Quest Journals
Journal of Research in Pharmaceutical Science
Volume 8 ~ Issue 3 (2022) pp: 22-27
ISSN(Online) : 2347-2995
www.questjournals.org

Research Paper

Comparative Evaluation of Quality of Some Brands of Nifedipine Retard Tablets in Ondo State, Nigeria

Ibukun Olanrewaju ADELEKE* and Miyen-EpiriPere-EbiBEKEWE
Department of Pharmaceutics and Pharmaceutical Technology, College of Pharmacy, Igbinedion University Okada, Nigeria. Corresponding author

ABSTRACT:*This study evaluated the quality of ten brands of Nifedipine 20 mg tablets available for sale in various pharmaceutical shops in Ondo State, Nigeria employing standard methods. The ten brands of Nifedipine were evaluated for tablet uniformity,hardness,thickness, diameter, friability, disintegration and dissolution. It was found that all the brands of Nifedipinecomplied with the requirements in the British Pharmacopoeia with hardness value ranging between 4.1 kgF and 7.9 kgF. The percentfriability of all the brandswas less than 1% which showed that the tablets can withstand abrasion during handling, packaging and transportation. Three of the brands of Nifedipine 20 mg tablets failed the disintegration test, while the other seven brands passed the test. All the brands of Nifedipine 20 mg tablets evaluated released about 50% of their content within one hour which indicate their ability in attaining a good blood pressure control level within an hour.From this study, it can be concluded that all the brands of Nifedipine 20 mg tablets performed well based on the specified requirements in theBritish Pharmacopoeia for each of the test carried out except brands B, F and H failed the disintegration time test while they passed other tests.*

KEYWORDS: *Nifedipine 20 mg tablets, ten brands, standard methods,British Pharmacopoeia*

R*eceived 01 Mar, 2022;* ***R****evised 11 Mar, 2022;* ***A****ccepted 13 Mar, 2022* © *The author(s) 2022.*
P*ublished with open access at* ***www.questjournals.org***

I. INTRODUCTION

The United States Pharmacopoeia defined tablet as solid dosage forms that contain medicinal substances with various diluents. In general, a tablet is a pharmaceutical dosage form which comprises of active ingredients and excipients usually in powder form, pressed or compacted into a solid [1]. In tablet formulation, the manufacturing process and the raw materials used affect the finished product. Tablet properties should be determined during manufacturing process so as to ascertain the quality of the finished product [2]. Nifedipine is a calcium channel blockers. It is the prototype dihydropyridines with a rapid onset and short duration of action. The overriding action of nifedipine is arteriolar dilation, total peripheral resistance decrease, Blood Pressure falls. The direct depressant action on heart requires much higher dose, but a weak negative inotropic action can be unmasked after B blockade.Nifedipine was developed by the German Pharmaceutical Company Bayer, with most initial studies being performed in the early 1970s [3].The study was carried out in order to find out if the active ingredients in the tablets meet the specifications in the pharmacopoeia. Problems of drug dissolution, friability, content uniformity, drug disintegration are seen in solid dosage form of drugs. Variable clinical response to the same dosage form of a drug product by different manufacturers have been reported, these variable clinical responses include inefficacy of drug, inability to have a desired therapeutic outcome, side effects.

II. MATERIALS AND METHODS

Nifedipine powder (Aldrich, Germany), ten different brands of nifedipine 20mg tablets purchased from different pharmacy shops in Ondo state, Nigeria.

2.1 Tablet Weight

The average weight of randomly selected tablets from each brand was determined by individually weighing twenty tablets of each brand of product using an analytical weighing balance. The weight of each individual tablets was compared with the average weight. The percentage coefficient of variation was calculated from the equation below.

$$\text{Coefficient of variation} = \frac{\text{Standard deviation}}{\text{Mean weight}} \text{ X } 100 - - - - \text{Equation 1}$$

Table 1: Information on the various brands of nifedipine retard (20 mg) tablets

Brand Code	Country of manufacturer	Manufacturing date	Expiring date
A	Israel	01/2017	01/2020
B	India	07/2017	09/2019
C	China	06/2017	06/2020
D	India	09/2016	08/2019
E	Nigeria	04/2017	03/2020
F	India	08/2017	07/2020
G	China	05/2017	05/2020
H	India	06/2017	05/2020
I	Nigeria	12/2016	11/2019
J	China	03/2017	03/2020

NOTE: This research was conducted in 2018

The various brands of Nifedipine retard (20 mg) tablets were evaluated for tablet properties.

