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Research

In-Vitro Pharmaceutical Equivalence Studies for Paracetamol and Atorvastatin Formulations

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Abstract

Quality control is an essential operation of the pharmaceutical industry. The drugs must be marketed as safe and therapeutically active formulations whose performance is consistent and predictable. The objectives of the present study were to carry out quality control tests on different brands of Paracetamol and (Atorvastatin) tablets available in Oman and to find out the best brand of each drug in terms of its C_{max}, T_{max} and AUC. Different brands of Paracetamol and Atorvastatin tablets available in Oman were procured from different community pharmacies. Quality control tests such as weight variation, hardness, friability, disintegration and dissolution tests were done on Paracetamol and Atorvastatin tablets. Release studies were carried out according to USP dissolution test guidelines on all the marketed tablets of Atorvastatin. C_{max}, T_{max} and AUC were compared for the marketed formulations of drugs (Paracetamol and Atorvastatin) by studying their release profile. The study found that all four brands of Atorvastatin film-coated tablets (Tovast, Torvast, Storvas and Lipitor) met the pharmacopoeia specifications and complied with the criteria laid in the official monographs. The pharmacokinetics parameters (C_{max}, T_{max} and AUC) obtained from this study were 20.10 mg, 30 minutes and 1471.35mg. min/ml for Torvast, 14.21mg, 180 minutes and 1393.35mg.min/ml for Torvast, 12.60mg, 60 minutes and 1056.9mg.min/ml for Storvas, 9.40mg, 180 minutes and 1046.4mg.min/ml for Lipitor respectively. This study on four brands (Panadol, Adol, Tylenol Forte and Omol) of Paracetamol tablets met the pharmacopoeia specifications with respect to different parameters and they differed slightly in terms of various parameters like weight variation, hardness, friability, and disintegration tests.

Key words: Pharmaceutical Equivalent; Quality Control; Dissolution; Area Under Curve

Introduction

Quality Control is a small part of the quality assurance and includes sampling, testing and documentation during manufacture and even after the end of production. It is the monitoring process by which the manufacturer measures the actual performance of the quality standards and finds the causes of deviation from the standard to ensure quality and reproducibility of product. Quality control is an essential operation of the pharmaceutical industry. The drugs must be marketed as safe and therapeutically active formulations whose performance is consistent and predictable. There are various quality control tests done on tablets before they are marketed. Some of them include weight variation test, hardness test, friability test, disintegration and dissolution tests.

Weight variation test is applicable when the tablets contain 50 mg or more of drug substance or when the drug substance represents 50% or more (by weight) of the dosage form unit.

Tablet hardness test measures the crushing strength property which is defined as the compressional force applied diametrically to a tablet which just fractures it. Among a large number of measuring devices, the most favored ones are Monsanto tester, Pfizer tester, and Strong Cobb hardness tester. All are manually used. So, strain rate depends on the operator.

In Friability test the tablet may be subjected to a tumbling motion, for example, coating, packaging, transport, which are not severe enough to break the tablet, but may abrade the small particle from tablet surface. To examine this, tablets are subjected to a uniform tumbling motion for specified time and weight loss is measured. Roche Friabilator is most frequently used for this purpose. Disintegration is the time required for the tablet to break into particles. The disintegration test is a measure only of the time required under a given set of conditions for a group of tablets to disintegrate into particles which will pass through 10 mesh screen. Basket Tablet Disintegration Tester is most frequently used for this purpose.

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The dissolution rate is defined as the amount of drug substance that goes into solution per unit time under standardized conditions of liquid / solid interface, temperature, and solvent composition. Dissolution is one of most important quality control tests and is considered as a tool for predicating bioavailability, in some cases, replacing clinical studies to determine bioequivalence. Rotating basket and Paddle apparatus are most frequently used to determine dissolution.

Tablet thickness and Tablet diameters are also important tests. Pfizer tester is used for checking the diameter of the tablet. Screw gauge and calipers are also used. Tablet thickness can be measured by micrometer or by other device. Tablet thickness should be controlled within a ± 5% variation of standard value. Very thick tablet affects packaging either in blister or plastic container. Tablet thickness is determined by the die of the tablet. Pfizer tester is used for checking tablet thickness.

In content uniformity test 30 tablets are randomly selected. 10 of these are assayed individually. The batch passes the test if 9 of the 10 tablets must contain not less than 85% and not more than 115% of the labeled drug content and the 10th tablet may not contain less than 75% and more than 125% of the labeled content. If these conditions are not met, remaining 20 tablets are assayed individually and none may fall outside of the 85 to 115% range.

Bioequivalence studies consisting of single-dose pharmacokinetic assessments are required for the registration of the most common formulations. As a rule, the bioequivalence test is a useful method for comparing different brand products containing the same active ingredient. In this regard, each brand has its own excipients and formulation features which affect the release and delivery of drugs. Bioavailability is the degree and rate at which a substance (as a drug) is absorbed into a living system or is made available at the site of physiological activity.

Bioequivalence is the property where two drugs with identical active ingredients (as a brand-name drug and its generic equivalent) or two different dosage forms (as tablet and oral suspension) of the same drug possess similar bioavailability and produce the same effect at the site of physiological activity. The most common parameters include C_{max}, T_{max} and AUC. C_{max} refers to the maximum concentration of a drug achieved after dosing. Tmax refers to the time after administration of a drug when the maximum plasma concentration is reached and when absorption equals the rate of elimination. Area under the plasma drug concentration versus time curve is a measure of drug exposure.

It is necessary to carry out study on the quality control parameters of the formulations. The objective of our present study was to conduct the evaluation of quality control parameters on four different brands of Paracetamol and Atorvastatin tablets available in Oman and also to perform quality control tests to assess Paracetamol and Atorvastatin tablets for weight variation, friability, hardness, dissolution and disintegration. Moreover, to find out Cmax, Tmax and AUC of Paracetamol and Atorvastatin the release profile of the drugs was studied. Also, such parameters or physical properties of tablet are also useful tools for maintaining consistency in batch-to-batch manufacturing and it should be performed for every drug product. All of these parameters are closely related to each other and have effect on drug absorption and bioavailability.

The work done on Paracetamol and Atorvastatin tablets by various scientists is tabulated in Table 1.

Aim and Objectives of the study

Aim

To carry out quality control tests on different brands of Paracetamol and Atorvastatin tablets available in Oman and to find out the best brand of each drug in terms of its C_{max}, T_{max} and AUC.

