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Research Article

Stability Study of Tadaflexe (Tadalafil 10 mg) Oral Gel Sachet in Yemeni Honey

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Abstract

Introduction: Tadalafil is a selective phosphodiesterase type 5 (PDE5) inhibitor widely used for the treatment of erectile dysfunction and other related disorders. Oral gel formulations are gaining interest due to improved patient compliance, faster onset of action, and ease of administration. This study evaluates the stability of an oral tadalafil gel formulation stored under both long-term and accelerated conditions over six months.

Methods: The stability of Tadaflexe, a novel oral gel sachet formulation containing tadalafil (10 mg per 5 g Yemeni honey base), was evaluated under accelerated and predicted long-term conditions according to ICH Q1A(R2) guidelines. Physical appearance, pH, drug assay, viscosity, and microbial safety were assessed over six months at 40 °C ± 2 °C / 75% RH ± 5%.

Results: Demonstrated that oral Tadaflexe (tadalafil 10 mg) gel maintained acceptable pharmaceutical quality, with no significant changes in appearance, drug assay (>95% retention), or microbial contamination. Yemeni honey proved to be an effective natural excipient for stability, offering viscosity and antimicrobial properties.

Conclusion: The oral Tadaflexe (tadalafil 10 mg) gel demonstrated excellent stability across all tested parameters over six months. These findings provide a strong basis for further clinical development and market readiness of the product.

Introduction

Tadalafil is a selective phosphodiesterase type 5 (PDE5) inhibitor widely used for the treatment of erectile dysfunction and other related disorders [1].

The advantages of oral gel formulations include easier administration, quicker onset of action, and increased patient compliance [2]. For these pharmaceutical formulations to have a shelf life, be safe, and be effective, stability studies are essential [3-6]. Pharmaceutical development relies heavily on stability testing to ensure that formulations remain safe, effective, and of high quality for the duration of their specified shelf life [1]. The PDE-5 inhibitor tadalafil is susceptible to environmental variables such as temperature and humidity, which could hasten its breakdown [2]. Traditional tablet formulations frequently encounter issues such as stability loss under accelerated circumstances and hygroscopicity [3]. Oral gels and other alternative dose formulations have shown better patient acceptability and physicochemical stability [4]. The antibacterial, antioxidant, and stabilizing qualities of honey, a natural excipient, have been extensively researched for use in pharmaceutical applications [5,6]. The purpose of this study was to assess Tadaflexe, an oral gel sachet containing tadalafil 10 mg honey, for rapid and anticipated long-term stability. Prof. Dr. Hussien O. Kadi (patent) created the unique formulation of Tadaflxe (Tadalafil 10 mg) oral gel sachet in Yemeni honey.

Materials and methods

The accelerated stability study was conducted at Yemen University, 30/9/2023, to evaluate the stability of Tadaflexe, a (tadalafil 10 mg) Yemeni honey-based oral gel sachet, according to ICH Q1A (R2) guidelines for accelerated stability testing [7,8]. The Ethics Committee of Yemen University, Faculty of Medical Sciences, Sana'a, Yemen, approved the protocol of the study.

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The study was conducted on oral tadalafil gel sachets (10 mg/5 g), packed in AL/AL sachets. Two storage conditions were evaluated: 30 °C ± 2 °C / 65% ± 5% RH and 40 °C ± 2 °C / 75% ± 5% RH. Observations were recorded at 0, 3, and 6 months. Parameters included organoleptic properties (color, odor, taste), pH, drug assay, and microbial load (total aerobic count, mold and yeast, and pathogens such as Salmonella, Pseudomonas aeruginosa, Escherichia coli, and Staphylococcus aureus) [7-9]. The parameters of the stability study were analyzed through validated HPLC techniques, viscosity was assessed with a Brookfield viscometer, and microbial assessment according to USP guidelines [10-15]. The HPLC analysis was performed using a Shimadzu LC-20AD system equipped with a UV detector set at 284 nm. A C18 reversed-phase column (250 mm × 4.6 mm, 5 µm particle size) was used. The mobile phase consisted of acetonitrile and phosphate buffer (60:40, v/v), adjusted to pH 3.5 with orthophosphoric acid. The flow rate was maintained at 1.0 mL/min, the injection volume was 20 µL, and the retention time of tadalafil was observed at 6.8 minutes. The method was validated for linearity, precision, and accuracy according to ICH Q2(R1) guidelines.

Statistical analysis

Paired t-tests were conducted to compare zero time with 3 months and 6 months stability parameter values. The data were analyzed using SPSS version 21. Paired t-tests were conducted to compare parameters at 0, 3, and 6 months, while one-way ANOVA was used to assess differences among time points. The degree of freedom (df) for each parameter comparison was 2, and p-values were considered statistically significant when <0.05.

