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DETERMINATION OF TAMSULOSIN HYDROCHLORIDE FROM PHARMACEUTICAL FORMULATION (URIMAX 0.4) USING THIN LAYER CHROMATOGRAPHY

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ABSTRACT

A common medication used to treat benign prostatic hyperplasia is tamsulosin hydrochloride, a selective α α-adrenergic receptor antagonist (5,7). Its detection in pharmaceutical formulations and biological samples is crucial in situations of drug abuse, overdose, and medico-legal investigations in forensic and clinical toxicology (21,22). Thin Layer Chromatography (TLC) provides a quick, affordable, and dependable screening procedure, even if instrumental techniques like HPLC and LC- MS are frequently used (3,4,16).

In this investigation, tamsulosin hydrochloride from a commercial modified-release capsule formulation (URIMAX 0.4, 400 µg) was identified using a straightforward TLC approach (11,12,14). Using a chloroform solvent solution, chromatographic separation was accomplished on silica gel 60 F_{254} plates: The ratio of methanol to ammonia (25%) is 8:2:0.2 (v/v/v) (16,18). The existence of the basic alkaloidal substance was confirmed by visualization under UV light at 254 nm and by spraying with Dragendorff reagent, which formed a distinctive orange-brown spot (10,18,20). For regular forensic screening of tamsulosin in pharmaceutical and toxicological samples, the established approach is straightforward, sensitive, and appropriate (2,3,4).

Keywords: Tamsulosin hydrochloride, URIMAX 0.4, Rf value, etc.

INTRODUCTION

A Sulfonamide derivative, tamsulosin hydrochloride is a member of the class of selective α_2A- adrenergic receptor blockers (7,11). It is widely used to treat lower urinary tract problems brought on by benign prostatic hyperplasia (BPH) (5,7). Chemically speaking, it is (R)-(–)-5-[2-[[2-(o- ethoxyphenoxy)ethyl]amino]propyl]-2-methoxybenzene sulfonamide hydrochloride], with a molecular weight of 444.98 and a formula of $C_{22}H_{22}N_2O_2S{\cdot}HCl$ (8,10).

Tamsulosin may be used in forensic practice in situations including drug interactions, compliance testing, and unintentional or deliberate overdoses (21,22). Although advanced instrumental methods like HPLC, GC-MS, and LC-MS/MS offer excellent sensitivity and specificity, many standard forensic labs may not have access to them (6,8). Because of its ease of use, affordability, speed, and capacity to analyze several samples at once, thin-layer chromatography is still a useful preliminary and confirmatory technique (3,4,16). In accordance with the methodological pattern frequently used in forensic toxicology labs, the current work attempts to develop and standardize a TLC method for the identification of tamsulosin hydrochloride from a commercial modified-release formulation (URIMAX 0.4) using an optimized

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solvent system and appropriate visualization reagents (10,14,15).

MATERIALS AND METHODS

1. Materials and Reagents

URIMAX 0.4 capsules (containing 400 µg tamsulosin hydrochloride), Methanol (AR grade), Chloroform (AR grade), Ammonia solution (25%), Dragendorff reagent, Silica gel 60 F_{254} TLC plates, Capillary tubes, Hot water bath, UV chamber (254 nm)

2. Preparation of sample solution

Capsule contents equivalent to 0.4 mg (400 µg) of tamsulosin hydrochloride were accurately weighed and transferred to a test tube. To this, 10 mL of methanol was added and the mixture was heated on a hot water bath for 5–10 minutes to ensure complete dissolution of the drug from the modified-release matrix (14,15,16). The solution was allowed to cool and then filtered. The clear filtrate was used as the test solution (18,19).

3. Chromatographic conditions

1. Stationary phase: Silica gel 60 F_{254} TLC plate
2. Mobile phase: Chloroform: Methanol: Ammonia (25%) (8:2:0.2,v/v/v)
3. Application volume: 5–10 µL
4. Development: Ascending method in a saturated chamber
5. Visualization:
    - o UV light at 254 nm
    - o Dragendorff reagent spray

4. Procedure

The TLC plates were activated at 105 °C for 30 minutes. Using a fine capillary tube, 5–10 µL of the prepared methanolic extract was spotted on the baseline (16,18). The plate was developed in a pre-saturated chromatographic chamber containing the mobile phase Chloroform : Methanol : Ammonia (25%) in the ratio 8 : 2 : 0.2 (15,17). After development, the solvent front was marked and the plate was air-dried (3,4).

The developed plate was first examined under UV light at 254 nm, where a distinct quenching spot was observed (20). Subsequently, the plate was sprayed with Dragendorff reagent, which produced an orange–brown colored spot, characteristic of nitrogen-containing basic drugs such as tamsulosin (10,24).

RESULTS AND DISCUSSION

Using the chosen solvent solution, tamsulosin hydrochloride was successfully separated on silica gel (14,15,19). The drug's absorption of UV light at 254 nm caused it to appear as a dark patch against a luminous background (20). The existence of a tertiary amine group was confirmed by the spot's vivid orange-brown coloring after being sprayed with Dragendorff reagent (10,24).

Good chromatographic behavior and the solvent system's appropriateness for routine screening were indicated by the Rf value, which was repeatable and constant for multiple runs (3,16). By decreasing tailing brought on by contact with acidic silanol groups on silica, the introduction of ammonia in the mobile phase enhanced the basic drug's migration (18,19). The findings show that tamsulosin hydrochloride can be reliably identified using UV detection and Dragendorff reagent, which can be used successfully in forensic pharmaceutical analysis and first toxicological screening (4,21).



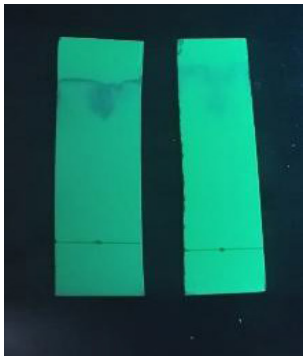


Figure1: Thin layer chromatogram of tamsulosin hydrochloride (URIMAX 0.4) after visualization with Dragendorff reagent showingorange–brown spot.

Figure 2: Thin layer chromatogram of tamsulosin hydrochloride (URIMAX 0.4) observed under UV light at 254 nm.

CONCLUSION

To identify tamsulosin hydrochloride from the modified-release capsule formulation URIMAX 0.4, a straightforward, quick, and affordable TLC approach has been developed (9,14). The solvent system Chloroform: Methanol: Ammonia (25%) (8: 2: 0.2) provided adequate separation, while the Dragendorff reagent with UV light viewing created distinctive reactions (18,20,24). Tamsulosin can be

found in pharmaceutical and suspected toxicological materials using this method as a preliminary or confirmation procedure in forensic and quality control labs (4,21,23).

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