2.2 Tablet Hardness

The hardness of five tablets from each brand was measured using a Monsanto hardness tester. The force to break each tablet was applied diametrically by placing the tablet in between the anvil and spindle of the tester. The knurled knob was turned until the tablet fits into the space, the scale adjusted to zero and the pressure applied by further turning the knurled knob until the tablet breaks. The force required to break the tablet was read from the scale in kilogram unit. The result obtained from the five tablets for the different brands were recorded and the mean value calculated.

2.3 Thickness and Diameter

The thickness and diameter of ten randomly selected tablets were measured using the Mitutoyo gauge.

2.4 Friability Test

Ten previously weighed tablets were subjected to a series of rotation and free fall shocks in the drum of the friabilator. The friabilator was operated at 25 rpm for 4 minutes. The tablets were removed at the end of 100 rpm, dusted and re-weighed. The percentage friability was calculated using the equation below:

$$\frac{W1 - W2}{W1} \times 100 - - - - - - - - - - - - - - - - - \text{Equation 2}$$

W1 = Initial weight of tablets
W2 = Final weight of tablets

2.5 Disintegration Time

Disintegration time was measured by employing the British Pharmacopeia method and using the basket-rack assembly with disk. One tablet was placed in each of the six tubes of the basket-rack assembly and the apparatus operated. A total of six tablets were used in the determination of the disintegration time of each brand and their mean disintegration time calculated. The time taken for full disintegration of the tablet was recorded for each unit.

2.6 Drug Content

Ten tablets were randomly selected from each brand. They were crushed and powdered, using a mortar and pestle. The amount of this finely powder tablets equivalent to 20mg of nifedipine was obtained and dissolved in 50mL of methanol using a 100mL volumetric flask. This was shaken vigorously for some minutes until a clear solution is obtained. The flask was then made up to volume with more methanol.The mixture was filteredthrough Whatman No. 1 filter paper. A 25mL of the filtrate was taken and diluted to 50mL with methanol. The absorbance of this final solution was read at 350nm and the average drug content per tablet was calculated.

2.7Dissolution Test

0.1 N hydrochloric acid was used as the dissolution medium.Erweka dissolution apparatus, (GmbH Germany) was used. The aluminum vessel was wrapped with aluminum foil paper to exclude light due to the fact that nifedipine is photosensitive. The dissolution medium was maintained at 37^{o}C. A tablet was placed at the bottom of the dissolution flask and the paddle rotated at 50rpm. A 5mL sample waswithdrawn at intervals of 5,10,20,30,40,45 minutes respectively.The initial volume of the vessel was maintained by replacing with 5 mL of the dissolution medium, maintained at 37 ± 1^{o}C after each sampling. Each sample withdrawn was filtered immediately after collection through a 0.5 Whatman filter paper and diluted to 10mL.The samples were analyzed spectrophotometrically at 350nmand the percentage drug released was calculated.

III. RESULTS AND DISCUSSION

The result of weight uniformity on the various brands is shown in Table 2 and it is seen that brand C had the highest mean weight of 234.60 mg, while brand E had the lowest mean weight of 87.05 mg. All the brands complied with the B.P standard which states that not more than one or two of the tablets in each brand should not deviate from the average by more than the percentage deviation from the average of ±5% or ±10%. There will be variation in the content of the active ingredient in the tablets if a high variation occurs in the weight of tablets.

Result from Table 2 shows that all the brands exhibited acceptable hardness values. The hardness of a tablet depends on the particle size distribution, moisture content, compression pressure and the type and quality of binder used in the tablet formulation. Tablets are expected to be sufficiently hard in order to withstand breakage, chipping and crumbling during packaging, handling and transportation. But they should not be so hard that the disintegration time is unduly prolonged, as this will affect the onset of its therapeutic effect. Tablet hardness of 4kgF is considered to be the minimum for a satisfactory tablet[4].

