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COMPARATIVE EVALUATION OF PERCENTAGE LABEL CLAIM OF DIFFERENT BRANDS OF MARKETED AMLODIPINE

[1*]Amritha. A, [1*]Dileep.C. Babu, [1*]Varsha Suresh, [2]Mrs. Dhanya. S, [3]Mr. Nishad V.M, [4]Dr. R. Xavier Arulappa, [5]Dr. Prasobh G.R

[1]B Pharm students, Sree Krishna College of Pharmacy and Research Centre Parassala, Thiruvananthapuram, Kerala, India.

[2]Assistant Professor, Sree Krishna College of Pharmacy and Research Centre, Parassala, Thiruvananthapuram, Kerala, India.

[3]Associate Professor, Sree Krishna College of Pharmacy and Research Centre, Parassala, Thiruvananthapuram, Kerala, India.

[4]Professor and HOD, Department of Pharmaceutical Chemistry, Sree Krishna College of Pharmacy and Research Centre, Thiruvananthapuram, Kerala, India.

[5]Principal, Sree Krishna College of Pharmacy and Research Centre, Thiruvananthapuram, Kerala, India.

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 analyse the variation in quality parameters of different brands of Amlodipine tablets available in market. In the present work an inexpensive, easy, mercurial, particular,sensible, reproducible, and spectroscopic method has been used for the estimation of amlodipine in pure drug and marketed tablet formulation. Analysis was carried out at 238nm for pure drug amlodipine as well as for amlodipine marketed tablet formulation. The main purpose of the investigation was to measure that how much percentage of drug present in marketed tablet formulation for the estimation of amlodipine besylate tablet and amlodipine pure drug using distilled water as a solvent.

Key Words: *UV Spectroscopy, Amlodipine, Methodology,*

Corresponding authors:

Amritha.A – amrithaanil255@gmail.com

Dileep.C. Babu – dileepcb.99@gmail.com

Varsha Suresh – varshasuresh3854@gmail.com

B Pharm students,

Sree Krishna College of Pharmacy and Research Centre Parassala, Thiruvananthapuram, Kerala, India.

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INTRODUCTION [1-3]:

Amlodipine is a potent long-acting, lipophilic third generation dihydropyridine (DHP) calcium channel blocking agent (CCB) that exerts its action through inhibition of calcium influx into vascular smooth muscle cells and myocardial cells, which result in decreased peripheral vascular resistance (PVR). The drug has been widely used to treat high blood pressure (BP)/HTN, angina and is relatively safe. A starting dose of 5mg is usually recommended with a maximum daily dose of 10mg.

Amlodipine besylate is scientifically known as [RS]-3-ethyl-5 methyl-2-[2-aminoethoxymethyl]-4-[2- chlorophenyl]-1, 4-dihydro-6-methyl-3, 5-pyridinedicarboxylate benzene sulphonate. It was first introduced and prescribed for coronary artery disease.

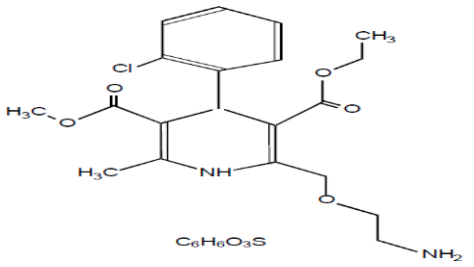

Fig no; 1: Chemical structure of Amlodipine

Amlodipine works by blocking the voltage-dependent L-type calcium channels, thereby inhibiting the initial influx of calcium. Thereby intra cellular calcium level reduces which leads to decreased vascular smooth muscle contractility, increased smooth muscle relaxation and resultant vasodilatation.

For the comparative evaluation of percentage label claim of different brands of marketed amlodipine tablets, UV Spectroscopic method of analysis was used. In the present work, an inexpensive, easy, mercurial, particular, sensible, reproducible and spectroscopic method has been used for the estimation of amlodipine in pure drug and marketed tablet formulation.

