A comparative study of quality parameters of different marketed brands of Amlodipine Tablets

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Abstract **- Presence of various brands of similar drug product at different rates creates a question of quality and therapeutic efficacy in the mind of consumer. The marketing practice to promote the brands also invites the confusion among the patients and market middleman. The comparative evaluation of quality parameters gives an idea of difference in therapeutic effectiveness of brands. This study was conducted to understand and analysed the variation in quality parameters of different brand of Amlodipine tablets available in local market. For this purpose, uniformity of weight, hardness, friability, drug content, disintegration time and dissolution study were conducted on different brands of Amlodipine tablets.**

Index Terms **- Amlodipine, Therapeutic efficacy, Tablet, Quality parameters.**

INTRODUCTION

In Indian pharmaceutical market various brands of any one drug product are available due to existence of process patent. So, most of the companies are selling similar product with different brand name. These products contain same drug amount but varies in the formulation composition mainly excipients. The quality and efficacy may differ because of use of different excipients and manufacturing process. The overall brand value of any product is dependent on the quality of product. To evaluate the quality and efficacy of formulation the quality control parameters must be evaluated.

Amlodipine besylate is a potent long-acting calcium channel blocking agent indicated in the treatment of mild to moderate essential hypertension and of chronic stable angina. It is also used to treat certain types of anginas (chest pain) and coronary artery disease (narrowing of the blood vessels that supply blood to the heart). It lowers blood pressure by relaxing the blood vessels, so the heart does not have to pump as hard. It controls chest pain by increasing the supply of blood to the heart.[1] Amlodipine is sparingly soluble in water so in tablet dosage form the rate of absorption is effected from the rate of dissolution. Chemically it is a dihydropyridine calcium-channel blocker that inhibits the trans membrane influx of calcium ions into vascular smooth muscles and cardiac muscles, which in turn affects their contractile process and results in reduced blood pressure.[2]

More than 50 brands of amlodipine are available in market with different brand names. The comparative efficacy of these brands may be established by evaluating the quality parameters of these brands. For this purpose, four brands of amlodipine were selected, and the quality control tests were performed for comparative assessment.

MATERIAL AND METHOD

For comparative evaluation of amlodipine tablets 4 tablet brands are purchased from the local market i.e. Stamlo (Dr. Reddy's), Amlopres (Cipla), Angicam (Blue cross), Amodep (FDC) and randomly coded A1, A2, A3 and A4 respectively. The comparative evaluation of these four brands was done on following Parameters:-

Uniformity of weight: 20 tablets of each brand was selected randomly, and individual weight of each tablet was determined with the help of analytical balance. Average weight of 20 tablets was calculated and deviation of individual weight from the average weight was measured in percentage. [3]

Hardness test: Tablet hardness has been defined as the force required to break a tablet in a diametric compression test. The tablet is crushed between two anvils and the forced applied to break was recorded. It is also termed as crushing strength of tablet. In the

present study the hardness of tablet was measured by using "Pfizer Hardness Tester". An average of five observations in each brand was reported. [4]

Friability Test: Tablet hardness is not an absolute indicator of strength since some formulation when compressed into very hard tablet tends to cap on attrition, losing their crown portions. Therefore, another measure of a tablet's strengths is its friability which is included in study. Friability of different brands was measured in "Roche friabilator". Ten pre-weighted tablets of each brand were rotated at 25 rpm for 100 revolutions. The tablets were dusted and re-weighted and percentage of weight loss during test was calculated and reported in percentage.[5]

Drug content: For evaluation of drug content in different tablet brand, 10 tablets of one brand was taken and crushed to make the powder and quality equivalent to 10 mg of drug was taken and dissolved in 10 ml of methanol and then liquid was filtered to remove solid residue. From the solution drug content was determined by UV-VIS spectrophotometer by measuring the absorbance at 237 nm after suitable dilution. The concentration was calculated from the standard curve prepared as reported by Gokul Ghenge *et. al.* [3,6]

Disintegration Test: For absorption through oral route the tablet must break to become soluble in body fluid. This step of breaking of tablet in solution is called disintegration. Disintegration is defined as "that state in which no residue of the tablet or capsule remain on the screen of apparatus or if a residue remain it consist of fragments of insoluble coating of tablet or of the capsule shell or will the soft mass with no palpable core. If disc have been used with capsules any residue remain on the lower surface of the discs consists only of fragment of shells." Standard disintegration time of uncoated tablets is 15 minuts. For this test 6 tablets of each brand were placed in the standard Disintegration apparatus, which contained distilled water 37°C ±2 °C and time for complete disintegration of tablet was recorded. [4,7]

Dissolution test: Dissolution is one of the most important in-vitro method to understand the release behavior of the drug from the formulation which reflects the solubility of the drug in the dissolution medium because as the solubility increase the dissolution rate increases. The rate of dissolution is directly related to the efficacy of the tablet product as well as to bioavailability difference between the formulations. [8]

Dissolution study was conducted using USP type II dissolution apparatus. Six tablets of one brand was studied for the release rate by placing it in the dissolution flask containing 500 ml. of 0.01 N Hydrochloric acid at 37± ºc and stirred at 75 rpm. The 5 ml sample was withdrawn at every 5, 10, 15, 20, 25 and 30 min. The sample withdraw was suitable diluted and absorbance of sample was measured by UV spectrophotometer at 237nm. Finally the percentage of drug release was plotted against the time and represented graphically. [9]

RESULT AND DISCUSSION

Data obtained from Hardness Test, Friability Test and Uniformity of weight are tabulated in Table1. The result shows that hardness was found to be 2.6 Kg/cm^2 (A3) to 3.1 Kg/cm^2 (A1) that is within the limit of 2.5-3.0 (Kg/cm^2). The Friability of A2 is 1% rest of the brands have less than 1% with a minimum of 0.5% (A3). Weight variations are also within the limit of 7.5%.

