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EVALUATION AND DRUG STABILITY STUDIES OF DIFFERENT BRANDS OF CLOPIDOGREL TABLETS AVAILABLE IN SANA'A CITY MARKET, YEMEN

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ABSTRACT
Clopidogrel is a medication orally administered drug used as to reduce the risk of heart disease. The most of the companies seek to achieve high quality of drug, but often it is very difficult to achieve. The aim of this study is to investigate quality parameters of some marketed Clopidogrel tablets at Sana'a City Market, Yemen. Six different marketed brands of Clopidogrel 75mg tablets available in Sana'a City Yemen, were collected from different pharmacies. Quality parameters, like weight variation, hardness, thickness and loss on drying test were determined according to established protocols. with the in-vitro dissolution test, potency, disintegration time were also carried out. The percentage of dissolution and assay were carried out used UV-spectrophotometer. All the brands comply the Pharmacopoeia requirements as they offer acceptable weight variation range, the hardness of all tested brands was within range and no significant differences in disintegration times as they disintegrated within 10minutes. In case of dissolution rate, all brands showed acceptable dissolution time as they released more than 80% of drug within 45 minutes. The most of selected brands also meet the assay specifications. This study suggested that the most of commercially tested brands of Clopidogrel tablets marketed in Sana'a City, Yemen comply with the pharmacopeia specifications and quality control specification, as the following: Plavix > Cloval > Plaviscot > Plavilate > Plavicare > Plavised.

KEYWORDS: Clopidogrel, Drug Stability, Evaluation, Sana'a City Market, Yemen.

INTRODUCTION
Clopidogrel and Drug Stability[1-82]
Clopidogrel is a routine component of the clinical management of patients after acute coronary syndrome. It has been reported that this drug would reduce rates of major cardiovascular adverse events. It is approved for the reduction of atherosclerotic events in patients with stroke, myocardial infection, cardiovascular disease and acute coronary syndrome. Quality of a product is an important factor in supporting the marketing of commercial drug products as well as patient compliance. Quality assurance processes may range from the performance of simple chemical experiments.

Quality control studies of drug products are regarded as a substantial process of the pharmaceutical industry, which includes all processes that are performed to ensure the desired level of quality of drug products. If the quality of the product is low then there will be increased return of the product from the market and then profitability and customer loyalty are decreased United States of Pharmacopeia and British Pharmacopeia are such two Pharmacopeias that provide the necessary specifications. Quality is essential for the survival and growth of the organization and customer satisfactions. The controlled gastric retention of formulation may be achieved by the various approaches such as mucous adhesion, sedimentation, expansion, floatation and modified shape systems.

Prolonged gastric retention improves bioavailability, reduces drug waste and improves solubility for drugs that are less soluble in a high pH environment. However, the gastric retention is influenced by many factors such as level of fluids in the stomach, gastric mobility, pH and presence of food. Although the majority of the drug is hydrolyzed by esterase to an inactive carboxylic acid metabolite, the full anti-aggregating activity of the drug is achieved by biotransformation to 2-oxo-Clopidogrel by cytochrome P450-1A.

The United States Pharmacopoeia recommended a reverse phase HPLC method with UV detection at 220nm for determination of Clopidogrel in tablets. survey reveals that there are different types of assay methods for the determination of clopidogrel in pharmaceutical dosage forms. The processes of quality control were performed before releasing a drug into the market, so it must be subjected to strict control to ensure that the quality and performance concerning safety, efficacy, potency, stability, and elegance of medications of the final drug product were accepted by consumers. Currently, all solid oral conventional drug products require an in vitro dissolution study as part of their quality control appreciation; this includes testing the drug-release profile of various batches of a marketed product to confirm manufacturing and product consistency.

Products are available on the market in different companies which differ from each other in accuracy and quality level, so the quality level of the product is tested as a regular procedure in each step of manufacturing of the product and the results of tests are compared with standard characteristics under the Pharmacopoeia**.** Clopidogrel is a carboxylic ester of S-configuration. The R-enantiomer is devoid of antithrombotic activity. It is rapidly absorbed and undergoes extensive metabolism and metabolic activation, as evidenced by the absence of detectable amounts of unchanged drug in plasma. Assay, evaluation of the active pharmaceutical ingredient (API) concentration in drug-containing dosage form. The time of disintegration is directly proportional to the rate of dissolution. Disintegration is evaluated to ensure that the drug substance is fully available for dissolution and absorption from the gastrointestinal tract.