MATERIALS AND METHODS [4-8]:

AIM OF THE STUDY

To compare the percentage label claim of different brands of marketed Amlodipine tablet.

REAGENTS REQUIRED

- Different brands of Amlodipine tablets
- Distilled water

METHODOLOGY [9-14]:

APPARATUS REQUIRED

- Standard volumetric flask (100 ml)
- Standard volumetric flask (50 ml)
- Standard volumetric flask (10 ml)
- Measuring cylinder
- Beaker
- Funnel
- Pipette (10 ml)
- Pipette (1 ml)
- UV Spectrophotometer

SAMPLES

- PURE SAMPLE OF AMLODIPINE
- BRAND 1: Amlodipine 5mg
- BRAND 2: Amlodipine 5mg
- BRAND 3: Amlodipine 5mg
- BRAND 4: Amlodipine 5mg
- BRAND 5: Amlodipine 5mg

INSTRUMENT

UV Spectrophotometer
Model: Smart UV-VIS Double Beam Spectrophotometer 2203

- Micro controller based Double beam
- Graphite LCD
- Automatic source optimisation, baseline calibration and cell optimisation
- 200-1100 nm range
- 2.0nm bandwidth
- Single wavelength, multi wavelength, scan and time scan operating modes
- Printer interface for 80 column D.M. Printer
- Automatic 5 position sample changer
- Single position sample changer

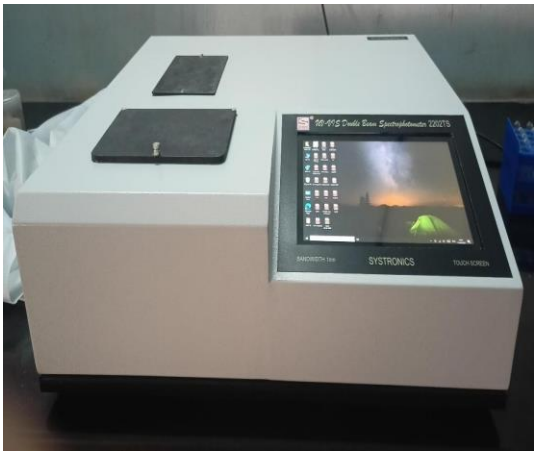

Fig no;2: Smart UV-VIS Double Beam Spectrophotometer 2203

PURE SAMPLE

1mg of pure sample of Amlodipine besylate was transferred into a 100ml standard flask containing small amount of distilled water and the solution was sonicated for about 5min. Makeup the volume up to 100ml with distilled water. Filter the above solution and pipette out 1ml and transferred it into a 10ml standard flask and makeup to 10ml distilled water (I^{st} dilution).

SERIAL DILUTION

Pipette out 0.5ml from the I^{st} dilution and makeup the volume up to 10ml. Pipette out 1ml from the I^{st} dilution and makeup the volume up to 10ml. Pipette out 1.5ml from the I^{st} dilution and makeup the volume up to 10ml. Pipette out 2ml from the I^{st} dilution and makeup the volume up to 10ml. Pipette out 2.5ml from the I^{st} dilution and makeup the volume up to 10ml.

Five dilutions of 0.5ml, 1ml, 1.5ml, 2ml, and 2.5ml were made from 100ml sample of Amlodipine Besylate solution.

Fig no;3: Dilution of pure sample and stock volume.

BRAND 1
Weigh and powder 20 tablets. Weigh a quantity of powder containing 5mg of amlodipine, add small amount of distilled water, and shake for 20 minutes and dilute to 100ml with distilled water. Mix, filter, pipette out 1ml from the above prepared solution and transferred into a 10ml standard flask, then makeup the volume up to 10ml with distilled water and then transfer it 1cm cell at the wavelength of maximum absorbance at about 238nm, using a spectrophotometer, using the blank solution.

