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The Viability of Emerging Public and Private Generic Drug Infrastructure in India: An in-vitro Case Study Using Statins as Model Drug

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ABSTRACT: ***The healthcare system has been fundamentally altered by the introduction of generic medications, and their market share continues to rise because these are genuine, dependable, secure, affordable, and accessible to all the needy and poor in society. In this regard, the generic drug industry, which strives for authenticity, affordability, and accessibility, plays a significant role. Using HMG CoA reductase inhibitors (Atorvastatin and Rosuvastatin) as model drugs, the study aimed to determine the viability of the emerging public and private generic drug infrastructure in India, which included Janaushadhi, Dava India, and other assorted companies. The organoleptic properties and official and non-official quality control tests were evaluated. According to the in-vitro dissolution profiles, the Mankind brand of atorvastatin has shown the highest dissolution profile (75.29%), and the Dava India brand of rosuvastatin has the maximum drug release (97.26%) in one hour release. The Peppas model best explained the drug release model, which inferred the release profile to be diffusion-specific. The compatibility analysis of the tablet formulation has been shown through FTIR studies. These results concluded that public generic drugs are as effective as private generic drugs, and patients can easily take the cost-effective brand of medication.***

Keywords: ***Generic drug, healthcare, Atorvastatin, Rosuvastatin, Dissolution Studies, Kinetic Release***

I. INTRODUCTION

The World Health Organization (WHO) defines generic medicines as "pharmaceutical products typically intended to be interchangeable with the innovator product, marketed after the period of patent or other exclusivity rights" [1]. India holds a very important position in the pharmaceutical industry at the moment.

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It is regarded as the world's largest supplier of generic drugs. India manufactures more than 500 different Active Pharmaceutical Ingredients (APIs) and approximately 60,000 generic brands for approximately 60 distinct therapeutic categories.

India's ability to export generic drugs empowers the nation's economy. In this regard, the generic drug industry, which strives for authenticity, affordability, and accessibility, plays a significant role [2,3][28][29][30]. People who typically tend to ignore the potentially harmful effects on their health due to the high cost of branded medications can benefit greatly from generic medications. The quality of the treatment that patients receive is determined by the quality of the marketed drugs, which in turn ensures the well-being of the patient. While manufacturing the drugs, Pharmacoeconomics plays a crucial role in the effective marketability of the drugs. Various pharmaceutical companies provide the same chemical entity at various price points. In a country like India, where nearly 32% of the people fall below the poverty line cannot afford medicines from multinational pharma companies with higher price tags [4]. To address this issue, the Pradhan Mantri Jan-Aushadhi Yojana campaign was launched by the Department of Pharmaceuticals to provide affordable and good quality generic medicines for the general masses [5]. Another organization has also claimed to provide generic drugs at reasonable rates to the public known as Dava India. Dava India is a division of Zota Healthcare Ltd that has a wide variety of Pharmaceutical, Ayurvedic, and Nutraceutical medicines [6].

The study aimed to test the viability of the emerging public and private generic drug (Jan-Ausadhi, Dava India, and other assorted companies) infrastructure in India by taking HMG CoA reductase inhibitor (Atorvastatin and Rosuvastatin) as the model drugs. The 3-Hydroxy-3-methyl-glutaryl-CoA reductase inhibitors are lipid-lowering drugs that decrease illness and mortality in patients having cardiovascular disease [7]. They are mainly used as cholesterol-lowering drugs. In cholesterol biosynthesis, the transformation of 3-hydroxy-3-methyl- glutaryl-CoA to mevalonate by HMG-CoA reductase is the rate-limiting step. Statins regularly block the HMG-CoA reductase enzyme. They bind to the enzyme's active site and prompt a conformational change in the structure of the enzyme resulting in a decrease in the action [8].

Some of the commonly used Statins are atorvastatin, rosuvastatin, simvastatin, and lovastatin [9,10]. Atorvastatin, a competitive HMG CoA inhibitor decreases low-density lipoprotein, and triglycerides and enhances high-density lipoprotein. The molecular formula of atorvastatin is $C_{33}H_{35}FN_2O_5$ with a molecular weight of 558.64 g/mol. It has an approximate elimination half-life of 14 hours [11,12]. Similarly, Rosuvastatin is a selective and competitive inhibitor of HMG-CoA reductase. It lowers cholesterol and triglycerides in the blood. The molecular formula of rosuvastatin is $C_{22}H_{28}FN_3O_6S$ with a molecular weight of 481.539 g/mol. It has an approximate elimination half-life of 19 hours [13,14]. The dose range of atorvastatin is 10-80mg per day whereas for rosuvastatin, it is 5-40mg once a day. All these dosage forms are available in tablet form which is the safest route of oral administration. At present around 70% of medications are administered as tablets [15,16].

In this research, we have evaluated the physicochemical properties of five different Atorvastatin (10mg) and Rosuvastatin (10mg) marketed tablets currently available in India. They were chosen for the study in terms of price differentiation of different brands. This study was conducted for a general organoleptic characterization as well as a comparison of quality control parameters like weight variation, thickness, hardness, friability, disintegration, and in-vitro dissolution of the tablets. Compatibility analysis of the tablet formulations was carried out by the FTIR studies [17,18].

