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| RESEARCH ARTICLE

Post-Market Quality Surveillance: Assessing Physicochemical Parameters and Inter-Brand Variations of Cinnarizine Tablets in Thi-Qar_Iraq

Hussein Jabbar Alhazza
Department of Pharmacognosy, College of Pharmacy, University of Thi-Qar, Thi-Qar, Iraq
Corresponding Author: Hussein Jabbar Alhazza, **E-mail**: hussein.alhazza@utq.edu.iq

| ABSTRACT
As a first-line medication for vertigo management, cinnarizine has been authorized for the treatment of nausea, vomiting, motion sickness, and illnesses affecting the inner ear. Blood viscosity and nystagmus in labyrinth are both reduced by its anti-vasoconstrictor action. The primary objective of the study was to evaluate the worth of both brand-name and generic Cinnarizine available in Iraq. The following tests were performed on 25 mg cinnarizine tablets available in Iraq: in vitro dissolving test, disintegration, friability, drug content, and hardness. The innovator product, Janassen, was coded as CA1. The generic brands, Ibn Hayyan (Syria) and Sama alfayhaa (Iraq), were coded as CA2 and CA3, respectively. A spectrophotometric method was employed for the purpose of drug analysis. Results: Using spectrophotometers, we could detect active drug levels between 95% and 98% in CA1, CA3 having the maximum potency at 99.99%. In terms of mechanical qualities, all the formulations presented similar and excellent resistance to abrasion. The mean friability values were very low, ranging between 0.11% and 0.12%. The tablet hardness and the disintegration behaviors were somewhat different. The innovator product (CA1) had the maximum mechanical strength (9.5 ± 0.21 Kg) and the disintegration time was 4.15 min. The Iraqi generic (CA3) had the lowest hardness (6.5 ± 0.54 Kg) and the disintegration time was almost equal to 4.12 min. The Syrian generic (CA2) was characterized by a quick breakdown (1.47 min) in spite of its intermediate hardness (8.2 ± 0.28).

| KEYWORDS

Cinnarizine, Dissolution, Friability test, disintegration test, hardness

| ARTICLE INFORMATION

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1- Introduction

The white crystalline powder known as cinnarizine (CN) (chemical formula: C26H28N2, and molar mass: 368.50 g mol^{-1}) is visually appealing (Figure 1) [1]. In addition to promoting blood flow, it is employed as an antihistamine. It has high permeability and low water solubility, according to the biopharmaceutical categorization system (BCS), which places it in BCS class II [2]. Due to its high partition coefficient value (log P = 5.8), this weak base is almost insoluble in water [3]. Because to its poor dissolving rate and low solubility, CN has limited oral absorption and bioavailability. CN has limited bioavailability, low solubility, and unstable structure, making it an inefficient therapeutic molecule from a physicochemical perspective [4]. The current commercially marketed dosage forms are tablets and capsules [5]. Both of these exhibit low and erratic oral bioavailability, which is mainly due to the poor and pH-dependent dissolution of the drug[6].

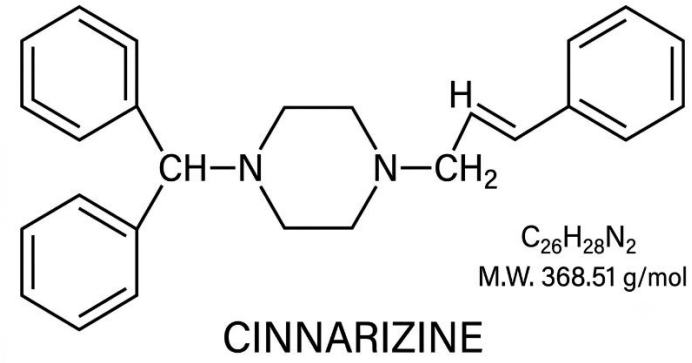

Fig. 1 Chemical structure of Cinnarizine

A large number of studies examining the in vitro drug release of different commercial tablet forms from different countries have been documented. Nevertheless, research on the promotion of cinnarizine in Iraq is scarce. The evaluation focused on the dissolving characteristic of locally accessible cinnarizine tablets because of its importance in predicting medication bioavailability and product quality. Pal et al. evaluated five brands of cinnarizine 25 mg tablets (Stugeron, Vertigon, Cinzan, Sinarzine and Cinnifit) commercially available and reported that all brands met acceptable quality-control specifications with respect to weight variation, drug content, friability, disintegration and in vitro dissolution. Dissolution test was performed using USP II paddle device using 900 mL simulated stomach juice pH 1.2 / 0.1 N HCl at 50 rpm instead of 75 rpm. Further, no similarity factor f1/f2 is present in the sample and no comparison of six generics specific to Pakistan is available [7]. They have developed and validated an LC-ESI-MS/MS method for the quantitative measurement of cinnarizine in human plasma. The authors stated that the study used protein precipitation instead of liquid-liquid extraction, as in earlier attempts, which was easier, cheaper and reproducible. The approach showed high accuracy, selectivity, sensitivity and repeatability with short run time of 3.5 min and met the US FDA validation requirements. This procedure was then applied in a comparative pharmacokinetic study of cinnarizine 25 mg tablets. Pharmacokinetic results demonstrated bioequivalence between the test and reference products. There were no ill effects, no dropouts among participants and volunteers tolerated the experiment well, it stated.