Table 2: Tablet properties of some brands of Nifedipine retard (20 mg) tablets

Tablet Properties	A	B	C	D	E	F	G	H	I	J
Average weight (mg)	209.85±003	196.20±0.003	234.60±0.003	149.60±0.006	87.05±0.004	140.05±003	118.10±0.005	149.40±003	126.60±0.003	127.25±0.006
% Coefficient of variation	1.25	1.74	1.26	3.71	4.39	1.79	4.27	1.72	1.98	5.00
Hardness (KgF)	4.1	4.2	4.4	5.6	4.7	7.9	4.4	6.1	5.1	4.5
Thickness (mm)	4.15	3.77	3.82	3.87	2.96	3.77	3.35	4.20	3.18	3.18
Diameter (mm)	8.20	8.19	8.76	7.19	6.16	7.38	7.15	7.25	7.17	7.13
Friability (%)	0	0	0	0.49	0.23	0	0	0	0.16	0
Disintegration (min)	0.34	84.38	3.72	1.25	12.08	81.37	5.00	78.37	4.73	5.75
% Drug released	54	47	51	50	56	53	49	49	54	50

A-J: Various brands of Nifedipine retard (20 mg) tablets

Table 2 shows the result for tablet thickness. Brand H had the highest mean thickness of 4.20mm while brand E had the lowest mean thickness of 2.96 mm. All the tablet passed the standard specification for tablet thickness from the mean value by more than ±5. The standard specification for tablet thickness is ±5.All the brands complied with the specification of the USP which specifies that the standard deviation permitted for less than 12.50mm tablets should not exceed ±5% of the mean diameter.

From the friability results Table 2, it is seen that seven brands (A, B, C, F, G, H, and J) showed zero percentage friability while the remaining three brands (D, E, and I) showed friability value of 0.49%, 0.23% and 0.16% respectively. The friability results showed acceptable values. The acceptable values for friability range between 0.5% - 1.0%. Friability test measures that ability of tablets to withstand abrasion during handling, packaging, and transportation.

The British Pharmacopoeia stipulates maximum disintegration time of 60mins for enteric coated tabletswhile the stipulated disintegration time for uncoated tablets is 15minutes [5]. From the disintegration time result shown in table 2 it can be seen that brands B, F, and H has the highest disintegration time of 84.38min, 81.37min and 78.37min respectively. The three brands failed the disintegration test. The other seven brands (A, C, D, E, G, I, and J) passed the British Pharmacopoeia specification for disintegration test, with one of the brands (brand A) having the least disintegration time of 34secs. Disintegration time of a tablet is controlled by a number of formulation and process factors. This includes the type and quality of granulating agent used, type and amount of disintegrating agent used and the force of compression applied during the compaction of the granules into tablet. Tablet disintegration time is one of the most important physicochemical properties of a solid dosage form and this is because tablets that fail this test and most likely to be unavailable for dissolution.

The in-vitro drug release profile (Figure 1) shows that all the brands released about 50% of their contents within 1h. The need to release up to 50% within 1h is important because there is benefit in attaining a good blood pressure control level within 1h and then maintaining it for at least the next 2 h [4].

From the result obtained in this study, all the brands of Nifedipine retard 20mg tablets performed well based on the specified standards for each of the test carried out. Brands B, F and H failed the disintegration time

test while they passed other tests. It is also important that the manufacturers of Nifedipine 20mg tablets formulate tablets of equivalents sizes and weight in other to ensure easy acceptance of any of the brands of the drugs by patients without doubting the quality and efficacy of any of the brands.