II. MATERIALS AND METHODS

A. Materials

Five different marketed brands of atorvastatin and rosuvastatin (10 mg) were purchased from different drug stores. The Janaushadhi brand was brought from Pradhan Mantri Janaushadhi Kendra while the Dava India brand was purchased from the outlets of Dava India Pvt. Ltd. Other than these two generic products, the branded ones from assorted companies like Sun Pharma, Mankind Pharma, Corona Pharma, and Eris Pharma have been procured from the local retail market. The batch number, manufacturing date, expiry date, manufacturing license number, and dose of the samples were thoroughly examined. The solvents and chemicals used were of analytical grade.

B. Methods

During the research of various marketed brands of Atorvastatin and Rosuvastatin, the following official and non-official quality control studies were carried out.

III. ANALYTICAL METHOD FOR DETERMINATION OF ATORVASTATIN AND ROSUVASTATIN FORMULATION

A. Determination of Maximum Wavelength

Atorvastatin (10 mg) was weighed accurately and dissolved in 100 ml of pH 6.8 phosphate buffer, which forms a stock solution. It was further diluted to get a working standard solution of concentration 100µg/ml and then scanned in the UV range 400-200 nm to get the maximum wavelength. It showed a maximum wavelength of 245 nm. Similarly, rosuvastatin (10 mg) was weighed and dissolved in 100 ml of pH6.8 phosphate buffer to form a stock solution which was further scanned in the UV range to get the maximum wavelength. Rosuvastatin showed absorption maxima at 242 nm.

B. Preparation of Standard Curve

Standard curves of atorvastatin and rosuvastatin were plotted by taking absorbance and concentration in the respective axis. The standard calibration curve showed the slope of atorvastatin is 0.0339 while the slope of rosuvastatin is 0.0354. The curves of atorvastatin and rosuvastatin were found linear in the range between 5-20µg/ml at 245 nm and 2-12µg/ml at 242 nm.

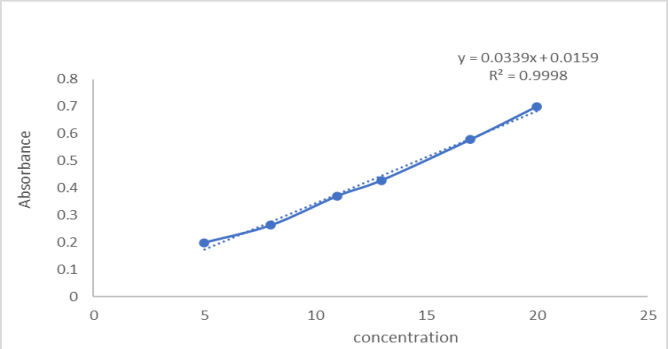

Fig 1: Atorvastatin Standard Curve at Phosphate Buffer ph. 6.8

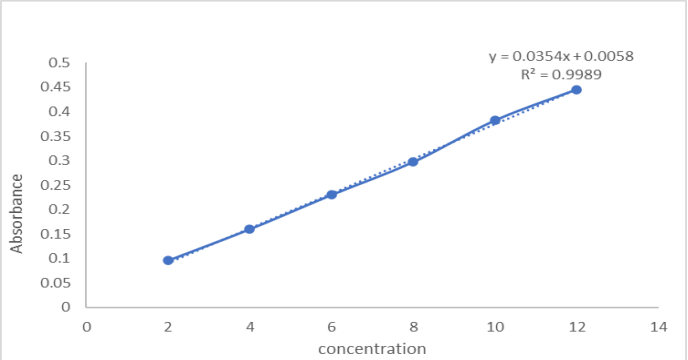

Fig 2: Rosuvastatin Standard Curve at Phosphate Buffer ph. 6.8

C. Weight Variation

The weight of 20 tablets of different marketed products of atorvastatin and rosuvastatin was determined with the help of an electronic balance. The average weight and standard deviation were determined. As per Indian Pharmacopoeia, the weight variation limit for tablets of 80mg or less weight is ±10%, 80-250mg is ±7.5% and more than 250mg is 5% [17].

D. Thickness and Circumference

Tablet thickness and circumference were measured with a digital Vernier Caliper. An average of ten tablets were taken for the study from different marketed brands. Mean thickness, mean circumference, and standard deviation were calculated. It was expressed in terms of millimeters.

E. Hardness

Hardness denotes the measure of the resistance of the tablet to chipping, abrasion, or breakage during storage, transportation, and packing. The tablet hardness was determined using a digital hardness tester. A tablet was placed at the center which was perpendicular to the hardness tester, the tool was first turned slowly from the zero position until the tablet was broken. When the tablet was broken, the reading was recorded. For the study, ten tablets, one from each commercial brand, were taken. Hardness was expressed in terms of lb.