BRAND 2
Weigh and powder 20 tablets. Weigh a quantity of powder containing 5mg of amlodipine, add small amount of distilled water, and shake for 20 minutes and dilute to 100ml with distilled water. Mix, filter, pipette out 1ml from the above prepared solution and transferred into a 10ml standard flask, then makeup the volume up to 10ml with distilled water and then transfer it 1cm cell at the wavelength of maximum absorbance at about 238nm, using a spectrophotometer, using the blank solution

BRAND 3
Weigh and powder 20 tablets. Weigh a quantity of powder containing 5mg of amlodipine, add small amount of distilled water, and shake for 20 minutes and dilute to 100ml with distilled water. Mix, filter, pipette out 1ml from the above prepared solution and transferred into a 10ml standard flask, then makeup the volume up to 10ml with distilled water and then transfer it 1cm cell at the wavelength of maximum absorbance at about 238nm, using a spectrophotometer, using the blank solution.

BRAND 4
Weigh and powder 20 tablets. Weigh a quantity of powder containing 5mg of amlodipine, add small amount of distilled water, and shake for 20 minutes and dilute to 100ml with distilled water. Mix, filter, pipette out 1ml from the above prepared solution and transferred into a 10ml standard flask, then makeup the volume up to 10ml with distilled water and then transfer it 1cm cell at the wavelength of maximum absorbance at about 238nm, using a spectrophotometer, using the blank solution.

BRAND 5
Weigh and powder 20 tablets. Weigh a quantity of powder containing 5mg of amlodipine, add small amount of distilled water, and shake for 20 minutes and dilute to 100ml with distilled water. Mix, filter, pipette out 1ml from the above prepared solution and transferred into a 10ml standard flask, then makeup the volume up to 10ml with distilled water and then transfer it 1cm cell at the wavelength of maximum absorbance at about 238nm, using a spectrophotometer, using the blank solution.

RESULTS AND DISCUSSIONS:

PURE SAMPLE:

Values of Pure Sample at 238nm

CONCENTRATION(ml)	SPECIFIC ABSORBANCE(nm)
0.5	0.170
1	0.230
1.5	0.300
2.0	0.370
2.5	0.420

Table no 1 :- Values of Pure Sample At 238nm .