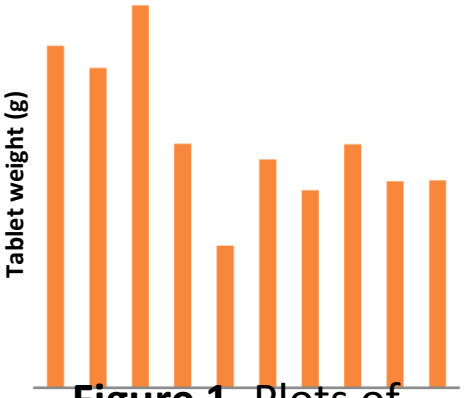

Figure 1. Plots of Tablet Weight of various Brand of Nifedipine (20mg) Retard Tablets

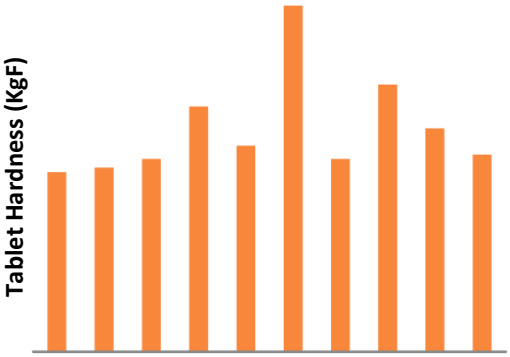

Figure 2. Plots of Hardness of various Brands of Nifedipine (20mg) Retard Tablets

