

DISCUSSION & CONCLUSION

Based on the obtained dissolution results, omeprazole release from four of the tested enteric coated capsules (OME-1 to OME-4) have complied with the pharmacopeial specifications while the drug release from one product (OME-5) has slightly exceeded the acceptance limit in the acidic medium.

REFERENCES

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