Brand	Hardness* (Kg/cm^2)	Friability (%)	Weight variation* (mg)
A1	3.1 ± 0.02	0.8	132 ± 2.12
A2	2.9 ± 0.13	1.0	153 ± 5.06
A3	2.6 ± 0.19	0.5	147 ± 2.40
A4	3.0 ± 0.08	0.7	162 ± 3.45

*Values are expressed as ± SD where n= 5

Table 1: Quality Parameter of Tablets

The Drug Content in the different brand was found to be 99.5% (A3) to 97.5% (A2) whereas Disintegration Time varies from 3.0 min (A4) to 5.0 min (A1) both the parameter are found to be within the limit for all the 4 brands.

Brand	% Drug content	Disintegration Time* (min.)
A1	98.02	5.0± 0.07
A2	97.5	4.0± 0.24
A3	99.5	4.0± 0.06
A4	98.60	3.0± 1.02

*Values are expressed as ± SD where n= 3

Table 2: Disintegration Time & Drug Content of tablets

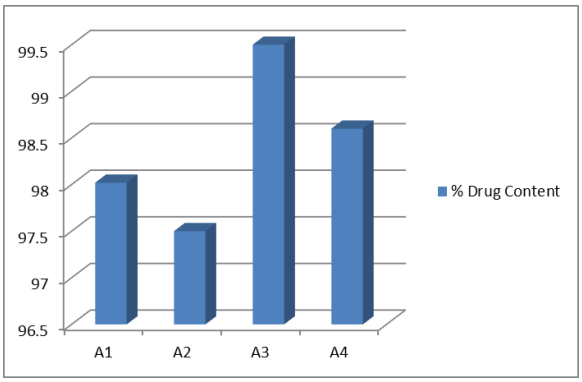

Figure 1: Comparative % Drug Content in different brands

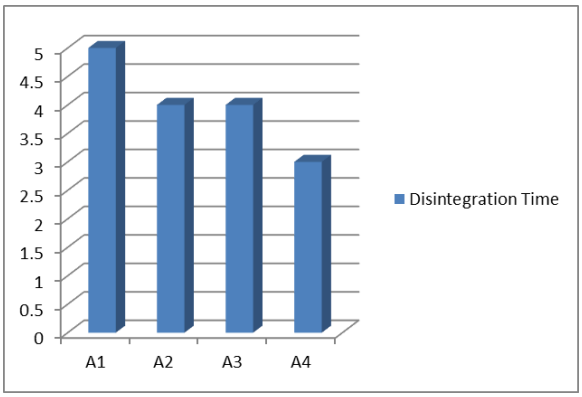

Figure 2: Comparative Disintegration time of different brands

Dissolution Profile data of different brands are tabulated in table 3. The drug release was found to 94% (A2) to 99% (A3) in 30mint of time. Almost all brand release 50 % of drug in first 5 minutes.

Time (minutes)	Percentage drug release*			
	A1	A2	A3	A4
0	0	0	0	0
05	52.10 ± 0.76	48.63 ±0.87	60.21 ±1.63	59.26 ±1.25
10	59.10 ±1.80	68.35 ±2.10	70.56 ±1.49	72.80 ±2.59
15	75.60 ±2.32	75.14 ±1.65	81.27 ±0.57	83.24 ±1.06
20	87.98 ±1.58	89.24 ±2.08	99.14 ±1.51	98.85 ±3.21
25	95.52 ±2.14	90.23 ±1.68	99.45 ±1.02	97.29 ±2.52
30	97.20 ±1.32	94.56 ±1.36	99.49 ±0.89	98.23 ±2.04

*Values are expressed as ± SD where n= 3

Table 3: Dissolution Profile of Tablet Brands

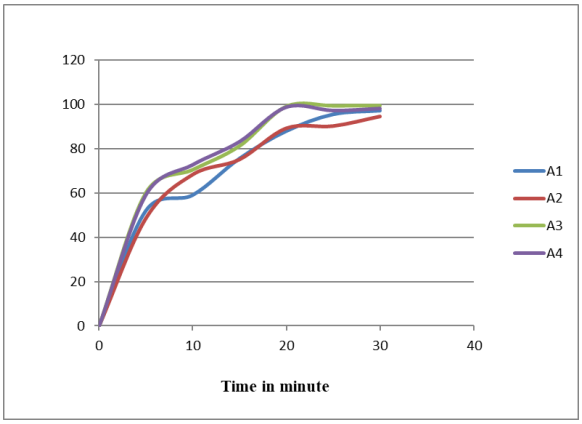

Figure 3: Comparative Dissolution Profile of Tablet Brands

CONCLUSION

The results from this study indicate that different brands may haves varying quality parameters. The hardness and friability reflects mechanical strength of the formulation whereas the uniformity of weight, drug contain, disintegration time and the release rate profile is most important factor for therapeutic efficacy of the formulation. All selected brands were found to follow quality standards. Overall A3 brand was found to be most suitable among all the selected brands.

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