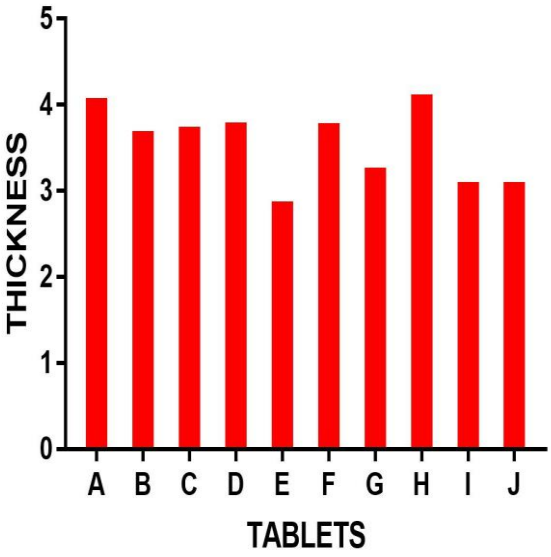

Figure3: Plot of thickness of various brands of Nifedipine (20mg) retard tablets

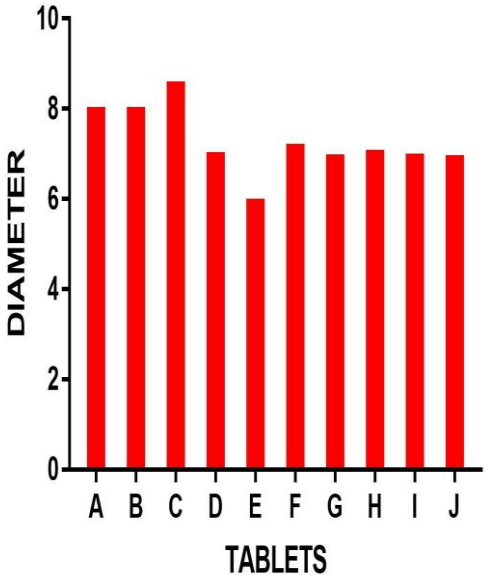

Figure4: Plots of diameter of various brands of Nifedipine (20mg) retard tablets

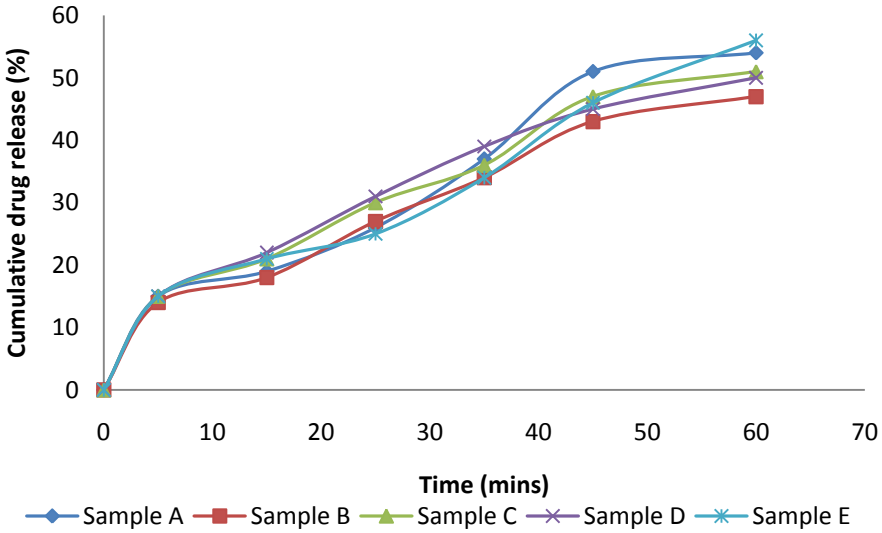

Figure 5: In vitro release profile of Nifedipines 20mg Retard Tablets

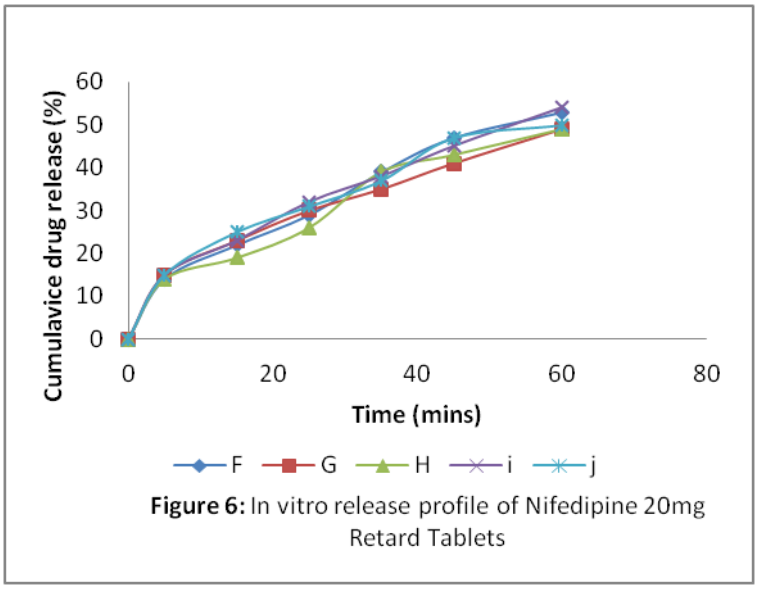

Figure 6: In vitro release profile of Nifedipine 20mg Retard Tablets

IV. CONCLUSION

From the result obtained in this study, all the brands of Nifedipine 20mg tablets performed well based on the specified standards for each of the test carried out. Brands B, F and H failed the disintegration time test while they passed other tests.It is also important that the manufacturers of Nifedipine 20mg tablets formulate tablets of equivalents sizes and weight in other to ensure easy acceptance of any of the brands of the drugs by patients without doubting the quality and efficacy of any of the brands.

REFERENCES

[1]. United States Pharmacopoeia/ national formulary (USP 25/Nf20) 2002
[2]. Muhammed S.Q., Gul R., Pooja D.K., Asiya F. and Madhin H. A comparative study of on conventional paracetamol tablets available in Pakistan. Research in Pharmacy and Health Sciences. 2016; 2(3): 205-210.
[3]. Miyen-Pere P.B. B. Pharm Project. Igbinedion University, Okada, Nigeria.
[4]. Okoye, E.I. and Iwuagwu,M. A. Physicochemical Equivalence Of Some Brands of Nifedipine Retard Tablets Available in Nigeria. African Journal of Biotechnology.2010; 9(8): 1274-1279.
[5]. Ayorinde, J.O., Odeniyi. M.A., and A.O.Itiola. Evaluation of Pharmaceutical and Chemical Equivalence of Selected Brands of Diclofenac Sodium Tablet. East and Central African Journal of Pharmaceutical Sciences. 2012; 15, 3-9.