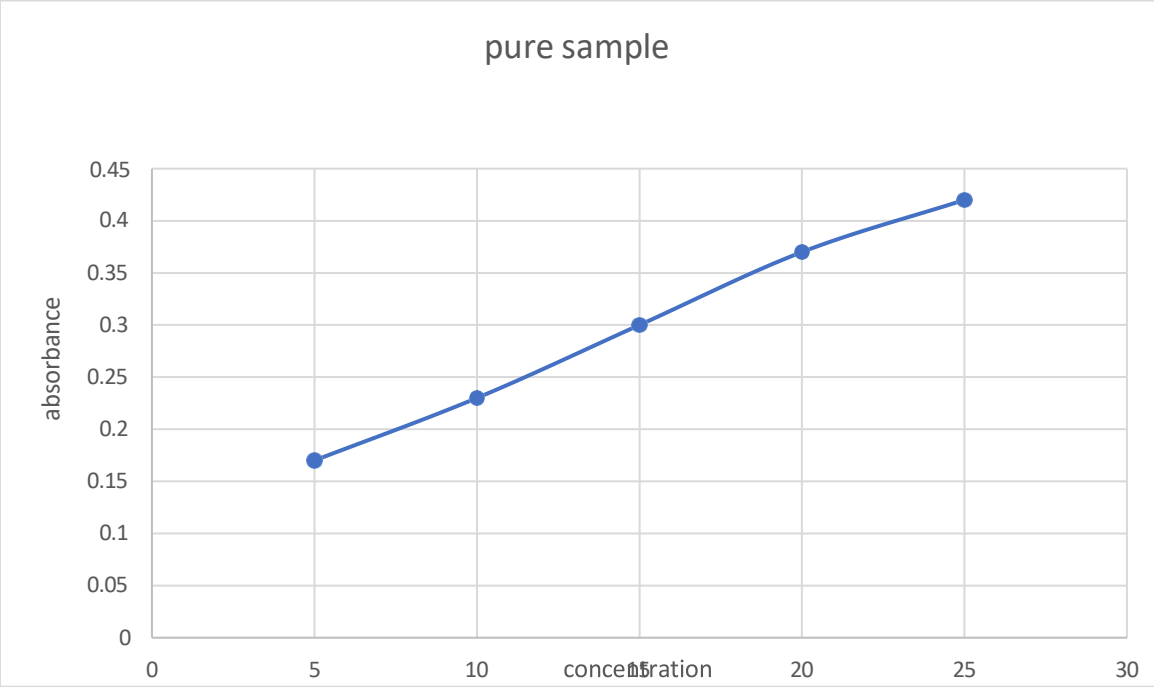

Fig no 4: Graph plot between concentration and specific absorbance of pure sample

6.1. BRAND1

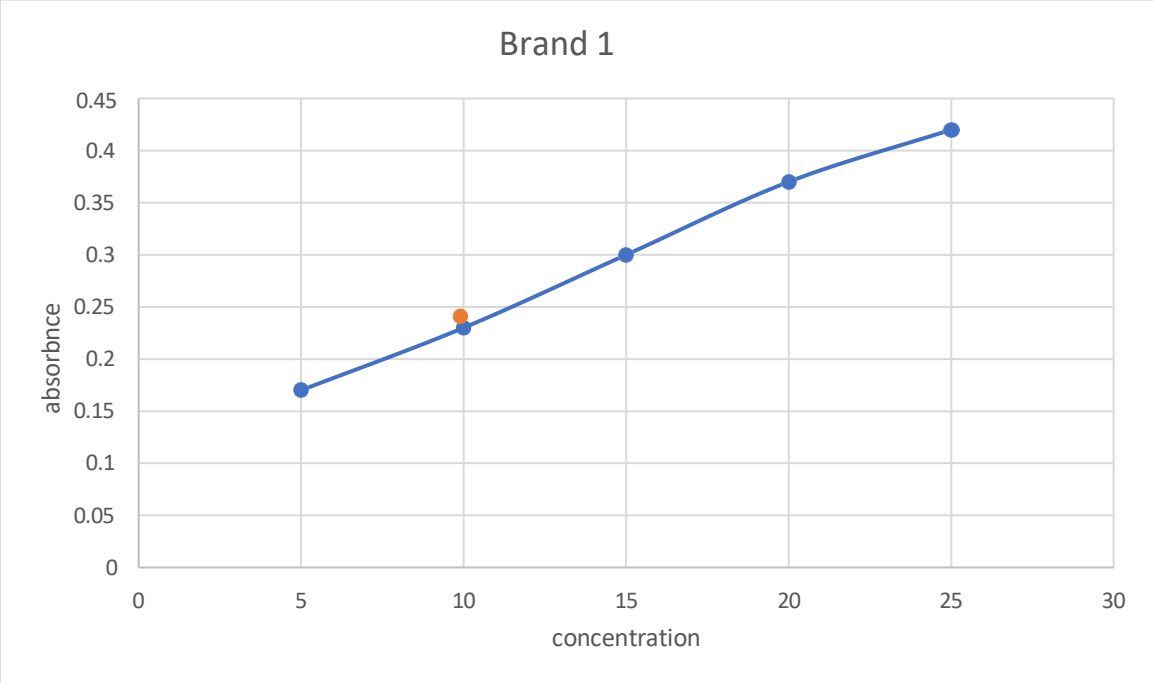

Fig no 5: Graph plot between concentration and specific absorbance of brand 1

REPORT

The percentage label claim of the BRAND 1 Amlodipine 5mg Tablet was found to be 95.00 %w/w.