Objectives

- To procure all different brands of Paracetamol and Atorvastatin tablets available in Oman from different community pharmacies.
- To carry out quality control tests such as weight variation, hardness, friability, disintegration and dissolution tests on Paracetamol and Atorvastatin tablets available in Oman.
- To Perform release studies according to USP dissolution test guidelines on all the marketed tablets of Paracetamol and Atorvastatin.
- To compare the quality control test results of different brands of Paracetamol and Atorvastatin tablets.
- To find out Cmax, Tmax and AUC and compare the same for the marketed formulations of drugs (Paracetamol and Atorvastatin)by studying their release profile.
- To find out the best brand in terms of quality control tests and release from the formulations.

Experimental

Materials

Pure Paracetamol and pure Atorvastatin were obtained as gift samples from NPI, Rusaiyl, Oman. Distilled water, methanol, sodium hydroxide, potassium dihydrogen orthophosphate and disodium hydrogen phosphate were obtained from the laboratory and were of laboratory grade. Apparatuses used for the studies were pipettes, small beakers, volumetric flasks, stop watch, boats for weighing. In addition, spatulas, filter papers, containers, test tubes and thermometer were used. Equipments used for the study were analytical balance, Friabilator, Monsanto hardness tester, Disintegration test apparatus, Dissolution test apparatus (Rotating Paddle) and UV-VIS Spectrophotometer.

Table 1: Work done by different scientists on quality control tests on Paracetamol and Atorvastatin tablets

Year	Work done	Results	References/Number
2000	Comparative dissolution testing of Paracetamol commercial tablet dosage forms- nine brands. Paddle and rotating basket apparatus methods were applied to all the formulations	All the preparations were in accordance with the pharmacopeial standards. Best fitting kinetics was found to be the Hixson-Crowell kinetics.	Yalcin Ozcan et al., Turkey [1]
2004	Dissolution of extemporaneous Paracetamol capsules of varying sizes.	Over a 4-hour period, paracetamol dissolution decreased with increasing hypromellose content. The dissolution rate was faster from small capsules and slower from capsules with a lower content weight. The method used to mix the powders also had a significant effect on the dissolution rate.	Sadaf Mukhtar, Australia[2]
2007	Studied the pharmaceutical quality of Chloroquine and Paracetamol products sold in a major Nigerian market.	Results showed that there were still some defects in the pharmaceutical quality of these drugs. The pharmaceutical properties of the products indicated that 6, 15, 9, and 9% of them failed tests for disintegration, dissolution, crushing strength, and percentage of active content, respectively. These defects could have resulted from deliberate counterfeiting, poor quality control during manufacture or decomposition of the products.	Justina O Ofonaike, et al.[3]
2010	Paracetamol tablets manufactured using the dried fruit of Phoenix dactylifera Linn as an excipient. Uniformity of weight, hardness, friability, disintegration and dissolution tests were done	The granules manufactured using the binders had good flow properties and compressibility. As the concentration of the binders increased, the binding ability improved producing tablets with good uniformity of weight and hardness. The tablets manufactured using dried date palm was found to be less friable than tablets manufactured using acacia and tragacanth. Although, the tablets did not disintegrate, the drug release from the tablets passed the USP and BP specification for dissolution of Paracetamol.	N. C. Ngwuluka, et al.,Nigeria[4]
2011	Study was done by on the post-market in vitro equivalency evaluation of Paracetamol tablets. Six brands of Paracetamol 500 mg tablets had been evaluated using specific quality control tests for uniformity of weight, friability, content, disintegration, and dissolution with the aim to assess their bioequivalence.	There were minor differences in tablet hardness, and disintegration time profiles. The dissolution characterization of various Paracetamol tablets appeared to be similar and not significantly different amongst various manufacturers.	A.R. Chandrasekaran, et al., Malaysia[5]
2012	A study was conducted on the quality of brands of Atorvastatin Calcium tablets marketed in Lagos, Nigeria. This study was done to evaluate the physico-chemical parameters like uniformity of weight, hardness, friability and disintegration test which was carried out according to British pharmacopoeia. In addition, assay of active ingredient and in-vitro dissolution evaluation were conducted using USP apparatus 2 satisfying the general conditions for film tablets.	They concluded that out of 3 brands of immediate-release Atorvastatin Calcium tablets available in the market at the time of the study, only 2 passed all the pharmacopoeia tests for satisfactory quality.	Moshood O et al.[6]

2012	Worked on the comparative evaluation of the biopharmaceutical and chemical equivalence of some commercial brands of Paracetamol tablets. They used non official tests-hardness and friability; official tests-disintegration, dissolution, and drug content.	The results revealed that all Paracetamol tablet brands complied with the official USP specifications. All the tested brands were biopharmaceutically and chemically equivalent.	Raniah Al-Shalabi, et al.[7]
2012	A study was done on the in-vitro comparative evaluation of quality control parameters between Paracetamol and Paracetamol/Caffeine tablets available in Bangladesh. This study was done to evaluate weight variation, hardness, friability, disintegration times and dissolution profile between the commercially available tablet brands.	All tablets either Paracetamol or Paracetamol/Caffeine showed acceptable weight variation and friability (below 1%). Formulations were somewhat different in their hardness, disintegration time and dissolution profile. All tablets of Paracetamol/caffeine were found harder than Paracetamol tablets of the same manufacturer. 1 out of 5 for Paracetamol and 3 out of 5 for Paracetamol/Caffeine tablets exceeded the limit of tablet hardness. The disintegration time in 0.1N HCl of Paracetamol tablet brands were less than the Paracetamol/Caffeine brands. On the other hand in phosphate buffer, pH 7.4, Paracetamol/Caffeine tablets dissolved quickly and showed better release profile than tablets containing only Paracetamol.	Palash Karmakar, et al.[8]
2012	Worked on the determination of the quality control parameters of Paracetamol tablets in Bangladesh pharma market. Hundred tablets from each batch of each brand were taken from the market and were determined for the quality control parameters including weight variation, hardness, friability and disintegration test.	Various results were obtained from the test and compared with the specification. The tablets met with the specification and hence, it could be concluded that the tablets had the desired and optimum therapeutic efficacy.	Zinia Mosharraf[9]
2012	Worked on the comparative quality evaluation of Paracetamol tablets marketed in Somali region of Ethiopia. In this study, the tests for weight variation, friability, disintegration time, identification test and assay were conducted	All the brands under the study were within the specification for weight variation test. But from the contraband brands, two for friability, one for disintegration and all for percentage content. Paracetamol failed to satisfy the requirement though all of the products contained the right active ingredients.	Samuel Belay Sahle, et al.[10]
2012	Worked on the formulation and evaluation of Atorvastatin loaded extended release tablets. Three Atorvastatin loaded formulations were prepared by using varying polymer ratios of 1:1, 1: 3, 1:5 and other excipients. The formulations were evaluated for hardness, friability, weight variation, disintegration and in-vitro release study.	On the basis of evaluation parameters formulation FA3 was found to be the best.	Pranshu Tangri, et al.[11]