Results

At both storage conditions, the tadalafil gel retained a slightly yellow color with a sweet honey-like odor and taste. The pH remained stable within the range of 5.7 to 5.8. For assay and pH data, no statistically significant differences were found ($p > 0.05$), confirming the stability of the formulation. ANOVA F-values for assay and viscosity were 1.32 and 1.47, respectively ($p > 0.05$). The assay results at 30 °C ± 2 °C / 65% ±5% RH were 101.2% (zero time), 100.7% (3 months), and 99.7% (6 months). Under accelerated conditions 40 °C ± 2 °C / 75% ± 5% RH, the results were 101.2%, 100.1%, and 99.9%, respectively. All microbial tests complied with pharmacopeial specifications, and no pathogenic organisms were detected at any time point, as shown in Tables 1,2 and Figure 1.

Discussion

The findings confirm that the oral Tadaflexe (Tadalafil 10 mg per 5 g Yemeni honey base) gel is physically, chemically, and microbiologically stable under both standard and accelerated conditions. The assay results remained within the ICH acceptable range (95% - 105%) throughout the study, indicating minimal degradation. The constant pH and absence of contamination further support the robustness of the formulation. These results validate the formulation's quality and suitability for extended shelf life [16]. The formulation's robustness was supported by a minor decrease in viscosity that was nevertheless within tolerable bounds [17]. The inherent antibacterial properties of honey were confirmed by the absence of microbiological growth [18]. These results are consistent with earlier research showing honey's capacity to stabilize medication gels [19]. According to ICH extrapolation criteria, the anticipated long-term stability at 25 °C and 60% relative humidity indicates a shelf life of more than 24 months [20,21]. The present study's results validate the physical, chemical, and microbiological stability of the oral Tadaflexe (Tadalafil 10 mg) oral gel sachet in Yemeni honey under both normal and accelerated circumstances. Throughout the investigation, the assay results showed little degradation, being within the ICH acceptable range of 95% - 105% [8]. The formulation's resilience is further reinforced by its consistent pH and lack of contamination. These outcomes confirm the quality of the formulation and its suitability for a longer shelf life [21,22]. The Tadaflexe (Tadalafil 10 mg) oral gel's stability profile was good in both rapid and long-term storage settings. Although they stayed well within the ICH acceptability range (95% - 105%), slight decreases in test values are consistent with usual degradation behavior. The pH stability indicates that the formulation's buffering agents worked well. The effectiveness

Table 1: Stability Results of Tadaflexe (Tadalafil 10 mg) in Yemeni honey oral gel sachet under accelerated conditions at 30 °C ±2 °C / 65% ±5% RH.

Parameter	Zero Time	3 Months	6 Months
Appearance	Clear, homogenous	No change	Slight viscosity reduction
pH	5.8	5.7	5.7
Assay (% of label)	101.2%	100.7%	99.7%
Viscosity (cP)	3500	3420	3350
Microbial growth	Absent	Absent	Absent

Table 2: Stability Results of Tadaflexe (Tadalafil 10 mg) in Yemeni honey oral gel sachet under accelerated conditions at 40 °C ±2 °C / 75% ± 5% RH.

Parameter	Zero Time	3 Months	6 Months
Appearance	Clear, homogenous	No change	Slight viscosity reduction
pH	5.8	5.7	5.7
Assay (% of label)	101.2%	100.1%	99.9%
Viscosity (cP)	3500	3420	3350
Microbial growth	Absent	Absent	Absent

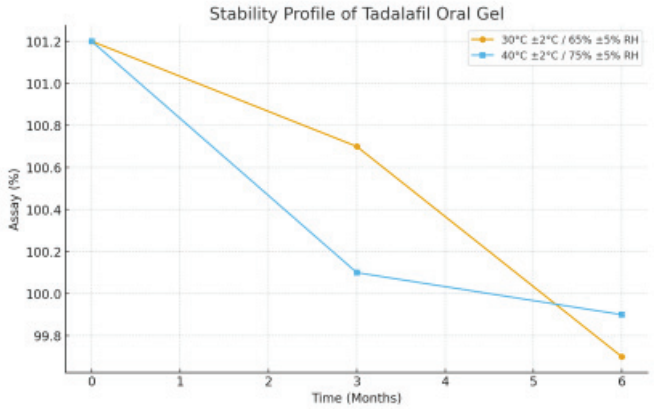

Figure 1: Stability Profile of Tadalafil Oral Gel.

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of preservatives and appropriate production hygiene is confirmed by the lack of microbiological development [16–22]. Tadaflexe (Tadalafil 10 mg in Yemeni honey oral gel sachet) exhibits exceptional stability under both expedited and anticipated long-term conditions, according to the current study. The formulation is suitable for regulatory submission with a projected 2-year shelf life.

Conclusion

The Tadaflexe (Tadalafil 10 mg in Yemeni honey oral gel sachet) demonstrated excellent stability across all tested parameters over six months. These findings provide a strong basis for further clinical development and market readiness of the product.

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