BRAND 2

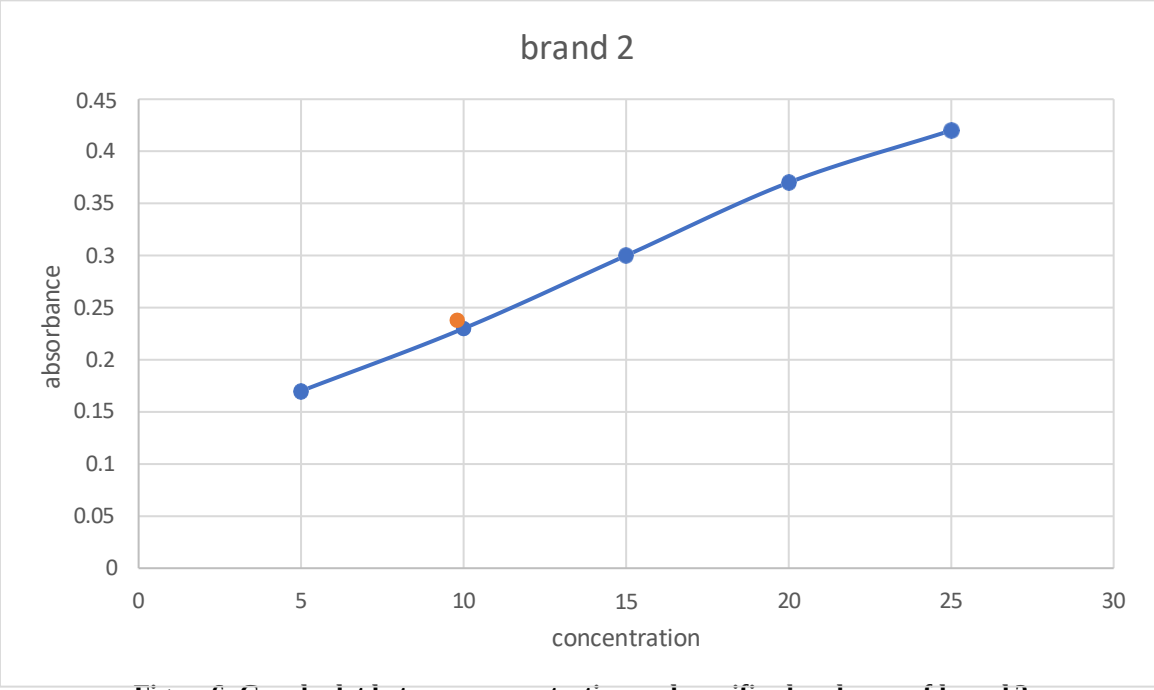

Fig no 6: Graph plot between concentration and specific absorbance of brand 2

REPORT

The percentage label claim of the BRAND 2 Amlodipine 5mg Tablet was found to be 99.00%w/w.

BRAND 3

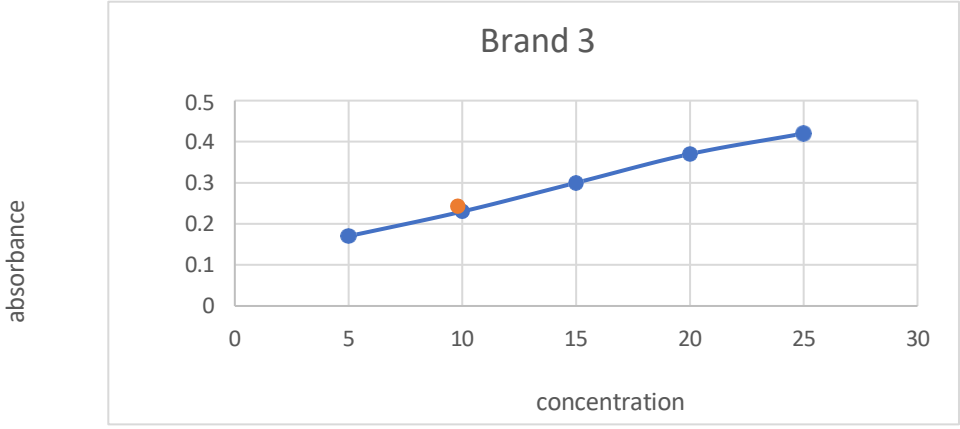

Fig no 7: Graph plot between concentration and specific absorbance of brand 3

REPORT

The percentage label claim of the BRAND 3 Amlodipine 5mg Tablet was found to be 98.00%w/w.