2012	Study was done by on the comparative in vitro release of some commercially available Paracetamol tablets. The main objective of the present study was to conduct the comparative dissolution studies of various brands of same dosage forms to determine whether all the formulations used were equivalent or significantly different. Five different brands of Paracetamol of 500 mg conventional tablets from different manufacturers were selected in the study and dissolution testing was done in 7.8 pH phosphate buffer for 30 mins, by using dissolution testing apparatus USP type-II.	The brands passed the test.	Syed Anees Ahmed, et al., India [12]
2013	Post-market in-vitro comparative evaluation of quality control parameters of Paracetamol compressed tablets. Evaluated the quality parameters of different brands by selecting samples of different batches. Types of quality tests performed were weight variation, disintegration time, dissolution, hardness and friability.	The results showed no significant deviations from the compendial standards and specifications. It shows that these brands of local manufacturers in KPK are safe enough and could be used to achieve the desired therapeutic effect	Zia-ur-Rahman, et al., Pakistan[13]
2013	Study on dissolution method ,development and validation for combination of Ibuprofen and Paracetamol tablets. The corresponding dissolution profiles were constructed.	All the selected brands showed more than 80% drug release within 45 minutes.	Zareena Yasmeen, et.al., Hyderabad [14]
2013	Study on the formulation, evaluation and development of immediate release film coated tablets of Atorvastatin and sustained release film coated tablets of Ezetimibe in capsules form USP was carried out. The tablets were prepared by wet granulation method using different binding agents. The prepared tablet formulations were evaluated for various parameters like weight variation, hardness, friability, disintegration time, and drug content. Along with these drug excipients interaction, In-vitro dissolution studies and stability studies were also performed by using 0.05M phosphate buffer pH-6.4 and 0.5% SLS in acetate buffer as dissolution medium.	The study showed no drug – excipients interaction.	P.Palanisamy, et al.[15]
2014	Carried out quality evaluation of Paracetamol tablets obtained from the common shops in Addis Ababa, Ethiopia. The tablets were assessed for different quality parameters like weight variation, friability, diameter, thickness, assay, disintegration and dissolution using compendial methods. The dissolution profiles of the two brands (Asmol and Kelvin) and a generic Paracetamol, Epharm were evaluated.	The results showed that all the samples investigated were within the limit set by the Pharmacopeia. All of the samples passed the assay test except Asmol.	Liya Teklu, et al.[16]

2014	Worked on the comparative study of four different brands of Acetaminophen available in Karachi. The quality control parameters which were studied were weight variation test, hardness test, thickness, friability, disintegration and dissolution specified by BP/USP Pharmacopoeia.	Weight variation and hardness value requirement was complied by all brands .Disintegration time for all brands was within 15 minutes which was also complying the BP/USP recommendation. All the brands showed more than 80 % drug release within 45 minutes. The present findings suggested that almost all the brands of Acetaminophen that were available in Karachi met the BP/USP specification for quality control analysis.	Huma Dilshad, et al.[17[
2014	A study was conducted on the comparative assessment of quality on the brands of Atorvastatin tablets marketed. This study evaluated the quality of seven commercially available (European or Asian sourced) Atorvastatin Calcium tablets products marketed in Southern-Nigeria with a view to determine their interchangeability in clinical practice. In this study, they did quality assessment for drug products and a validated UV-Vis Spectrophotometric method was employed in the assay.	From the results it was observed that the European sourced Atorvastatin calcium tablets may not be interchangeable with those sourced from Asia.	Bagbi Baribefe M, et al.[18]
2015	Comparative pharmaceutical quality control testing on different brands of Paracetamol tablets available in Trinidad & Tobago, west Indies.	All these parameters of different brands were in the pharmacopoeial limits so it could be concluded that marketed pharmaceutical tablets of Paracetamol were safe, effective and efficacious .	Madan Mohan Gupta, et al.[19]
2015	Evaluation of quality control parameters on various brands of Paracetamol tablet formulations like weight variation, hardness, friability, disintegration and dissolution test.	They found only slight difference in terms of various quality control parameters.	Neha Mathur, et al.[20]
2015	Comparative in-vitro evaluation of Metformin HCl and Paracetamol tablets commercially available in Kandy District, Sri Lanka. In this study, two tablets of Metformin HCl and Paracetamol were examined visually for their organoleptic properties and tested for uniformity of weight, disintegration time, assay value, dissolution rate, hardness or crushing strength and friability.	The results showed all the tested tablets complied with the official standards for the parameters. Despite some minor differences in tablet hardness and disintegration time profiles, other in-vitro characteristics of the tested brands; Paracetamol and Metformin HCl and their locally manufactured generics appeared to be similar and not significantly different from each other.	T. W. Hettiarachchi1, et al.[21]
2015	A study was conducted on the comparative in vitro pharmaceutical equivalence studies of different brands of Atorvastatin calcium tablets marketed in Bangladesh. The dissolution was carried out using the apparatus II according to USP guidelines. The study was done to evaluate the physicochemical parameters such as content uniformity test, weight variation analysis, hardness, friability and disintegration test carried out according to United States of Pharmacopoeia.	The results showed that three brands of Atorvastatin Calcium tablets out of five passed all the pharmacopoeia tests for satisfactory quality.	Md. Abir Khan, et al.[22]