F. Friability

The friability of the tablets was assessed using the Roche friability tester. This test was used to decide the drug loss during transportation. 20 tablets were taken, weighed (W) placed in the friability tester, and rotated for 4 mins (100 revolutions) at 25 rpm. After that, the tablets were taken out, dedusted, and weighed once more(W1) [19]. The following formula was used to determine the % of friability:

$$\%F = [\,1 - (W1 \div W)] \times 100\%$$

G. Disintegration Test

A disintegration apparatus was used to conduct the test. It measured the capacity of the tablet to break down into smaller particles to evaluate the effectiveness of tablets. The tester consists of six tubes filled with distilled water. One tablet is placed in each tube at 37±2°C so that on its upward movement the tablet remains 2.5cm below the liquid's surface. Six tablets were placed in the cylindrical glass and the time for the tablets to disintegrate was recorded as disintegration time. The disintegration time for each tablet was noted and the average disintegration time for each brand was calculated [20].

H. In Vitro-Dissolution Studies

The drug's efficacy is directly linked to its rate of dissolution. Using a USP type-II apparatus with a paddle rotating at 50 rpm and pH 6.8 phosphate buffer, the dissolution of atorvastatin and rosuvastatin was performed at 37± 0.5 °C. Different brands of atorvastatin and rosuvastatin drugs of 10 mg were subjected to dissolution. Samples were taken at predetermined intervals (e.g.,5,15,30,45,60,90 minutes). The drug content of the withdrawn samples of atorvastatin and rosuvastatin were spectrophotometrically analyzed at 245 nm and 242 nm respectively at regular intervals. The % of drug release was calculated for each chosen brand of the drug. A graph was plotted between the % drug release in the X axis and time (mins) in the Y axis [21,22].

I. Kinetic Modelling of the Drug Release

Different kinetic modeling approaches have been adopted to understand the underlying mechanism of the drug release. Zero-order release kinetics describes the process of continuous and concentration-independent drug release from a drug delivery system. The concentration-dependent release rate from a system is described better by the first-order equation. In 1963, The first example of a mathematical model to explain drug release from a matrix system by diffusion and erosion was described by Higuchi. A straightforward relationship that described drug release from a polymeric system was derived by Korsmeyer et al. To explore the Fickian and non-Fickian drug release from swelling and non-swelling polymeric delivery methods, respectively, an empirical equation was developed [23].

J. Fourier Transform Infrared Spectroscopy

FTIR Spectra of powder samples were recorded utilizing the standard KBr disc method. The powder sample containing roughly 1mg of the drug and 100 mg of dried KBr was completely mixed in a mortar and pressed into a disc. The spectra manager software was used to analyze the data that were obtained after it was scanned over a range of 4000-400 cm-1 [24].

IV. RESULTS AND DISCUSSIONS

A. Weight Variation

The results obtained for weight variation are shown in Table 2. During the study, all the marketed products from different companies rosuvastatin and atorvastatin passed the weight variation uniformity test as per IP. As the tablets were of uniform weight, their drug contents were also presumably uniform.

Table 1: General Description of Rosuvastatin and Atorvastatin Marketed Tablets

Name of the Company	Batch no.	Mrp	Mfg Date	Exp Date
DAVA INDIA (Rosuvastatin)	MT215014C	21	Nov-21	Oct-23
JANAUSHADHI (Rosuvastatin)	RSVT21003	17	Jul-21	Jun-23
CORONA PHARMA (Rosuvastatin)	CG20284	47.91	Sep-20	Aug-22
MANKIND PHARMA (Rosuvastatin)	I4ABU013	92.92	Sep-21	Aug-23
SUN PHARMA (Rosuvastatin)	SIC1393A	177	May-21	Oct-23
DAVA INDIA (Atorvastatin)	NHD210BOA	12	Feb-21	Jan-23
JANAUSHADHI (Atorvastatin)	AVT837	8	Aug-20	Jan-23
ERIS PHARMA (Atorvastatin)	GATS21001	91.81	Feb-21	Jan-24
MANKIND PHARMA (Atorvastatin)	G71AV026	37.09	Aug-21	Jul-23
SUN PHARMA (Atorvastatin)	EMX1064	91.85	Apr-20	Mar-23

B. Hardness

The ability of each tablet to withstand mechanical stress and structural integrity during various processing, storage, and handling conditions before use can be evaluated by hardness. The average hardness of all the marketed products was in the range of 0.19-0.92 lb and it could be inferred that they could handle the stress of transportation and packing.

C. Friability

The tablet's ability to withstand abrasion and edge damage during packaging, handling, and shipping is evaluated by the friability test. Friability values of all the tablets were in the range of 0.17%-0.47%, which indicates all the marketed products met the pharmacopeial requirements of tablet formulation.

D. Disintegration

The disintegration study provides an estimate of drug absorption. The results of the disintegration test are listed in Table 2. US Pharmacopoeia stated that film-coated should be coated within 30 minutes. The disintegration time of both the samples of rosuvastatin and atorvastatin was within 5 minutes, so they passed the test. Mankind brand of Rosuvastatin has taken a maximum disintegration time of 248 sec.