According to the report, the experiment went smoothly, with no negative side effects and no participants dropping out. Various quality control checks were conducted by the generic brands, and considerable discrepancies were identified [8]. The reason for comparing an innovator and generic formulation of cinnarizine is because the efficacy of tablets is formulation and manufacturing dependent and dissolving based testing is one of the most common tests used to predict the quality and possible bioequivalence of the product. Because hardness, friability, disintegration, and dissolution are routine in-process or post-compression testing that are pertinent to the mechanical integrity and drug-release behavior, the data also supports their inclusion as core tablet quality tests [9]. Small changes in excipients or processing can affect the behavior of a dosage form. Process variability might influence the physicochemical properties and in vitro release of acyclovir creams. Therefore, the production parameters such as pH, emulsification length, homogenization speed and temperature were evaluated explicitly. The disintegration and dissolution of oral tablets depend on a variety of parameters such as the properties of the raw materials, the fillers employed, the porosity of the tablet, and the compression conditions [10].

2- Materials

Table 1: Materials Used in the Study.

Materials	Supplier
hydrochloric acid	Thomas baker,india
Methanol	Merck- Darmstadt, Germany
Cinnarazine	Janssen(UK), (Ibn Hayyan(syria)) and (sama alfayhaa(Iraq))

2.1 Sampled Drug Products

The products were coded as CA1 (innovator), CA2 (generic 1) and CA3 (generic 2). The generic products were compared against the innovator product.

2_2 Drug Content:
Each company's drug content test consisted of combining the contents of three pills. The next step was to, filter the mixture. After the required amount of methanol had been diluted, the spectrophotometric measurement was carried out [11].

2.3 In vitro Disintegration Test
We used 0.1N HCl as a disintegration medium to find the CN's disintegration time (DT). A basket rack structure with six open-ended tubes was used to estimate the DT using specialized disintegration testing equipment from Copley Scientific in the UK. Each tube contained one tablet, and 900 ml of 0.1N HCl maintained at 37 ±0.5 ºC was poured into the basket, which had a bottom surface formed of a stainless-steel screen (mesh no. 10). Using a timer, we predicted how long it would take for the pill to completely dissolve in each tube [12].

2.4 Friability test
The friability of the tablets was assessed by weighing the tablets before and after tumbling in an Erweka friabilator (Germany). The pharmacopoeial friability test is a typical method for assessing the quality of solid dosage forms following formulation as it examines the mechanical strength of the batch. The % weight loss and the tendency of each tablet to abrade under stress was determined by running the device at 25 rpm for four minutes. This approach is consistent with the standard quality-control procedures employed by the USP, BP, JP and other applicable compendial frameworks for tablet [13].

2.5 Hardness test
A YD-1 tablet hardness tester (Beijing, China) was used to determine the hardness of the cinnarizine tablets [14]. To illustrate variability from batch to batch or unit to unit, the individual tablets were tested many times and the average hardness value and standard deviation were calculated. Along with friability, disintegration, drug content, and dissolution, hardness is a crucial post-compression quality characteristic often included in cinnarizine research. The tablet's hardness should be just right to ensure mechanical integrity without causing it to break too easily, as cinnarizine formulations aim for rapid disintegration and drug release [15].

2.6 Dissolution test:
The in vitro dissolving profile of the CN tablets was determined using USP dissolution equipment II (rotating paddle). The experiment was performed in 900 mL of 0.1 N HCl at 37 ± 0.5 °C with a paddle speed of 50 rpm. The dissolving media was replaced by 5 mL of fresh medium at 5, 10, 15, 20, 25 and 30 min using a Millipore filtered syringe. The collected materials were analyzed spectrophotometrically. The absorbance of cinnarizine at 251 nm was measured by the reported method [16].

3- Results and discussion

3.1 Hardness test
The brands' ability to resist pressure and retain all of the tablet's components throughout packaging and handling was confirmed by a hardness test. According to Table 2, we found that the CA2 and CA3 generic products had hardness values (equal to or higher than 4 Kg) that were similar to the CA1 [17].

3.2 Friability test
The tablets' capacity to withstand abrasion is determined by conducting the friability test [18]. The USP, 1995 now includes friability as a compendia test. For the friability test, one percent of compendia is needed. Table 2 shows that the friability test results for all of the CN products that were part of our analysis were less than 1%.

3.3 In vitro disintegration test
In vitro, at 0.1 N HCL, the medicine was completely released within 30 minutes by both brand and generic goods, which had the quickest disintegration times (Table 2).