2016	Evaluation of pharmaceutical quality of conventional dosage forms containing Paracetamol and Caffeine available in the Turkish drug market was done. Weight variation, content uniformity, diameter and thickness, hardness, friability, disintegration, and dissolution tests were carried out. Content uniformity and dissolution tests were performed by a validated high-performance liquid chromatography (HPLC) method.	The results of this study indicated that PA- and CA-containing conventional dosage forms available in the Turkish drug market passed all the established quality control tests successfully.	Emrah Akgeyik, et al.[23]
2016	The study included development of quality control method for dissolution analysis of Tapentadol and Paracetamol in tablet. The optimized dissolution conditions included USP apparatus II using a paddle rotation rate of 50 rpm and 900 ml of 6.8 pH Phosphate buffer at 37°C± 0.5°C.	Under these conditions, the in vitro release profiles of Tapentadol and Paracetamol showed good results.	Krishna R Gupta, et al.[24]
2016	In Palestine, a study was conducted on the pharmaceutical quality of generic Atorvastatin products compared with the innovator product. Innovator Atorvastatin and four generic products were tested for their pharmaceutical quality. In addition, tablets were tested for their drug content, weight uniformity, hardness, disintegration and dissolution.	Pharmaceutical quality assessments were satisfactory and within limits for all Atorvastatin tested products. All products disintegrated within permitted time limits and showed very rapid dissolution. Also, products released more than 85% of their drug contents in less than 15 min. The results showed that all tested innovator and generic atorvastatin products were of good pharmaceutical quality.	Shawahna R, et al.[25]
2017	In Bangladesh a study was done on the development and characterization of Atorvastatin Calcium sustained release tablet using carbomer-974 and hypromellose-15000 cps. The drug release studies was carried out in USP dissolution test apparatus II (paddle) using phosphate buffer of pH 6.8 as dissolution medium for 8 hours and documented the effects of polymers on the drug release profile.	The drug release pattern, compactibility and swelling index property of the formulated preparations were concentration dependent of the polymers used. Additional study is very important to evaluate the in vitro-in vivo relationship, but this study will be helpful for future to exploit the potential of this drug delivery system for the benefit of mankind.	S. Akbar, et al.[26]
2017	Journal of pharmaceutical science and clinical research published a study conducted on uniformity of test tablets of atorvastatin using ultraviolet spectrophotometer. The study was done by measuring the uniformity of tablet weight and content uniformity and was done using ultraviolet spectrophotometry in methanol at the maximum wavelength of 246.2 nm.	Based on the calculation of CV it was shown that all the tablets of atorvastatin in the market already qualified uniformity of weight as indicated by the value of CV < 5 %.	Sholichah Rohmani, et al.[27]

Methods

Sample Collection

Table 2 : Following brands of Paracetamol tablets were collected from the market.

Names of the brands	Strength/ Nature of the Formulation	Company Name
Panadol(Paracetamol)	500mg/ Film-Coated Tablet	GlaxoSmithkline
Adol(Paracetamol)	500mg/Caplets	Julphar
Tylenol Forte(Paracetamol)	500mg/Tablet	Janssen
Omol(Paracetamol)	500mg/Uncoated Tablet	NPI Pharma

Table 3 : Following brands of Atorvastatin tablets were collected from the market.

Names of the brands	Strength/Nature of the Formulation	Company Name
Tovast (Atorvastatin Calcium Trihydrate)	20mg/ Film-Coated Tablet	Spimaco
Torvast (Atorvastatin Calcium)	20mg/ Film-Coated Tablet	NPI Pharma
Storvas (Atorvastatin Calcium Trihydrate)	20mg/ Film-Coated Tablet	Ranbaxy
Lipitor (Atorvastatin Calcium)	20mg/ Film-Coated Tablet	Pfizer

Evaluation of tablets

Following tests were carried out

Weight Variation

Ten tablets of each sample were weighed using analytical balance. The average weight and standard deviation were calculated for weight variation test. According to the USP, the requirements for weight variation should be:

Table 4 :

Average weight of tablets (mg)	Maximum percentage difference allowed
130mg or less	10
130mg-324mg	7.5
More than 324mg	5

Not more than 2 tablets should deviate from the average weight by more than the percentage listed in the table.

Friability Test

Ten tablets for each sample were weighed on the analytical balance and then placed in the friability tester which was rotated at 100 rpm. Finally, the tablets were dedusted and reweighed again. The difference in weight was taken and percent loss in weight was calculated.

Hardness Test

Ten tablets of each sample were subjected for hardness testing and the crushing strength of the tablet was measured. Average hardness of the tablets was calculated and standard deviation was determined. A force of 4-6 kg is the minimum requirement for a satisfactory tablet.

Disintegration Test

Six tablets of each sample were placed in the disintegration apparatus, where the volume of disintegration medium was 600 ml of water maintained at 37±1°C. The time taken to break each tablet into small particles and pass through the mesh was recorded and average time was calculated.

Dissolution Test

Atorvastatin

The release rate of Atorvastatin was determined by using Tablet Dissolution test apparatus (USP apparatus II Paddle). At first, phosphate buffer of pH6.8 was prepared with disodium hydrogen phosphate and potassium dihydrogen phosphate.28.8g of disodium hydrogen phosphate was measured and made up to 1000ml with distilled water in a volumetric flask.11.45 g of potassium dihydrogen phosphate was measured and made up to 100ml with distilled water in a volumetric flask. Then 920 ml of disodium hydrogen phosphate and 80ml of potassium dihydrogen phosphate were mixed and made to 1000 ml with phosphate buffer. pH was adjusted to 6.8 with 0.1N HCL as needed. 900ml of this was used as dissolution medium for each study. The in vitro release of Atorvastatin 20mg tablet (single) was studied by running batches in dissolution test apparatus-USP type2. The tablets were weighed using analytical balance. Then tablets were placed in the dissolution apparatus beaker containing 900ml of phosphate buffer pH6.8, using paddles rotating at a speed of 75rpm. The temperature was maintained at 37°C during the duration of release studies. The temperature was measured using thermometer. 10ml samples from each vessel were withdrawn during the duration of release studies and kept in marked test tubes. Fresh dissolution medium (10ml) was added to the vessels after each sample was taken to replace for the sample withdrawn. All the samples were filtered using funnel and filter paper. Absorbance of the samples was measured using UV spectrophotometer at wavelength of 242nm. Phosphate buffer pH 6.8 was used as a blank.

Preparation of Calibration Curves for Atorvastatin in Phosphate Buffer

Stock solution was prepared by dissolving 100mg of accurately weighed Atorvastatin in 100 ml of methanol to get 1mg/ml solution. Further 10 ml of this solution was pipetted into 100ml volumetric flask and made up to 100ml with phosphate buffer pH 6.8 to get 100mcg/ml solution. From this 5, 10,15,20,25,30,35,40,45,50,55 and 60 ml solutions were pipetted into series of 100ml volumetric flask and were made up to 100ml with phosphate buffer pH6.8 to get 5-60mcg/ml solutions of Atorvastatin respectively. The absorbance of resulting solutions was measured at λ_{max} against the blank. A graph was plotted by taking concentration on X-axis and absorbance on Y-axis.

