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الجمهورية اليمنية
جامعـــــة صنعـــــاء
نيابة الدراسات العليا والبحث العلمي
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Formulation & Evaluation of Bisoprolol as fast Dissolve Sublingual Tablets.

Master thesis submitted by the pharmacist.

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Abstract

Fast dissolving drug delivery systems offer a solution for pediatric, geriatric, mentally ill people and those patients having difficulty in swallowing tablets or capsules. In the present study, an attempt had been made to prepare fast dissolving tablets of Bisoprolol fumarate, an antihypertensive and antiarrhythmic agent for this category of patient.

The powders were evaluated for pre-compression parameters such as drug-excipients physical compatibility studies were carried, & studies of excipients and drug chemical compatibility was carried out using FT-IR spectroscopy. Bulk Density, Tabbed Density, Angle of Repose, Carr's Index and Hausner's Ratio. The fast-dissolving tablets of Bisoprolol 10 mg were prepared by direct compression method. Nine formulations were prepared at same conditions, using Sodium Starch Glycolate (SSG) three formulae (F_1, F_2, F_3), Croscarmellose Sodium (CCS) three formulae (F_4, F_5, F_6), and Crospovidone (CP) three formulae (F_7, F_8, F_9) as super disintegrates in different concentration (2.72, 3.74, & 4.55 %) respectively for each formulation. The prepared tablets were evaluated for post compression parameters such as weight variation, thickness, hardness, friability, drug content, wetting time, and in vitro drug release. Based on results three best formulations which is F3, F6, & F9, were subjected to accelerated stability studies for 180 days which undergo to different evaluated parameters at different period according to ICH guidelines. So, according to stability results the optimized formula, which is F9 based on results obtained, was subjected to further evaluated tests like Stability Studies for 90 days, in different temperatures degrees (15°C & 30°C\75%RH), disintegration time, In Vitro dissolution time, and In Vivo studies in experimental animals to measure absorption from mouth & GIT & reach systemic circulation to elect receptors to regulate heart rate of induced animals (Rabbits).

All the precompression results occur in acceptance value, and all post compression parameters occur in acceptable value. The physical and chemical compatibility studies results indicate that there was no interaction between Bisoprolol and the excipients. Formulations (F3, F6, & F9) contain (4.55%) of super-disintegrates give the best results as compared with others which showed maximum drug release, ~92%, ~85% & ~97% after 5 minutes & disintegration time ~10 sec, ~8 sec, & ~4 sec respectively at zero time. The results of stability studies for 180 days explain that F_9 gives the best results among others (maximum drug release ~97% after 5 minutes, & disintegration time ~6 sec). The evaluated results of 2ed stability studies after 90 days were in acceptance value. In Vivo study results that show significant ($p = 0.05$) reduction

in heart rate (clinical effects) of induced rabbits after ingestion of Bisoprolol as fast dissolving sublingual tablet.

In conclusion, fast dissolving sublingual Bisoprolol tablets was prepared successfully and pass all tests so it could be used for reduction of heart rate, and blood pressure.

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صياغة وتقييم بيسوبرولول كأقراص سريعة الذوبان تحت اللسان

(FDSLTs)

رسالة ماجستير في العلوم الصيدلانية مقدمة من الصيدلاني

اسماعيل عبد الخالق محمد يحيى شمسان

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