Table 2: Quality Control Evaluation of Rosuvastatin and Atorvastatin Marketed Tablets

Name Of The Company	Weight (Gm)	Thickness (Mm)	Circumference (Mm)	Hardness (Lb)	Friability (%)	Disintegration (Sec)
DAVA INDIA (Rosuvastatin)	0.18 ± 0.012	3.02 ± 0.010	8.24 ± 0.011	0.26 ± 0.011	0.28 ± 0.002	18 ± 2
JANAUSHADHI (Rosuvastatin)	0.10 ± 0.011	2.69 ± 0.010	6.35 ± 0.009	0.19 ± 0.010	0.47 ± 0.004	141 ± 3
CORONA (Rosuvastatin)	0.16 ± 0.016	3.82 ± 0.013	7.22 ± 0.010	0.92 ± 0.010	0.35 ± 0.003	120 ± 1
MANKIND PHARMA (Rosuvastatin)	0.15 ± 0.015	3.21 ± 0.013	7.1 ± 0.010	0.68 ± 0.012	0.18 ± 0.005	248 ± 2
SUN PHARMA (Rosuvastatin)	0.10 ± 0.010	3.55 ± 0.009	6.07 ± 0.011	0.46 ± 0.013	0.31 ± 0.003	67 ± 3
DAVA INDIA (Atorvastatin)	0.10 ± 0.014	3.06 ± 0.011	6.53 ± 0.011	0.35 ± 0.012	0.26 ± 0.003	87 ± 1.5
JANAUSHADHI (Atorvastatin)	0.12 ± 0.014	3.34 ± 0.009	6.67 ± 0.010	0.29 ± 0.011	0.17 ± 0.004	126± 2.3
ERIS PHARMA (Atorvastatin)	0.06 ± 0.010	2.57 ± 0.012	5.1 ± 0.012	0.72 ± 0.013	0.24 ± 0.006	201 ± 2.6
MANKIND PHARMA (Atorvastatin)	0.18 ± 0.016	3.85 ± 0.013	6.23 ± 0.013	0.41 ± 0.010	0.21 ± 0.004	39.6 ± 1.8
SUN PHARMA (Atorvastatin)	0.12 ± 0.015	3.33 ± 0.010	7.12 ± 0.009	0.33 ± 0.014	0.32 ± 0.005	204 ± 2.5

E. In-Vitro Dissolution

All the brands of rosuvastatin and atorvastatin have shown dissolution profiles well within the official pharmacopeial limit. Mankind brand of atorvastatin has shown the best dissolution profile (75.29%) among the other brands and the Dava India brand has shown the least drug release (41.35%) while the Dava India brand of rosuvastatin has the maximum drug release (97.26%) and corona brand of rosuvastatin has the minimum drug release (93.28%) in one hour.

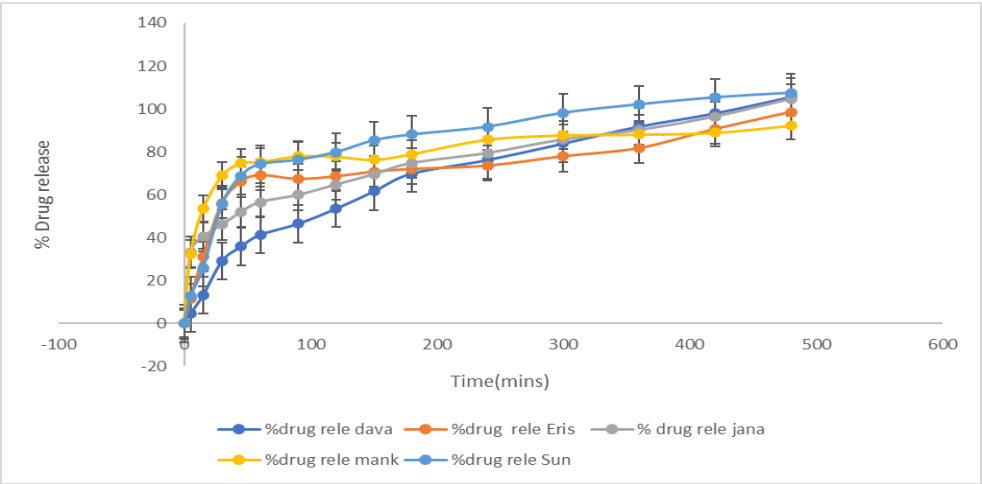

Fig.3: Drug Release Profile of different Marketed Products of Atorvastatin in pH 6.8 Phosphate Buffer