Results and Discussion

Results and Discussion for Paracetamol

Weight Variation Test Results for Paracetamol Tablets

Table 4.1: Weights of Tylenol Forte tablets (n=10)

Sample	1	2	3	4	5	6	7	8	9	10	∑
Weight(g)	0.671	0.665	0.668	0.671	0.671	0.662	0.672	0.676	0.664	0.53	6.673
Weight(mg)	671	665	668	671	671	662	672	676	664	653	6673
Deviation	3.7	-2.3	0.7	3.7	3.7	-5.3	4.7	8.7	-3.3	-14.3	0
d^2	13.69	5.29	0.49	13.69	13.69	28.09	22.09	75.69	10.89	204.49	388.1

Mean=6673mg÷10=667.3mg

Variation allowed: ±5% (to pass the weight variation test)

±5% = (667.3×5) ÷100= ±33.365 (633.935mg- 700.665mg-permissible range)

Table 4.1.2: Weights of Adol tablets (n=10)

Sample	1	2	3	4	5	6	7	8	9	10	∑
Weight(g)	0.652	0.646	0.653	0.046	0.046	0.641	0.644	0.639	0.655	0.640	6.462
Weight(mg)	652	646	653	646	646	641	644	639	655	640	6462
Deviation	5.8	-0.2	6.8	-0.2	-0.2	-5.2	-2.2	-7.2	8.8	-6.2	0
d^2	33.64	0.04	46.24	0.04	0.04	27.02	4.84	51.84	77.44	38.44	279.6

Mean=6462mg ÷10=646.2mg

Variation allowed: ±5% (to pass the weight variation test)

±5% = (646.2×5) ÷100= ±32.31 (613.89mg-678.51mg-permissible range)

Table 4.1.3: Weights of Panadol tablets (n=10)

Sample	1	2	3	4	5	6	7	8	9	10	∑
Weight(g)	0.676	0.668	0.678	0.676	0.678	0.677	0.671	0.675	0.675	0.674	6.748
Weight(mg)	676	668	678	676	678	677	671	675	675	674	6748
Deviation	1.2	-6.8	3.2	1.2	3.2	2.2	-3.8	0.2	0.2	-0.8	0
d^2	1.44	46.24	10.24	1.44	10.24	4.84	14.44	0.04	0.04	0.64	89.6

Mean=6748mg÷10=674.8mg

Variation allowed: ±5% (to pass the weight variation test)

±5% = (674.8×5) ÷100= ±33.74 (641.06mg-708.54mg-permissible range)

Table 4.1.4: Weights of Omol tablets (n=10)

Sample	1	2	3	4	5	6	7	8	9	10	∑
Weight(g)	0.547	0.555	0.542	0.556	0.548	0.559	0.537	0.542	0.541	0.554	5.481
Weight(mg)	547	555	542	556	548	559	537	542	541	554	5481
Deviation	-1.1	6.9	-6.1	7.9	-0.1	10.9	10.9	-6.1	-7.1	5.9	0
d^2	1.21	47.61	37.21	62.41	0.01	118.81	118.81	37.21	50.41	34.81	512.9

Mean= 5481mg÷10=548.1mg

Variation allowed: ±5% (to pass the weight variation test)

±5% = (548.1×5) ÷100= ±27.405 (520.695mg-575.05mg-permissible range)

Friability test results for different brands of Paracetamol tablets

The results of tests done on the tablets are listed in Tables

Table 4.2.1: Friability test results for various brands of Paracetamol tablets

Name of the brand (n=10)	Initial weight of 10 tablets(g)	End weight of 10 tablets(g)	Weight lost(g)	%weight lost
Tylenol Forte tablets	6.6806	6.6240	0.0566	0.8472
Adol tablets	6.4742	6.4661	0.0081	0.1251
Panadol tablets	6.7717	6.7706	0.0011	0.0162
Omol tablets	5.4909	5.4769	0.014	0.255

Hardness test for Paracetamol tablets

Table 4.3.1: Hardness test on Tylenol Forte tablets. (n=10)

Sample No.	1	2	3	4	5	6	7	8	9	10
Force required (Kg/cm^2)	6.5	6	6.5	5.5	6	6	7	5.5	7.5	7.5
Deviation	0.1	-0.4	0.1	-0.9	-0.4	-0.4	0.6	-0.9	1.1	1.1
D^2	0.001	0.16	0.001	0.81	0.16	0.16	0.36	0.81	1.21	1.21

Mean = 64/10= 6.4Kg/cm^2

Table 4.3.2: Hardness test on Adol tablets. (n=10)

Sample No.	1	2	3	4	5	6	7	8	9	10
Force required (Kg/cm^2)	6.5	6.5	6.5	5.5	6.5	6.5	6.5	5.5	6	5.5
Deviation	0.35	0.35	0.35	-0.65	0.35	0.35	0.35	-0.65	-0.15	-0.65
D^2	0.1225	0.1225	0.1225	0.4225	0.1225	0.1225	0.1225	0.4225	0.0225	0.4225

Mean = 61.5/10= 6.15Kg/cm

Table 4.3.3: Hardness test on Panadol tablets. (n=10)

Sample No.	1	2	3	4	5	6	7	8	9	10
Force required (Kg/cm^2)	6.5	6.5	6	6.5	6.5	6.5	6.5	6	7	6.5
Deviation	0.05	0.05	-0.45	0.05	0.05	0.05	0.05	-0.45	0.55	0.05
D^2	0.0025	0.0025	0.2025	0.0025	0.0025	0.0025	0.0025	0.2025	0.3025	0.0025

Mean = 64.5/10= 6.45Kg/cm^2

Table 4.3.4: Hardness test on Omol tablets. (n=10)

Sample No.	1	2	3	4	5	6	7	8	9	10
Force required (Kg/cm^2)	7	6	6	5.5	6	5.5	5	6.5	6	7
Deviation	0.95	-0.05	-0.05	-0.55	-0.05	-0.55	-1.05	0.45	-0.05	0.95
D^2	0.9025	0.0025	0.0025	0.3025	0.0025	0.3025	1.1025	0.2025	0.0025	0.9025

Mean= 60.5/10= 6.05Kg/cm^2

Disintegration test results for Paracetamol tablets

Table 4.4.1: Disintegration test on Tylenol Fort tablets: (n=6)

Sample	Disintegration time	deviation(d)	(d^2)
1	2.10min	-0.865	0.748225
2	2.41min	-0.555	0.308025
3	3.4min	0.435	0.189225
4	3.11min	0.145	0.021025
5	3.32min	0.355	0.126025
6	3.45min	0.485	0.235225
Σ	17.79min	0	1.62775

Mean=17.79/6=2.965min

Table 4.4.2: Disintegration test on Adol tablets :(n=6)