The drug stability studies are important in all stages of pharmaceutical manufacturing, marketing, or post-marketing follow up because the drug stability is the basis for the effectiveness and safety of drug and to ensure that its bioavailability reach the site of action. Studying the factors that affect the validity of drug stability is part of the drug development stage and pharmaceutical innovations in manufacturing. Good medicine and advanced drug delivery systems. Drug stability is required preformulation, formulation, evaluation studies, in the marketing and clinical use stage. Formulation scientist from his experience and knowledge have to significantly in the stability study stage and is an important factor in the ADDS (Advanced Drug Delivery Systems) product development process and bioavailability.[78-152]

The objective of the present study was to evaluate the quality of marketed oral tablets containing Clopidogrel supply by various companies marketed in Sana'a City, Yemen.

MATERIALS AND METHODS

Materials

The Clopidogrel tablets (75mg) are six brands were purchased from different pharmacies in Sana'a City Market, Yemen. Different brands of Clopidogrel were used in the study and were purchased from the local market. The brands analyzed were Plaviscot, Plavicare, Plavised, Plavilate, Cloval and Plavix the Various pharmaceutical parameters were employed as in (USP) and (BP), as weight variation thickness, diameter, hardness, loss on drying test, disintegration time, assay and dissolution rate.

Equipment's

Analytical balance, (electronic balance type bl-220h, Shimadzu corporation Japan), weight variation, (electronic balance type bl-220h, Shimadzu corporation Japan), thickness & diameter tester (G.T. tools micrometer Japan), friability test (Veego, India and Aoe, instruments), hardness tester, (Erweka GmbH, Germany), disintegration test apparatus, (digital table disintegration test apparatus) and dissolution spectrophotometer tester, (Veego, India and Aoe, instruments).

METHODOLOGY

Evaluation of Different Brands of Clopidogrel Tablets[70-154]

Weight Variation Test

The test used for ensuring the proper amount of the drug in the tablet by weight of 20 tablets is routinely evaluated. An analytical balance and the average weights were then determined. **(BP)**.

Thickness and Diameter

The measurement of 20 tablets is routinely evaluated to ensure the proper size of the drug in the tablet. An analytical balance (G.T. Tools micrometer Japan) was used to determine the Thickness Diameter of 20 tablets. **(BP)**.

Hardness Test

Hardness of the tablet is controlled by the degree of the pressure applied during the compression stage. A hardness tester (PTB111E (Erweka GmbH, Germany) was used for 10 tablets which were taken randomly within limit (4-10 Kg/cm). **(BP)**.

Loss on Drying Test

Loss on drying the test the measurement of amount of moisture in tablets by drying that used through oven by weight drug before and weight drug after the limit NMT 0.5%. **(USP)**.

Disintegration Time Test

Disintegration time was observed for 6 or 12 tablets at a 5 to 30min time to ensure quality control using a disintegration apparatus (digital tablet disintegration test apparatus) having a rigid basket rack assembly suspended in medium pH at 2.5 hydrochloric acid and solution 700 ml beaker, at 37±2°C. **(USP)**.

Assay Test

Dissolve an accurately weighed quantity of Clopidogrel reference in 0.1 N HCl to get 0.0075 mg/ml solution of Clopidogrel determined λ max**.** Then 4 tablets of Clopidogrel were grinded and then transferred 75 mg, add about 100 ml of 0.1 N HCL and stir for about 20 minutes to dissolve, filter the solution and diluted and then absorbance was measured at 220 nm. Clopidogrel Bisulfate contains NLT 90.0% and NMT 110% of clopidogrel calculated on the dried basis. The content was mixed well, and the absorbance was measured at 220 nm against a reagent blank. Calculate the percentage of clopidogrel and any other individual impurity in the portion of the sample taken; Result = $(r_u/r_s) \times (C_s/C_u) \times 100$. **(USP)**.

Dissolution Rate Test

Dissolution studies were conducted using a USP the standard preparation, about 75 mg of was placed in a pH 2.5 and Apparatus is paddle and Temperature: 37±2°C. Dissolution test was by using 1000ml Medium of HCL (35%) and KCL 0.2M buffer solution. sample was drawn at time intervals of 5, 15, 25, 35 and 45 minutes for each formulation Procedure Determine the amount of Clopidogrel dissolved by employing UV absorption at a wavelength of about 240 nm on littered portions of the solution under test in comparison with the Standard solution. Tolerances Not less than 80% of the labeled amount of Clopidogrel is dissolved in 45 minutes. Drug concentrations were measured spectrophotometrically. (AOE, instruments) was used. **(USP)**.