BRAND 4

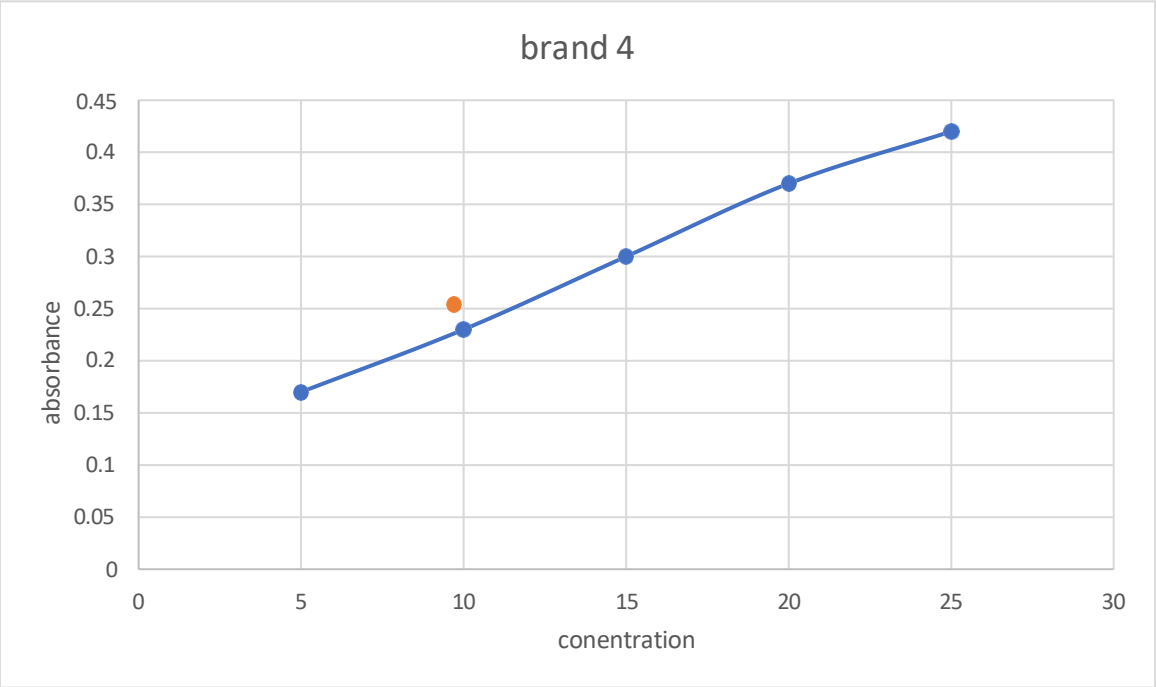

Fig no 8: Graph plot between concentration and specific absorbance of brand 4

REPORT

The percentage label claim of the BRAND 4 Amlodipine 5mg Tablet was found to be 97.00%w/w.