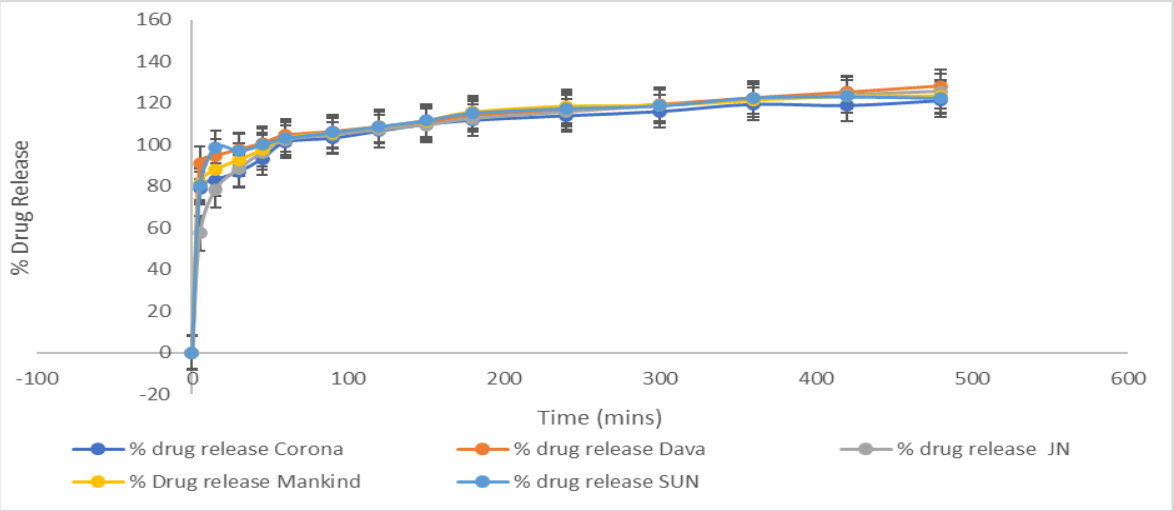

Fig.4: Drug Release Profile of different Marketed Products of Rosuvastatin in pH 6.8 Phosphate Buffer

F. Kinetic Model of Drug Release

To understand the drug release kinetics of the different marketed products, data of in-vitro drug release was fitted to the appropriate kinetic models and equations in Table 3. The zero-order equation, the first-order equation, the Higuchi release, and the Korsmeyer 's-Peppas models were the kinetic models used. Different drug release kinetic models were applied to the drug release profiles, and the best-fit model was chosen based on the correlation coefficient (R) and the values of 'n'. The best-fit model was shown by the Peppas model which inferred the release profile to be diffusion-specific.

Table 3: Kinetics Modeling of Drug Release of Different Marketed Products of Rosuvastatin and Atorvastatin

Different Brands	n value of Peppas	The R^2 value of Peppas	The R^2 value of zero order	The R^2 value of the first order	The R^2 value of Higuchi
Dava India (Rosuvastatin)	0.1599	0.6507	0.2653	0.215	0.441
Janaushadhi (Rosuvastatin)	0.1949	0.8571	0.3716	0.3236	0.6008
Mankind Pharma (Rosuvastatin)	0.1694	0.7247	0.2912	0.2428	0.4946
Sun Pharma (Rosuvastatin)	0.1653	0.6791	0.1533	0.1401	0.4396
Corona Pharma (Rosuvastatin)	0.1692	0.7453	0.3082	0.2613	0.5152
Dava India (Atorvastatin)	0.4304	0.6484	0.5739	0.3946	0.7905
Janaushadhi (Atorvastatin)	0.2428	0.9043	0.43	0.3932	0.6777
Mankind Pharma (Atorvastatin)	0.1803	0.8691	0.3657	0.3638	0.5931
Sun Pharma (Atorvastatin)	0.303	0.7752	0.6175	0.4667	0.8305
Eris Pharma (Atorvastatin)	0.2597	0.7041	0.5423	0.4022	0.7434

G. FTIR studies

The pure Atorvastatin's FTIR spectra has shown characteristic peaks at 1104.39 cm−1 (O-H-bending), 1381 cm−1 (C-N-stretching), 1315.56 cm−1 (C-HO-stretching), 1564.97 cm−1 (C=O-stretching), 1775.97 cm−1 (C=C-bending), 2965.15 cm−1 (C-H-stretching), 696.95 cm−1 (C-F stretching), and 3403.27 cm−1 (N-H stretching). The pure Rosuvastatin's FTIR spectra have shown characteristic peaks at 3382 cm−1 (O-H stretching), 1149 cm−1 (C-F stretching), 1541 cm−1 (C=C stretching), 2968 cm−1 (N-H stretching), 1379 cm−1 (symmetric vibration of CH3), 1436 cm−1 (asymmetric vibration of CH3) and 775 cm−1 (C-H plane blending) [18]. In the present study, there is not much change in the fingerprint region of the FTIR spectra of the pure drug with its excipients. It is seen that the shift decreases when combined with the excipients. The crystalline form is slightly changed to the amorphous form. So, the amorphous form is more soluble and it has a good dissolution profile.