RESULTS AND DISCUSSION

Results

Table 1: Weight Variation, Thickness, Diameter and Hardness Results of Different Brands of Clopidogrel Tablets.

Brand Code	Weight Variation (mg) ±SD	Thickness (mm) ±SD	Diameter (mm) ±SD	Hardness (Kg) ±SD
C1/Plaviscot	159±11.925	3.5±0.175	8±0.45	3.35±0.579
C2/Plavicar	295.5±14.775	4.5±0.225	9±0.45	6.3±0.788
C3/Plavised	241±18.075	4.5±0.225	9±0.45	6.25±2.188
C4/Plavilat	232.5±17.437	4±0.2	9±0.45	6.85±0.709
C5/Cloval	269.5±13.475	4.5±0.225	9±0.45	11.4±1.234
C6/Plavix	245.5±18.41	4±0.2	8.8±0.45	9.4±0.926

Weight Variation Test

Tablet weight is mainly affected by factors such as tooling of the compression machine, head pressure, machine speed and flow properties of the powder. Weight variation test was done to check the uniformity of contents and active ingredients so that a uniform product can be guaranteed with an elegant appearance. The results obtained from the study revealed that all brand tablets were pass according to (BP) as shown in Table 1.

Thickness and Diameter

The thickness diameter of Clopidogrel in vitro of branded tablets from the tested was results obtained from the study revealed that all brand tablets were pass at percent of average value deviation less than 5%, as shown in Table 1, according to the **(BP)**.

Hardness Test

If the tablet is too hard, it may not disintegrate in the required period and if it is too soft, it will not withstand the handling during subsequent processing such as coating or packaging and shipping operations. Hardness of Clopidogrel in vitro of branded tablets using an automatic tablet hardness tester and the results were all brand tablets within the acceptable range as shown in Table 1, according to the **(BP).**

Table 2: Loss on Drying, Disintegration Time and Assay Results of Different Brands of Clopidogrel Tablets.

Brand Code	Loss on Drying (%)	Disintegration Time (min) ±SD	Assay (%) ±SD
C1/Plaviscot	0.3	7.518±2.255	95.79±0.028
C2/Plavicar	0.1	7.966±2.75	77.86±0.042
C3/Plavised	0.1	7.121±2.440	76.47±0.035
C4/Plavilat	0.1	7.12±2.489	83.19±0.056
C5/Cloval	0.3	8.048±2.210	95.37±0.021
C6/Plavix	0.1	9.34±0.352	100.00±0.014

Loss on Drying Test

Loss on drying tests of the Clopidogrel in vitro of branded tablets used for ensure the moisture contents of tablet that results were all brand tablets within the range as shown in Table 2, according to the **(USP)**.

Disintegration Time Test

Disintegration test is very important for tablet because the dissolution rate of drug depends on it, which ultimately affect the rate of absorption of drug. Disintegration of Clopidogrel in vitro of branded tablets

the results obtained from the study revealed the were all brand tablets disintegrated within 10 minutes as shown in Table 2, according to the **(USP)**.

Assay Test

The Assay of the Clopidogrel is percentage content of tablet should comply with the specification due to very highly potent drug may give toxic effect and very less potent drug may give sub-therapeutic effect, assay of all brands was found within 76.47±0.035(%) – 100.00±0.014(%). The results revealed that Plavix showed the highest drug content whereas Plavised gave the lowest results. USP specification for the drugs are equivalent to not less than 90.00% and not more than 110.00%. Only three brands are within the limit of assay according to the USP specification, was found to be Plavix, Plaviscot and Cloval. The results obtained from the study as shown in Table 2, according to the **(USP)**.

Table 3: Dissolution Rate Results of Different Brands of Clopidogrel Tablets.