BRAND 5

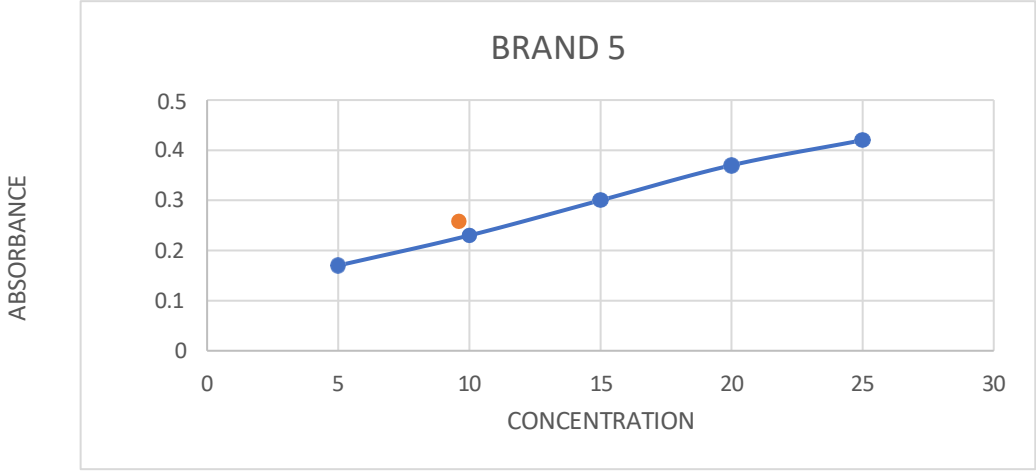

Fig no 9: Graph plot between concentration and specific absorbance of brand

REPORT

The percentage label claim of the BRAND 5 Amlodipine 5mg Tablet was found to be 96.00%w/w.

COMPARISON OF PERCENTAGE LABELLED CLAIM OF DIFFERENT BRANDS OF AMLODIPINE

DIFFERENT BRANDS OF AMLODIPINE TABLET	PERECENTAGE LABELLED CLAIM OF DIFFERENT BRANDS OF AMLODIPINE (%w/w)
BRAND 1	95.00 %w/w
BRAND 2	99.00%w/w
BRAND 3	98.00%w/w
BRAND 4	97.00%w/w
BRAND 5	96.00%w/w

Table no 2:- Comparison of percentage labelled claim of different brands of Amlodipine.

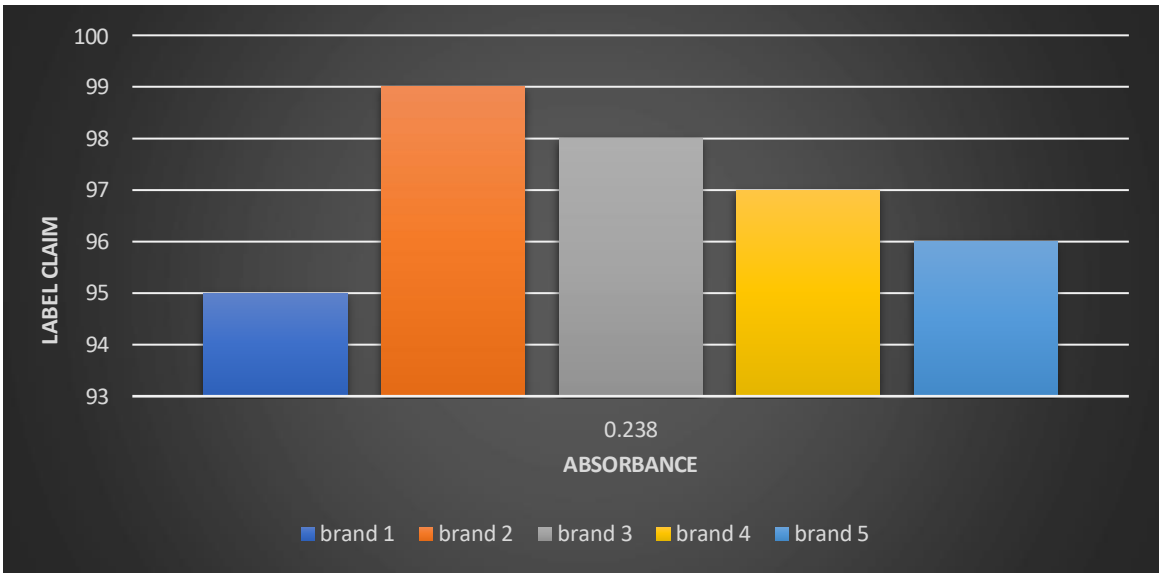

Fig no 10:- Comparison of Label Claim of different brands of Amlodipine

SUMMARY AND CONCLUSION:

The project work deals with the comparison of the percentage labelled claim of different brands of the marked amlodipine tablets, which is used in the treatment of hypertension.

The different brands of the amlodipine tablet were collected from different medical stores, hospital and online pharmacy.

The assay was performed by the procedure mentioned in the American Journal of Chemistry and Application.