Table 4: FTIR Study of Pure Drug and Different Marketed Products of Atorvastatin

Stretching	Wavenumber of pure drug (cm−1)	Wavenumber of Janaushadhi (cm−1)	Wavenumber of Eris Pharma (cm−1)	Wavenumber of sun pharma (cm−1)	Wavenumber of Mankind Pharma (cm−1)	Wavenumber of Dava India (cm−1)
C-N	1381	1382.71	1385.6	1384.64	1340.28	1384.64
C-H	2965.15	2976.59	2918.73	2917.77	2931.27	2917.77
C-HO	1315.56	1295.93	1340.28	1324.86	1295.93	1319.07
C=O	1564.97	1578.45	1557.24	1577.49	1577.49	1558.2
N-H	3403.27	3524.27	3524.27	3379.64	3378.67	3382.53
C=C	1775.97	1771.3	1771.3	1792.51	1771.3	1792.51
C-F	751.62	778.13	746.31	747.28	746.31	748.24
O-H	1104.39	1115.62	1094.2	1094.4	1115.62	1115.62

Table 5: FTIR Study of Pure Drug and Different Marketed Products of Rosuvastatin

Stretching	Wavenumber of pure drug (cm−1)	Wavenumber of Janaushadhi (cm−1)	Wavenumber of Corona Pharma (cm−1)	Wavenumber of sun pharma (cm−1)	Wavenumber of Mankind Pharma (cm−1)	Wavenumber of Dava India (cm−1)
carboxylic O-H	3382	3386	3291	3379	3378	3406
N-H	2968	2917	2976	2917	2900	2918
C=C	1541	1546	1548	1577	1577	1546
asymmetric vibration of CH3	1436	1438	1419	1435	1434	1439
C-F	1149	1142	1159	1142	1142	1147
symmetric vibration of CH3	1379	1341	1384	1340	1340	1380
C-H	775	778	769	747	778	773