Brand Code Time	C1/Plaviscot	C2/Plavicar	C3/Plavised	C4/Plavilate	C5/Cloval	C6/Plavix
0	0.00±0.00	0.00±0.00	0.00±0.00	0.00±0.00	0.00±0.00	0.00±0.00
5	66.41±1.075	72.16±0.640	69.46±0.707	71.56±0.564	64.83±1.071	61.62±1.310
15	73.43±1.274	75.57±0.517	71.82±0.422	79.48±0.482	68.57±1.062	71.54±0.680
25	76.44±1.068	78.48±1.049	89.15±1.126	79.72±0.927	70.72±0.464	77.61±0.605
35	84.69±0.492	84.08±0.820	92.61±0.671	82.98±0.217	72.70±0.414	83.43±0.576
45	91.54±1.123	96.20±0.264	97.36±0.483	94.78±0.767	99.11±0.195	93.62±0.570

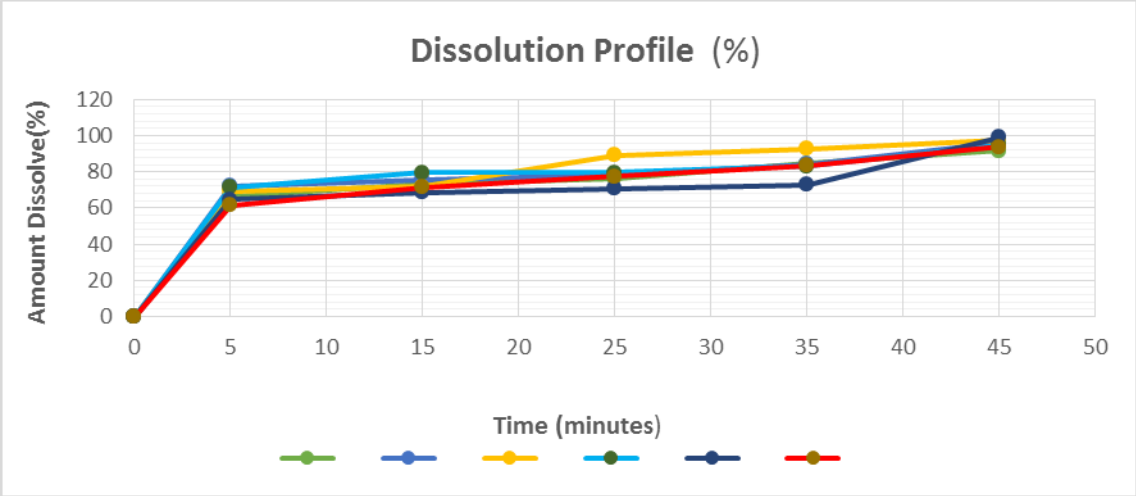

Fig. 1: Dissolution Profile of Different Brands of Clopidogrel Tablets.

Dissolution Rate Test

The results of dissolution rate of the Clopidogrel in vitro release of branded tablets. By the end (45 minutes) of the in-vitro release test, the percentage drug released for brands C1, C2, C3, C4, C5 and C6 was found to be 91.66, 96.20, 97.16, 94.24, 99.24 and 93.52 (%) respectively. The results obtained from the study revealed that all the brands' tablets released within 45 minutes released the drug more than (80%) as shown in Table 3 and Figure 1, according to the **(USP)**.

Table 4: Rank Order of Branded Tablets According to Quality Control Tests.

Brand Code Test	C1/Plaviscot	C2/Plavicar	C3/Plavised	C4/Plavilate	C5/Cloval	C6/Plavix
Weight Variation	1	3	5	4	2	6
Hardness	6	4	5	3	1	2
Thickens	1	5	6	3	4	2
Diameter	1	5	6	4	3	2
Disintegration	3	4	2	1	5	6
Dissolution	6	3	2	4	2	1
Leaking	6	2	3	4	5	1
Assay	2	5	6	4	3	1
Total Rank Order	26	31	35	27	25	21
Conclusive Rank Order	3	5	6	4	2	1

DISCUSSION

The most tested brands of Clopidogrel 75mg tablets complied with the official quality specifications. By comparing the quality results, the best brand was Plavix while six different brands of Clopidogrel, i.e. Plaviscot, Plavicar, Plavised, Plavilate, Cloval and Plavix were analyzed.

Clopidogrel tested tablet have uniform weight and sufficient physical stability to maintain physical integrity, as shown in Table 4, where the results study obtained of six different brands Plavix > Cloval > Plaviscot > Plavilate > Plavicare > Plavised, were evaluated by used (**USP** & **BP**) parameters. The results of the clopidogrel brands show that differences are present during the manufacture of these products, i.e., excipients, speed of machine, etc.

CONCLUSION

Quality control of Clopidogrel tablets is essential to determine the quality of brands. The drugs have been arranged according to the USP and BP quality control, as the following: Plavix > Cloval > Plaviscot > Plavilate > Plavicare > Plavised. It was concluded that the most of tested brands tablets were evaluated it complies to **(USP)** and **(BP)** specifications and parameters.

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