Reagents used for the study is distilled water. The absorbance was measured using UV Spectrophotometer at the maximum of about 238nm. After taking the absorbance of all the brands, the percentage label claim for each tablet was calculated and then the result were compared to find out which of the brand had the highest labelled claim.

The study on different brands of marketed amlodipine tablets was performed and the conclusion obtained from the studies made that Brand-2 was found to be having the highest labelled claim of 99.00%w/w.

By performing the study, we can draw the percentage labelled claim of the different brands of the marked amlodipine tablets and can compare the results obtained of each of the marketed product. By comparing these results, the product having the highest labelled claim can be identified and reported.

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CONFLICT OF INTEREST

The authors declared no conflict of interest.

REFERENCES:

1. Reynolds EF, editor. The Extra Pharmacopoeia. 31st ed. London: The Royal Pharmaceutical Society; 1996; 819-20.
2. Pahor M, Psaty BM, Alderman MH, et al. Health outcomes associated with calcium antagonists compared with other first-line antihypertensive therapies: a meta-analysis of randomised controlled trials. Lancet. 2000; 356:1949-54.
3. Saravu K, Balasubramanian R. Near-fatal amlodipine poisoning. J Assoc Physicians India. 2004; 52:156-7.
4. Ostroumova OD, Kochetkov AI. [Effects of Amlodipine/Lisinopril Fixed-Dose Combination on Severity of Left Ventricular Hypertrophy and Parameters of Myocardial Stiffness in Patients with Hypertension]. Kardiologiia. 2016 Dec; 56(11):27-37.
5. Lee EY, Park JK, Lee W, Kim YK, Park CS, Giles JT, Park JW, Shin K, Lee JS, Song YW, Lee EB. Head-to-head comparison of udenafil vs amlodipine in the treatment of secondary Raynaud's phenomenon: a double-blind, randomized, cross-over study. Rheumatology (Oxford). 2014 Apr; 53(4):658-64.
6. Naveed S, Qamar F, Sarwer G. Percentage assay of metformin in different medium using UV- spectrophotometer. World Res J Org Chem. 2014;2(1):12-14.
7. Naveed S. Simple UV spectrophotometric assay of Atorvastatin API formulation and their comparative study. Glob J Med Res. 2014;14(2):35-38.
8. Naveed S, Qamar F. A simple assay of Esomeprazole using UV spectrophotometer. Glob J Pharm Res. 2014;3(2):1921-25.
9. Safila Naveed, Hina Qamar, Wardha Jawaid, Urooj Bokhari. Simple UV Spectrophotometric Assay of Amlodipine.American Journal of Chemistry and Application;2014 sept;1(4);66-69.
10. Kuriyama S, Tomonari H, Tokudome G, Horiguchi M, Hayashi H, Kobayashi H, Ishikawa M, Hosoya T. Antiproteinuric effects of combined antihypertensive therapies in patients with overt type 2 diabetic nephropathy. Hypertens Res. 2002 Nov; 25(6):849-55.
11. Whiteley WN, Gupta AK, Godec T, Rostamian S, Whitehouse A, Mackay J, Sever PS. Long-Term Incidence of Stroke and Dementia in ASCOT. Stroke. 2021 Oct; 52(10):3088-3096.
12. Zhu Y, Wang F, Li Q, Zhu M, Du A, Tang W, Chen W. Amlodipine metabolism in human liver microtomes and roles of CYP3A4/5 in the dihydropyridine dehydrogenation. Drug Metab Dispos. 2014 Feb; 42(2):245-9.

13. Brook RD, Kaciroti N, Bakris G, Dahlöf B, Pitt B, Velazquez E, Weber M, Zappe DH, Hau T, Jamerson KA. Prior Medications and the Cardiovascular Benefits from Combination Angiotensin-Converting Enzyme Inhibition plus Calcium Channel Blockade among High-Risk Hypertensive Patients. J Am Heart Assoc. 2018 Jan 04; 7(1)
14. Malha L, August P. Safety of Antihypertensive Medications in Pregnancy: Living with Uncertainty. J Am Heart Assoc. 2019 Aug 06; 8(15):e013495.