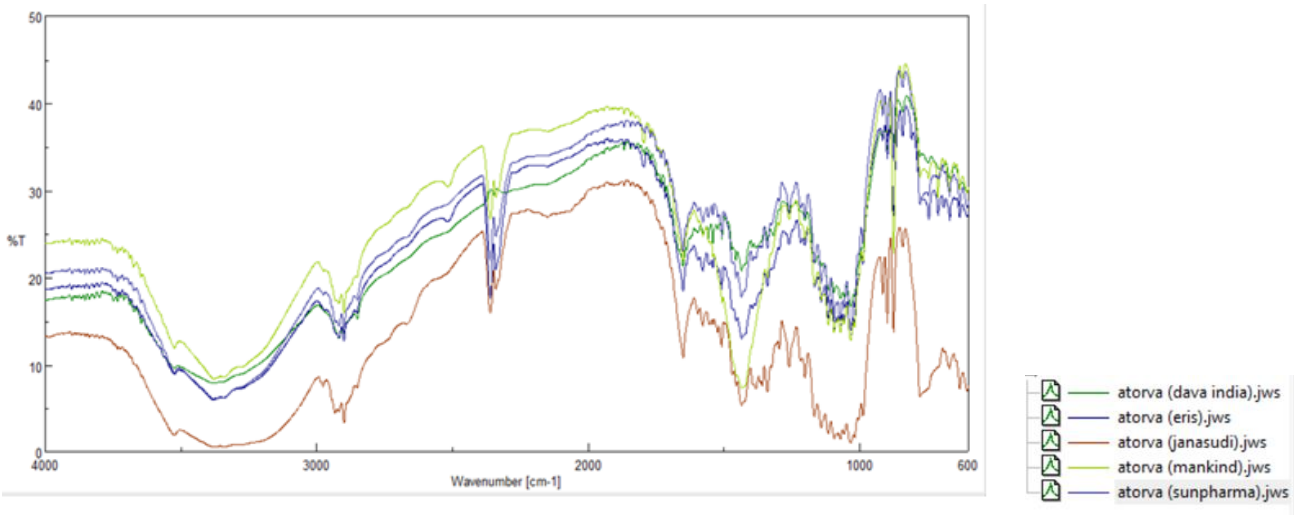

Fig.5: FTIR Spectra of Different Marketed Products of Atorvastatin

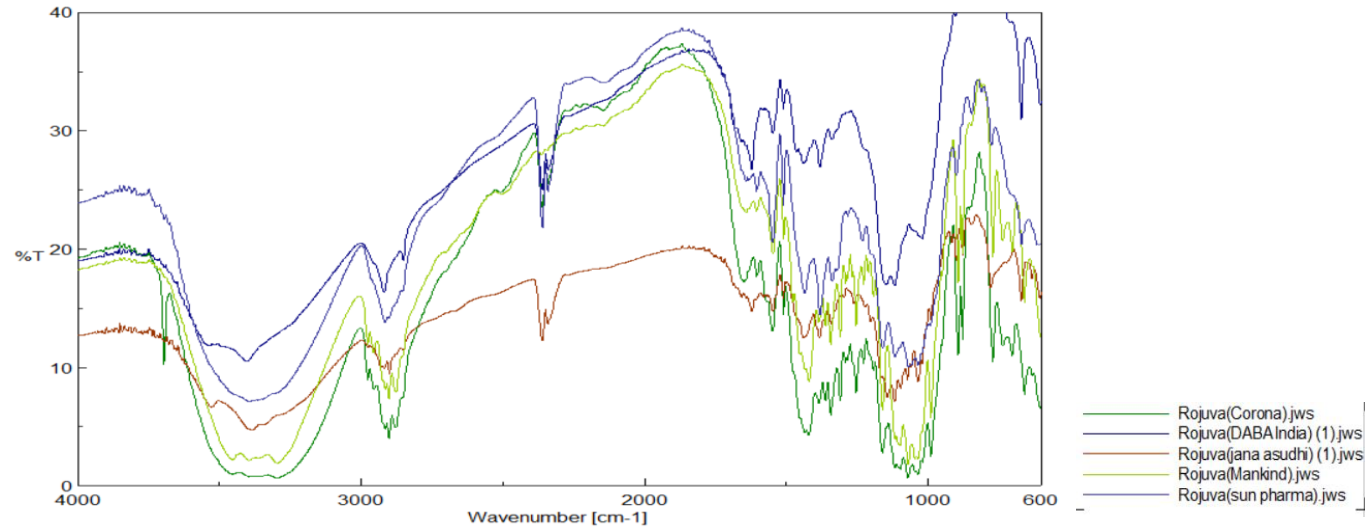

Fig.6: FTIR Spectra of Different Marketed Products of Rosuvastatin

V. CONCLUSION

Rosuvastatin and Atorvastatin are effective lipid-lowering medications that can be used as the first-line drug of choice. These tablets come in a wide variety of brands in the Indian pharmaceutical market today. To test the viability of public and private generic drug infrastructure in India, the above study was carried out. All the marketed products containing atorvastatin and rosuvastatin tablets fulfilled the specifications for their physical properties as well as their concentrations of active ingredients.

Weight variation, thickness hardness, friability, disintegration, and dissolution showed acceptable figures [25]. Through FTIR studies, the compatibility analysis of the tablet formulation has been demonstrated. During the process of prescribing and dispensing different brands of Rosuvastatin and Atorvastatin, pharmacists and other healthcare professionals will benefit greatly from this information regarding interchangeability. The patient can select the medication's most cost-effective brand based on the aforementioned data [26,27].

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Ethical Approval and Consent to Participate	No, the article does not require ethical approval and consent to participate with evidence.
Availability of Data and Material	Not relevant.
Authors Contributions	All authors have equal participation in this article.

