Proceedings International
Platinum Open Access Journal (ISSN 2668-6384)

Proceedings, Abstract
Volume 4, Issue 2, 2022, 30
https://doi.org/10.33263/Proceedings42.030

Development and Stability Studies of Bisoprolol Oral Formulations for Patients with Swallowing Disorders †

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† Presented at The Sixth International Meeting of Pharmaceutical Sciences (RICiFa), November 10-12, 2021, Córdoba, Argentina

Received: 26.04.2022; Revised: 4.05.2022; Accepted: 6.05.2022; Published: 8.05.2022

Abstract: Bisoprolol (a selective β1-adrenergic blocker) is used to treat pediatric and adult patients with dysphagia. Due to the drug is only available as tablets, the patients are treated by adapting the dose from solid formulations. Therefore, developing a liquid oral formulation would improve dosing accuracy, avoiding overdose and / /or toxicity, and allow the step treatment. To develop formulations containing Bisoprolol (2.5 and 5.0 mg mL^{-1}) and to carry out studies of physicochemical and microbiological stability. Two liquid formulations, each at two concentrations, were developed; F1: dissolving active pharmaceutical ingredient (API) (0.25 or 0.5 g) in glycerin (10 mL) and adding water (q.s.p 100 ml). F2: dissolving API (0.25 or 0.5 g) in syrup (50 mL) and adding syrup (q.s.p 100 ml). These formulations were stored at 4, 25, and 40 °C (75% RH). Recoveries of Bisoprolol were determined by high-performance liquid chromatography (HPLC). The formulations were stable for at least 24 months under all storage conditions (with recoveries greater than 92 %), also complying with the microbiological requirements. The formulations may be preserved at room temperature, are suitable for patients of all ages, and additionally, one of them (F1) is appropriate for diabetic patients.

Keywords: bisoprolol; oral formulations; dysphagia.

Funding

The authors gratefully acknowledge the Universidad Nacional de Rosario Argentina, Ministerio de Producción, Ciencia y Tecnología (ASACTEI, Santa Fe, Argentina), and CONICET (PUE 2016) Argentina for financial support.

Acknowledgments

This research has no acknowledgment.

Conflicts of Interest

The authors declare no conflict of interest.