Table 3: Evaluation of disintegration time, Friability and hardness of different product of atorvastatin tablets

Product code	CA1	CA2	CA3
Drug content (%)	95	98	99.99

Disintegration time (min)	4.15	1.47	4.12
Friability % Mean (n=20)	0.11	0.11	0.12
Hardness Kg Mean ± STD (n=3)	9.5±0.21	8.2 ± 0.28	6.5 ± 0.54

3.4 Dissolution test

The significance of dissolution studies as a method for examining batch-to-batch variation and medication release has increased in recent years [19]. To be bioavailable, drugs with low solubility, such as CNZ, need to dissolve from their solid dosage form. Since the dissolving profile is the initial factor in determining the rate of absorption, poorly soluble drugs will not have the intended therapeutic impact as rapidly since they are not as readily available in the body system. Utilizing the dissolving experiments, one may ascertain the quantity of medication that is accessible for absorption after oral administration [20]. The dissolving test findings (Figure 2) reveal that the CA-1 products exhibited a drug release of 99.99% within 20 minutes. Figure 2 shows that product CA-2 has a rate of 98.245% while product CA-3 has a rate of 98.22 %. Rapid breakdown and release of over 95% of the CNZ content occurred in all tested generic tablets within 20 minutes. Before issuing a marketing license to a generic, regulatory bodies want evidence of similarities between the generic and originator brands. The general consensus is that fast-dissolving tablets are functionally equivalent.

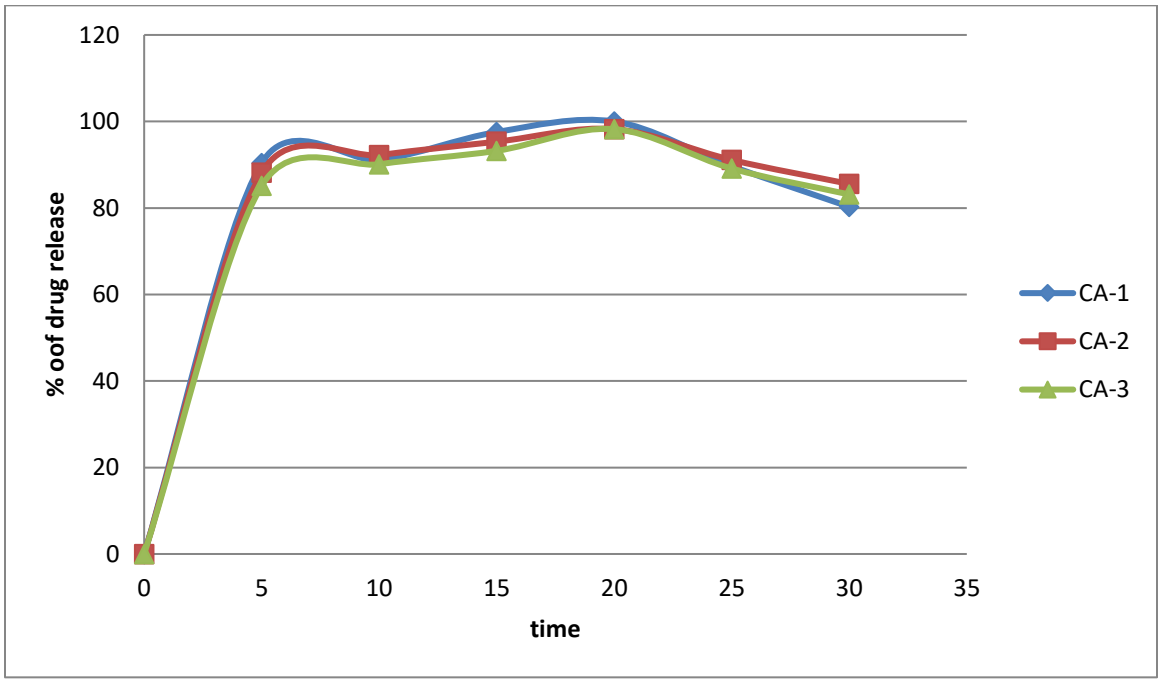

Figure 2: Dissolution profiles of the CN tablets (CN1) and its generic counterparts (CN2 and CN3) at pH 6.8.

4. Conclusion

Results from this study demonstrate that the generic CN tablets (25 mg) being studied are of high pharmaceutical quality and are competitive with the originator product. More than 95% of the medicine was released in less than 20 minutes after the innovator product and assessed generic brand tablets broke down, as seen in the dissolution profile. The results of the hardness, friability, and disintegration tests also show that the innovator and generic products are of acceptable value.Generic medicine and innovator product results are equivalent, according to the present study. Generally speaking, the cost of generic medicine is lower than that of brand-name medicine. To save a substantial amount of money, patients might switch to generic drugs. Therefore, both the patient and the hospital will end up saving a significant amount of money down the road. The results of this inquiry must be confirmed by conducting in vivo bioavailability experiments to determine if they can be applied to real-life situations.

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