REFERENCES

1. Mishra, R., & Sathyaseelan, B. (2019, January 2). Generic Drug Distribution in India- Issues and Challenges. *Journal of Pharmaceutical Care & Health Systems*, 06(01), 199. https://doi.org/10.4172/2376-0419.1000199
2. Mahato, T., & Raulji, D. (2021, August 16). Present scenario of generic medicines in India: A comparative study. *World Journal of Biology Pharmacy and Health Sciences*, 7, 053-059. https://doi.org/10.30574/wjbphs.2021.7.2.0086
3. Dixit, A., Kumar, N., Kumar, S. (2019, January 1). Use of Generic Medicines: Challenges and Benefits. *Journal of Health Management*, 20(1), 1-7. https://doi.org/ 10.1177/0972063417747747
4. Junofy, A.R. (2013, September). A Study on Poverty and Hunger in India. *Mediterranean Journal of Social Sciences*, 4(12), 147-153. https://doi.org/ 10.5901/mjss.2013.v4n12p147
5. Mukherjee, K. (2017, May 1). A Cost Analysis of the Jan Aushadhi Scheme in India. *International Journal Health Policy Management*, 6(5), 253-256. https://doi.org/ 10.15171/ijhpm.2017.02
6. Lennernas, H., Fager, G. (1997). Pharmacodynamics and pharmacokinetics of the HMG-CoA reductase inhibitors: similarities and differences. *Clin Pharmacokinet*, 32(5), 403–425. https://doi.org/10.2165/00003088-199732050-00005
7. Illingworth, D., Tobert, J. (2001, February). HMG-CoA reductase inhibitors. *Advances in protein chemistry*, 56, 77-114. https://doi.org/10.1016/S0065-3233(01)56003-9
8. Balasubramanian, R., Maideen. N. (2021). HMG-CoA Reductase Inhibitors (Statins) and their Drug Interactions Involving CYP Enzymes, P-glycoprotein and OATP Transporters-An Overview. *Curr Drug Metab*, 22(5), 328-341. https://doi.org/10.2174/1389200222666210114122729
9. Endo, A., Hasumi, K. (1994). HMG-CoA reductase inhibitors. *Natural product reports*, 10, 541-50. https://doi.org/10.1039/NP9931000541
10. Mukundan, D., Vasanthakumari, R. (2014). Basic analytical parameters of Atorvastatin Calcium IP (Atroveen-10) granular, compressed, and film-coated tablets. *Journal of Biochemical Sciences*, 1(1), 39-49.
11. Kogawa, A., Pires, A., Salgado, H. (2019, May 1). Atorvastatin: A Review of Analytical Methods for Pharmaceutical Quality Control and Monitoring. *Journal of AOAC International*, 102(3), 801-809. https://doi.org/10.5740/jaoacint.18-0200
12. Kundo, N., Dutta, S., Sarker, A., Sultana, C., Haque, M.A., Islam, M.N. (2016). Formulation and Evaluation of Rosuvastatin Immediate Release Tablets 10 Mg. *IOSR Journal of Pharmacy and Biological Sciences*, 11(05), 01-05. https://doi.org/ 10.9790/3008-1105030105
13. Lamb, Y. (2020, August). Rosuvastatin/Ezetimibe: A Review in Hypercholesterolemia. *A Journal of Cardiovasc Drugs*, 20(4), 381-392. https://doi.org/10.1007/s40256-020-00421-1
14. Parikh, B., Patel, D., Patel, C., Dave, J., Gothi, G., Patel, T. (2010, February). Formulation, optimization, and evaluation of immediate release tablet of telmisartan. *Journal of Global Pharma Technology*, 2(2), 79-84.
15. Ramu, B., Manasa, M.S. (2015). Formulation and Evaluation of Colon Specific Drug Delivery of Press Coated Lansoprazole Tablets. *Indo American Journal of Pharmaceutical Research*, 5(4),1522.
16. Tanni, A., Tabassum, S., Mahmud, R., Idris, J., Shahriar, M. (2017). Comparative in vitro analysis of physicochemical properties of some aceclofenac generic tablets marketed in Bangladesh. *Journal of Biomedical and Pharmaceutical Research*, 6(3), 99-105.
17. Desu, P., Rao, P., Prasanthi, T., Lakshmi, G., Sankar, K., Muneer, S. (2018). Formulation and Evaluation of Immediate Release Tablets of Nevirapine Solid Dispersions. *ARC Journal of Pharmaceutical Sciences*, 4(3), 13-20. https://doi.org/ 10.20431/2455-1538.0404001
18. Chavan, H., Chhabra, G., Gujarathi, N., Jadhav, A. (2018, July). Comparative study of In-process and finished products quality control test for tablet and capsules according to pharmacopeias. *Asian Journal of Pharmaceutical Research and Development*. 6(3), 60-68. https://doi.org/10.22270/ajprd.v6i3.370
19. Saleem, M., Shahin, M., Srinivas, B., Begum, A. (2014). Evaluation of tablets by friability apparatus. *International Journal of Research in Pharmacy and Chemistry*, 4(4),837-840.
20. Maclean, N., Walsh, E., Soundaranathan, M., Khadra, I., Mann, J., Williams, H., Markl, D. (2021, April). Exploring the performance-controlling tablet disintegration mechanisms for direct compression formulations. *International Journal of Pharmacy*, 599,120221. https://doi.org/ 10.1016/j.ijpharm.2021.120221
21. Bozal-Palabiyik, B., Uslu, B., Ozkan, Y., Ozkan, S. (2018). In-Vitro Drug Dissolution Studies in Medicinal Compounds. *Curr Med Chem*. 25(33),4020-4036. https://doi.org/10.2174/0929867325666180322145335.
22. Mohapatra, S., Sahoo, R., Mallick, S., Mohapatra, R. (2021). Enteric Dissolution Enhancement of Engineered Gastro Resistant Omeprazole Tablets using Hydroxypropyl Methylcellulose Acetate Succinate. *Indian Journal of Pharmaceutical Education and Research*, 55(3), 677-684. https://doi.org/ 10.5530/ijper.55.3.139
23. Kumar, N., Nath, G. (2013, September). Xanthan gum based once a day matrix tablet of cefixime trihydrate: development and evaluation. *International Journal of Pharmaceutical Sciences and Research*, 4(9), 3390-3399. http://dx.doi.org/10.13040/IJPSR.0975-8232.4(9).3390-99
24. Berthomieu, C., Hienerwadel, R. (2009, August). Fourier transform infrared (FTIR) spectroscopy. *Photosynth Res*, 101(2-3),157-70. https://doi.org/10.1007/s11120-009-9439-x
25. Noor, S., Salam, F.B., Hima, H.N., Bhuiyan, S., Chowdhury, S. (2017, June). Comparative in-vitro quality evaluation of some brands of metronidazole tablets available in Bangladesh. *International Journal of Applied Research and Studies*, 3(7),753-758.
26. Dash, S., Murthy, P., Nath, L., Chowdhury, P. (2010, May). Kinetic modeling on drug release from controlled drug delivery systems. *Acta Pol Pharm.*,67(3):217-23.
27. Nanjwade, V., Manvi, F., Nanjwade, B. (2013, March). Formulation and Evaluation of Dispersible Tablets of Lomefloxacin HCl. *International Journal of Drug Development and Research*, 5(1), 103-113.
28. Gopalkrishnan, Dr. S., Aggarwal, P., & Balabhadra, N. (2019). Developing Synergies in the Pharmaceutical Sector: M&A Activity post 2005. In International Journal of Recent Technology and Engineering (IJRTE) (Vol. 8, Issue 2, pp. 3256–3265). https://doi.org/10.35940/ijrte.b1651.078219
29. Sabitha, B., Akila, K., Radhakrishnan, G. A. A., Krishnan, G. A., & Naveen, S. (2019). Automatic Medicine Vending Machine. In International Journal of Engineering and Advanced Technology (Vol. 9, Issue 2, pp. 1850–1853). https://doi.org/10.35940/ijeat.f7977.129219
30. A Research on Employee Involvement in Pharmaceutical Industry in India. (2019). In International Journal of Innovative Technology and Exploring Engineering (Vol. 8, Issue 6S4, pp. 420–423). https://doi.org/10.35940/ijitee.f1085.0486s419

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