Sample	Disintegration time	deviation(d)	(d^2)
1	3.27min	-1.12	1.254
2	4.2min	-0.19	0.0361
3	4.7min	0.31	0.0961
4	4.45min	0.06	0.0036
5	4.53min	0.14	0.0196
6	5.2min	0.81	0.6561
Σ	26.35min	-0.07	2.0655

Mean=26.35min/6=4.39min

Table 4.4.3: Disintegration test on Panadol tablets: (n=6)

Sample	Disintegration time	deviation(d)	(d^2)
1	0.58sec	-0.69	0.4761
2	1.8min	0.53	0.2809
3	1.20min	-0.07	0.0049
4	1.24min	-0.03	0.0009
5	1.30min	0.03	0.0009
6	1.50min	0.23	0.0529
Σ	7.62min	0	0. 8166

Mean=7.62/6=1.27min

Table 4.4.4: Disintegration test on Omol tablets: (n=6)

Sample	Disintegration time	deviation(d)	(d^2)
1	1.41min	-0.83	0.6889
2	2.2min	-0.04	0.0016
3	2.6min	0.36	0.1296
4	2.8min	0.56	0.3136
5	2.14min	-0.1	0.01
6	2.29min	0.05	0.0025
Σ	13.44min	0	1.1462

Mean=13.44/6=2.24min

Discussion

The quality of different brands of Paracetamol tablets was assessed by weight variation, hardness, friability, disintegration and dissolution.

Weight Variation

As per USP, the permissible weight variation limit for the tablets which are having the weight equal to or more than 324 mg is 5 % and the given results have shown that all four brands of Paracetamol are having weight variation less than 5 % which proves that the four brands (Tylenol forte, Adol, Panadol and Omol) of paracetamol tablets passed the official weight variation test.The difference in weight between these four brands (Tylenol forte, Adol, Panadol and Omol) of Paracetamol tablets may be due to pressure difference during compression process and non-uniform amount of in-active ingredients.

Friability

Tables 2.1 to 2.4 show the % weight loss for Tylenol forte, Adol, Panadol and Omol. Tylenol forte showed the highest weight loss and Panadol exhibited the lowest percentage weight loss. All of them exhibited weight loss less than 1%, so they passed the test.

Hardness

The tablets require some strength or hardness to withstand the mechanical shocks of handling and transport and at the same time are still sufficiently flexible to be able to disintegrate properly after swallowing. Since there is also a relationship between the hardness and the disintegration rate of the tablets, it is essential that the hardness of the tablets is within the acceptable range. Tablets with increased hardness values tend to have an increasing disintegration time. However, a minimum hardness of 4kg is essential. All four brands of Paracetamol have hardness in the acceptable range and therefore comply with specification of USP.

Disintegration

Panadol showed the lowest disintegration time. Adol exhibited the highest disintegration time. The disintegration time for all the four brands met the USP requirement which states that the tablets disintegrated within 30 minutes.

Results and Discussion for Atorvastatin

Weight variation test results for Atorvastatin Tablets

Table 4.4.5: Weights of Tovast tablets: (n=10)

Sample	1	2	3	4	5	6	7	8	9	10	∑
Weight(g)	0.309	0.308	0.307	0.304	0.308	0.307	0.308	0.309	0.303	0.37	3.07
Weight(mg)	309	308	307	304	308	307	308	309	303	307	3070
Deviation	2	1	0	-3	1	0	1	2	-4	0	0
d^2	4	1	0	9	1	0	1	4	16	0	36

Mean=3070mg÷10=307mg

Variation allowed: ±7.5% (to pass the test)

±7.5%= (307 ×7.5) ÷100= ±23.025 (283.975mg-330.025mg-permissible limit)

Table 4.4.6: Weights of Torvast tablets: (n=10)

Sample	1	2	3	4	5	6	7	8	9	10	∑
Weight(g)	0.302	0.297	0.298	0.297	0.296	0.295	0.296	0.295	0.298	0.297	2.974
Weight(mg)	302	297	298	297	296	298	296	295	298	297	2974
Deviation	4.6	-0.4	0.6	-0.4	-1.4	0.6	-1.4	-2.4	0.6	-0.4	0
d^2	21.16	0.16	0.36	0.16	1.96	0.36	1.96	5.76	0.36	0.16	32.4

Mean=2974/10=297.4 mg

Variation allowed: ±7.5% (to pass the test)

±7.5%= (297.4×7.5)/100= ±22.305 (275.095mg- 319.705mg-permissible limit)

Table 4.4.7: Weights of Storvas and Lipitor tablets: (n=10)

Sample	1	2	3	4	5	6	7	8	9	10	∑
Weight(g)	0.319	0.318	0.309	0.313	0.312	0.310	0.321	0.314	0.322	0.320	3.158
Weight(mg)	319	318	309	313	312	310	321	314	322	320	3158
Deviation	3.2	2.2	-6.8	-2.8	-3.8	-5.8	5.2	-1.8	6.2	4.5	0
d^2	10.24	4.84	46.24	7.84	14.44	33.64	27.04	3.24	38.44	20.25	206.21

Mean=3158/10=315.8mg

Variation allowed: ±7.5% (to pass the test)

±7.5%= (315.8×7.5) ÷100= ±23.685 (292.115mg-339.485mg-permissible limit)

Table 4.4.8: Weights of Storvas and Lipitor tablets: (n=10)

Sample	1	2	3	4	5	6	7	8	9	10	∑
Weight(g)	0.315	0.315	0.314	0.313	0.318	0.317	0.308	0.319	0.314	0.316	3.149
Weight(mg)	315	315	314	313	318	317	308	319	314	316	3149
Deviation	0.9	0.9	-0.9	-1.9	-1.9	2.1	-6.9	4.1	-0.9	1.1	1.6
d^2	0.81	0.81	0.81	3.61	3.61	4.41	47.61	16.81	0.81	1.21	86.5

Mean=3149/10=314.9mg

Variation allowed: ±7.5% (to pass the test)

±7.5%= (314.9×7.5)/100=±23.6175 (291.2828mg-338.5175mg-permissible limit)

Friability Test for Different Brands of Atorvastatin Tablets

Table 4.5.1: Friability Test Results For Various Brands of Atorvastatin Tablets

Name of the brand (n=10)	Initial weight of 10 tablets(g)	End weight of 10 tablets(g)	Weight lost(g)	%weight lost
Tovast tablets	3.0697	3.0690	0.0007	0.8472
Torvast tablets	2.9858	2.9849	0.0009	0.030
Storvas tablets	3.1711	3.1707	0.0004	0.012
Lipitor tablets	3.1548	3.1537	0.0011	0.034

