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Raloxifene immediate release tablet for post-menopausal osteoporosis

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Formulation development and evaluation of immediate release tablet of estrogen receptor modulator drug

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The book involves a research work towards developing a formulation of anti-osteoporotic drug, which has in-vitro dissolution profile similar to that of the Innovators' formulation. The patents for dosage form of Raloxifene will expire in late future. Hence, our target was to develop a dosage form as that of Innovator product to file an ANDA application. The present study involves the development of a non-infringing formula for an orally administrable immediate release tablet of the anti-osteoporotic drug with reproducible and robust process. The objectives of the research work included (i) formulation and optimization of the coated tablets of Raloxifene with the aid of design of experiment; (ii) enhance dissolution and evaluate release kinetics of drug from the formulation; (iii) comparison of dissolution profiles of developed formulation with innovator product.

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Binapani Barik

By (author): PRAFULLA KUMAR SAHU

Dinesh Kumar Sharma

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