

Bambuterol and Its Competitive Brands; A Qualitative Study

Sabahat Abdullah^{1*}, Rimsha Abdullah², Mehroz Kalim³, Saima Iqbal³, Fozia Karim³

¹Department of Pharmaceutical Chemistry, Faculty of Pharmacy, University of Karachi, Karachi, 75270, Pakistan

²Dow Medical College, Dow University of Health Sciences, Karachi, 74200, Pakistan

³Jinnah University for Women, Karachi, Pakistan.

ABSTRACT

While not being appropriate for acute attacks, one beneficial attribute of bambuterol is that it is a long-acting beta adrenoceptor agonist, making it feasible to use in chronic illnesses to obtain long-term relief. It is a prodrug, which means it must be metabolized first to be activated and perform its respective tasks is noteworthy too. The purpose of this study is to determine which of the two bambuterol brands, namely, Pulmitac and Bambec meets our predetermined parameters by comparing their physicochemical qualities.

Keywords: Bambuterol, Pulmitac, Bambec, physicochemical properties.

INTRODUCTION

Bambuterol is a medicine that intrigued us in this instance, and it belongs to the category of long-acting beta-2 adrenoceptor agonist, and functions by inducing smooth muscle relaxation majorly bronchodilation, vasodilation, and a modest reduction in peripheral resistance^{1,2}. Although it is not as prominently recognized as its active counterpart terbutaline, its reversing effects on symptoms like coughing, chest tightness, wheezing, and shortness of breath which are all brought on by the primary culprits, asthma, and chronic obstructive pulmonary disorder (COPD), cannot be completely disregarded³. Considering asthma² and COPD⁴ being an insatiable and vicious cycle, this medication typically is quite helpful. Its extended duration of action is appropriate to prevent nighttime exacerbating bronchoconstriction attacks.

It is often used to treat respiratory issues, either alone or with other medications. When combined with a long-acting muscarinic antagonist, it exhibits a satisfactory response but also increases the cardiovascular side effects in COPD patients⁵. It is used with caution in pregnancy due to its tocolytic effects¹ and here, dose adjustments are necessary. It also should not be taken in individuals with hepatic and renal impairments and diabetes mellitus⁶.

Pulmitac and Bambec are two brands of bambuterol, and they are assessed in this respective study to check their physicochemical attributes.

MATERIALS AND METHOD

A comparison of physicochemical properties was carried out by acquiring two brands of bambuterol (10 mg) tablets Pulmitac and Bambec, from the market. This study was done in the Research Laboratory at the Jinnah University for Women's Faculty of Pharmacy in September 2023. To compare, the following parameters were considered.

Weight Variation

Twenty tablets from each brand were chosen at random and weighed separately on an FX-400 electronic balance. We measured their weight variation against the BP/USP standard, which indicates that NMT 2 tablets out of 20 should be more than the $\pm 10\%$ deviation⁷. Ensuring dosage form uniformity is the test's main goal. Additionally, the upper and lower control limits were computed using the following formula:

For upper control limit = Mean + 3x standard deviation

For lower control limit = Mean – 3x standard deviation

Thickness Test

This test measures the thickness of the tablet. This Ensures that every tablet's thickness falls within the range that the USP/BP has established. To test the thickness, 10 tablets of each brand were taken and measured using the Vernier caliper⁸.

Hardness Test

An MH-1 Galvano Scientific hardness tester was used to measure the crushing strength of 10 tablets from each brand, and the average was computed. The tablets must have sufficient sturdiness to endure NLT 4kg of force. The

*Address correspondence to this author

Email: sabahatabdullah07@gmail.com

tablets are deemed to have failed the test if their weight falls beyond the 4–12 kg range⁹.

Friability Test

Under mechanical strain, tablets may fracture into smaller fragments or detach a proportion of powder from their exterior surface, devoid of their elegant appearance, a physical condition termed friability. To test this, 10 tablets were extracted from each brand and subjected to a 4-minute friability analysis at 25 rpm, or 100 spins. The USP states that the friability test should not deviate from NMT 1%¹⁰.

Disintegration Test

This qualitative test determines if oral solid dosage forms, like tablets, would degrade in a predetermined amount of time when exposed to a liquid under the defined set of conditions. According to USP guidelines, uncoated tablet dissolution should occur in 15 minutes. The test needs to be redone on the other 12 tablets if one or two do not meet the requirements; 16 of the 18 pills need to dissolve in the given amount of time to pass the test. To carry out the test, each tablet was placed into a single cylindrical tube using the disintegration assembly DS-0702, which has two baskets containing six perforated tubes. The tablets were evaluated using water as the test medium.

RESULTS AND DISCUSSION

The goal of the present study was to evaluate two marketed brands of bambuterol in Karachi, Pakistan as mentioned in Table 1. The BP/USP's prescribed limitations were used to evaluate the brands.

Table 1. Brand profile of bambuterol.

Brand name	Registration No.	Mfg. License No.
Pulmitac	026684	000415
Bambec	017321	000457

Table 2 presents the mean weight, tablet thickness, and tablet hardness for the brands of bambuterol. The average weight of both the brands remained within the 7.5% pharmacopoeial limit. It was also discovered that the official pharmacopoeial limitations were met by thickness and hardness.

Statistical analysis revealed minor distinctions between each brand based on the results of the physicochemical

tests. In comparison to Pulmitac, it was discovered that the Bambec exhibits the maximum stability in the friability test. Both brands meet the requirements of BP/USP. To assess the effects of attrition and tumbling, during the life cycle of a tablet, it is required to compute the maximum degree to which bambuterol tablets may fracture during rotation in a drum.

Table 2 Statistical analysis of Tofranil and Imidol; standard deviation (STD), upper control limit (UCL) and lower control limit (LCL).

Test Parameters	Pulmitac	Bambec
Average Weight (mg)	140.8	121.9
STD	0.81	2.38
UCL	143.23	129.04
LCL	138.37	114.76
Average Thickness (mm)	8.8	9.2
STD	0.48	1.1
UCL	10.24	12.5
LCL	7.36	5.9
Average Hardness (Kg)	4.6	3.1
STD	0.5	0.1
UCL	6.1	3.4
LCL	3.1	2.8

Table 3. Results of friability and disintegration tests.

Tests	Acceptance criteria	Results	
		Pulmitac	Bambec
Friability (%)	NMT 1%	0.07	0.5
Disintegration (Min)	NMT 15 min	0.6 (40 sec)	1

The primary parameters influencing the overall performance of a drug from its compacted form are the disruption and dissolving pattern of the solid core. Since it optimizes and guarantees the API's bioavailability from most solid dosage forms, the disintegration process is crucial. Pulmitac and Bambec, two brands of bambuterol, disintegrated in 40 and 60 seconds, respectively. The findings showed that all bambuterol tablets of these two brands fall within the range permitted by the BP/USP,

which is not more than 15 minutes for uncoated solid dosage forms. Pulmitac readily disintegrates within a minute than Bambec which takes a complete minute for the disruption of the tablet core.

CONCLUSION

We selected Pulmitac and Bambec as our two bambuterol brands to determine their physicochemical properties. Surprisingly, both products are competitive and exhibit outstanding performance with their respective qualities. However, we do not believe that one is preferable to the other.

LIMITATIONS

This study is limited given that it solely evaluates the efficacy of two bambuterol brands based on their physiochemical properties; likewise, it lacks a quantitative analysis based on pharmacological criteria.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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