Hardness Test for Atorvastatin Tablets

Table 4.5.2: Hardness Test on Tovast Tablets. (n=10)

Sample No.	1	2	3	4	5	6	7	8	9	10
Force required (Kg/cm^2)	5	5	5.5	5.5	5.5	5.5	5	5.5	6	5.5
Deviation	-0.4	-0.4	0.1	0.1	0.1	0.1	-0.4	0.1	0.6	0.1
D^2	0.16	0.16	0.01	0.01	0.01	0.01	0.16	0.01	0.36	0.01

Mean= 54/10= 5.4Kg/cm^2

Table 4.5.3: Hardness test on Torvast tablets. (n=10)

Sample No.	1	2	3	4	5	6	7	8	9	10
Force required (Kg/cm^2)	6	5.5	5.5	5.5	6	6.5	6	7	6.5	7
Deviation	-0.15	-0.65	-0.65	-0.65	-0.15	0.35	-0.15	0.85	0.35	0.85
D^2	0.0225	0.4225	0.4225	0.4225	0.0225	0.1225	0.0225	0.7225	0.1225	0.7225

Mean= 61.5/10= 6.15Kg/cm^2

Table 4.5.4: Hardness Test on Storvas Tablets. (n=10)

Sample No.	1	2	3	4	5	6	7	8	9	10
Force required (Kg/cm^2)	6	6.5	6	6.5	6.5	6	6.5	6	5	6.5
Deviation	-0.15	0.35	-0.15	0.35	0.35	-0.15	0.35	-0.15	-1.15	0.35
D^2	0.0225	0.1225	0.0225	0.1225	0.1225	0.0225	0.1225	0.0225	1.3225	0.1225

Mean= 61.5/10= 6.15Kg/cm^2

Table 4.5.5: Hardness Test on Lipitor Tablets. (n=10)

Sample No.	1	2	3	4	5	6	7	8	9	10
Force required (Kg/cm^2)	6.5	7	6.5	8	7.5	7	6.5	7	7	7.5
Deviation	-0.55	-0.05	-0.55	0.95	0.45	-0.05	-0.55	-0.05	-0.05	0.45
D^2	0.3025	0.0025	0.3025	0.9025	0.2025	0.0025	0.3025	0.0025	0.0025	0.2025

Mean= 70.5/10= 7.05Kg/cm^2

Disintegration test for Atorvastatin tablets:

Table 4.4.5: Disintegration test on Tovast tablets: (n=6)

Sample	Disintegration time	deviation(d)	(d^2)
1	1.52min	-0.448	0.1936
2	1.57min	-0.398	0.158404
3	2.02min	0.052	0.002704
4	2.21min	0.242	0.058564
5	2.22min	0.252	0.063504
6	2.27min	0.302	0.091204
Σ	11.81min	0.002	0.56798

Mean=11.81min/6=1.968min

Table 4.4.6: Disintegration test on Torvast tablets: (n=6)

Sample	Disintegration time	deviation(d)	(d^2)
1	0.50sec	-0.335	0.112225
2	0.53sec	-0.305	0.093025
3	0.59sec	-0.245	0.060025
4	0.59sec	-0.245	0.060025
5	1.3min	0.465	0.21625
6	1.5min	0.665	0.442225
Σ	5.01min	0	0.983775

Mean=5.01min/6=0.835min

Table 4.4.7: Disintegration test on Storvas tablets: (n=6)

Sample	Disintegration Time	deviation(d)	(d^2)
1	0.59sec	-0.608	0.369664
2	1.8min	0.602	0.362404
3	1.13min	-0.068	0.004624
4	1.18min	-0.018	0.000324
5	1.20min	0.002	0.000004
6	1.29min	0.092	0.008464
Σ	7.19min	0.002	0.745484

Mean=7.190min/6=1.198min

Table 4.5.8: Disintegration test on Lipitor tablets: (n=6)

Sample	Disintegration Time	Deviation(d)	(d^2)
1	1.38min	-0.085	0.007225
2	1.40min	-0.065	0.004225
3	1.43min	-0.035	0.001225
4	1.48min	0.015	0.000225
5	1.54min	0.075	0.005625
6	1.56min	0.095	0.009025
Σ	8.79min	0	0.02755

Mean=8.79min/6=1.465min

Calibration Curve of Atorvastatin in Phosphate Buffer (pH 6.8)

The dilution of Atorvastatin in the concentration range from 5-60 mcg/ml were prepared in phosphate buffer (pH 6.8). Absorbance was obtained using UV spectroscopy. The absorbance is presented in the Figure 3

Table 5 .1:

Concentration(mcg/ml)	Absorbance
5	0.154
10	0.228
15	0.292
20	0.372
25	0.443
30	0.543
35	0.643
40	0.735
45	0.807
50	0.878
55	0.945
60	0.984

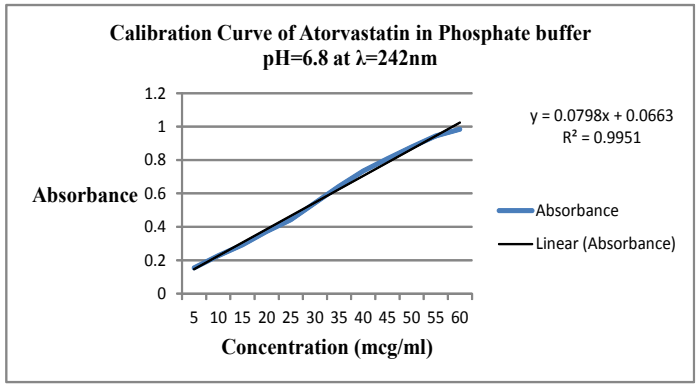

Figure 2: below shows the comparative dissolution profiles of various brands of Atorvastatin.

