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Development, assessment and stability studies of Naloxone hydrochloride sublingual drug delivery system

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Naloxone hydrochloride (NHCl) is a semi-synthetic opiate-receptor antagonist and is used to reverse the clinical effects of opiate analgesics. The drug is extensively metabolized in the liver. The objective of this study was to prepare sublingual tablet dosage form of NHCL for the purposes: 1- quick therapeutic effect, 2-by pass liver metabolism, 3- easy to manage with certain patients including pediatrics. To achieve this, 150 mg sublingual tablets each containing 2 mg drug were prepared applying direct compression technique. Pharmatose DLL-21, avicel pH 102, pregelatinized cornstarch, mannitol, talc, magnesium stearate and color (lake pigment HT red) were used as tablet excipient. The prepared tablets were evaluated for their physical characteristics, viz. uniformity of weight, thickness, hardness, disintegration time, content uniformity and in vitro drug release in distilled water. The optimized formulation was subjected to shelf-life stability testing for two months. The results showed that the average values ± SD of weight, thickness, hardness, disintegration time and content uniformity for tablets were 149.415±1.041 mg, 4.97±0.008 mm, 3.55±0.438 kg, 0.86±0.12 min and 102.325±2.256%, respectively. In dissolution study, 100% of drug appeared in the dissolution medium after 40 min. The results of stability study showed no significant difference compared with the fresh formulations when stored on shelf at room temperature ($p<0.05$). The results confirmed that NHCL sublingual tablets were successfully developed; *in vitro* evaluated and could be a potential drug delivery system to quickly reverse the clinical effects of opiate analgesics after in-vivo assessment.

Biography

Abdelazim Zaghloul is an Associate Professor at Faculty of Pharmacy, Kuwait University, Kuwait. He has earned his Bachelor of Pharmaceutical Sciences from Faculty of Pharmacy, Alexandria University and his MSc and PhD degrees from Faculty of Pharmacy, Al-Azhar University, Egypt. From1999-2003, he has worked as a Postdoctoral Research Fellow at School of Pharmacy, Texas Tech University, USA. He has published more than 30 articles in per-reviewed international journals and presented more than 50 podium and poster presentations to national and international meetings. His main research interest focus on drug delivery, development, characterization and optimization of various dosage forms.

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