Table 6.1: Dissolution test results on Tovast tablets :(n=3)

Time (minutes)	Absorbance	Total Amount Dissolved in 900ml (mg)	Total Amount Dissolved in 900ml (mg)
0	0.079	1.43±0.2	7.161%
15	0.2038	15.50±0.3	77.53%
30	0.2446	20.10±0.6	100.5%
45	0.2133	16.57±0.8	82.89%
60	0.2134	6.43±0.4	32.19%
90	0.1224	6.32±1	31.63%
120	0.1403	8.34±0.1	41.72%
150	0.1004	3.84±0.8	19.22%
180	0.1217	6.24±0.2	31.24%

Table 6.2: Dissolution test results on Torvast tablets: (n=3)

Time (minutes)	Absorbance	Total Amount Dissolved in 900ml (mg)	% of Drug Released
0	0.1155	2.77±0.9	13.87%
15	0.1831	6.58±0.7	32.93%
30	0.1821	6.53±0.9	32.65%
45	0.1990	7.48±0.5	37.41%
60	0.2521	10.47±0.3	52.38%
90	0.1844	6.65±0.1	33.29%
120	0.1979	7.42±0.8	37.10%
150	0.1804	6.43±0.2	32.17%
180	0.3184	14.21±0.5	71.08%

Table 6.3: Dissolution test results on Storvas tablets: (n=3)

Time (minutes)	Absorbance	Total Amount Dissolved in 900ml (mg)	% of Drug Released
0	0	0±0.1	0
15	0.0889	2.54±0.4	12.74%
30	0.1022	4.04±0.6	20.24%
45	0.1272	6.86±0.8	34.34%
60	0.1781	12.60±1	63.04%
90	0.1274	6.89±0.3	34.45%
120	0.1115	5.09±0.7	25.48%
150	0.1141	5.39±0.6	26.95%
180	0.0963	3.38±0.3	16.91%

Table 6.4: Dissolution test results on Lipitor tablets: (n=3)

Time (minutes)	Absorbance	Total Amount Dissolved in 900ml (mg)	% of Drug Released
0	0	0±0.1	0
15	0.1782	6.31±0.6	31.55%
30	0.184	6.63±0.5	33.18%
45	0.1646	5.54±0.4	27.71%
60	0.1537	4.92±0.5	24.64%
90	0.1773	6.25±0.7	31.29%
120	0.1704	5.87±0.9	29.35%
150	0.1574	5.13±1	25.68%
180	0.2330	9.40±0.2	47.00%

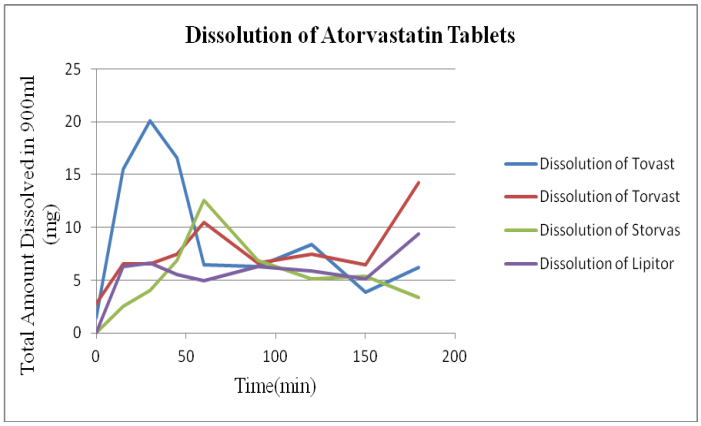

Figure 2: below shows the comparative dissolution profiles of various brands of Atorvastatin.

Discussion

The quality of different brands of Atorvastatin tablets was assessed by weight variation, hardness, friability, disintegration and dissolution.

Weight Variation

As per USP, the weight variation limit for the tablets which are having weight between 130mg-324mg is 7.5 % and the given results have shown

that all four brands of Atorvastatin are having weight variation less than 7.5% which proves that the four brands (Torvast, Storvas, Lipitor and Tovast) of Atorvastatin tablets passed the official weight variation test. The difference in weight between these four brands (Torvast, Storvas, Lipitor and Tovast) of Atorvastatin tablets may be due to pressure difference during compression process and non-uniform amount of in-active ingredient.

Friability

Table 4.2.5 to 4.2.8 showed the % weight loss for Torvast, Storvas, Lipitor and Tovast tablets. Lipitor tablet showed the highest weight loss and Storvas exhibited the lowest percentage weight loss. All of them exhibited loss less than 1%, so they passed the test.

Hardness

Hardness of Atorvastatin tablets was found to be in the range of 5.4 to 7.05 kg/cm^2 indicating all brands have good mechanical strength.

Disintegration

Torvast showed the lowest disintegration time. Tovast exhibited the highest disintegration time. The disintegration time for all the four brands met the USP requirement which states that the tablets disintegrated within 30 minutes.

Dissolution

A dissolution study gives an idea of the amount of drug available for absorption after oral administration. Drugs with poor dissolution profiles will not be available in the body system or target organ /tissues to elicit therapeutic effect. The in vitro dissolution profiles were found to be varying between Atorvastatin film- coated tablets. Maximum release of Tovast tablet was seen at 30 minutes (100.54%) and then it started decreasing until it became constant. On the other hand, Torvast showed the maximum release at 180 minutes (71.08%). Storvas showed the maximum release at 60 minutes (63.04%) and then started decreasing, while Lipitor showed the maximum release at 180 minutes (47.00%).

The area under curve was found from the values obtained from drug released at various time intervals. Trapezoidal method equation gave the values of Area under curve obtained for various brands of Atorvastatin.. Comparative values of various brands are shown as below.

Brands Names of Atorvastatin Tablets	Nature of the Formulation	AUC (mg.min/ml)
Tovast	Film-Coated Tablet	1471.35
Torvast	Film-Coated Tablet	1393.35
Storvas	Film-Coated Tablet	1056.9
Lipitor	Film-Coated Tablet	1046.4

The comparative table clearly shows that Tovast showed highest AUC concluding that the extent of drug availability is expected maximum from Tovast tablets.

Conclusion

The main objective of this study was to carry out quality control tests for different brands of Paracetamol and Atorvastatin tablets and to find the Cmax, Tmax and AUC for different brands of Atorvastatin tablets available in the local market. The study found that all four brands of Atorvastatin film-coated tablets (Tovast, Torvast, Storvas and Lipitor) met the pharmacopoeia specifications and complied with the criteria laid in the official monographs. The study also, found that the four brands of Atorvastatin differed slightly in term of various parameters of quality control tests like weight variation, hardness, friability, disintegration and dissolution tests. The pharmacokinetics parameters (Cmax, Tmax and AUC) obtained from this study were 20.10 mg, 30 minutes and 1471.35mg. min/ml for Torvast, 14.21mg, 180 minutes and 1393.35mg.min/ml for Torvast, 12.60mg, 60 minutes and 1056.9mg.min/ml for Storvas, 9.40mg, 180 minutes and 1046.4mg.min/ml for Lipitor respectively.

This study also showed that all four brands (Panadol, Adol, Tylenol Forte and Omol) of Paracetamol tablets met the pharmacopoeia specifications with respect to different parameters. As a result of this study we have concluded that all the four brands of Paracetamol tablets met the criteria laid in the official monographs and they differed slightly in terms of various parameters like weight variation, hardness, friability, and disintegration tests.

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