

COMPARITIVE STUDY OF DIFFERENT BRANDS OF ATENOLOL AVAILABLE IN KARACHI

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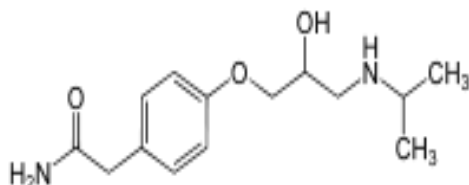
ABSTRACT

Atenolol is used in blood pressure therapy and available as different brands in the market which makes it difficult to select the brand. The aim of this study is to establish pharmaceutical equivalence among the different brands of atenolol tablets available in Karachi, Pakistan. Four different brands of atenolol tablets (100 mg) were included in the study. Quality control analysis using parameters: weight variation test, thickness, hardness test, friability and disintegration test were carried out specified USP and BP (United state and British Pharmacopoeia). Hardness value requirement was complied by all brands. Disintegration time for all brands was within 15 minutes complying the USP/BP recommendation. All brands showed more than 90 % drug release within 45 minutes. The present analysis suggest that all the brands of atenolol that are available meet the BP/USP specification for quality control analysis.

Key Words: Atenolol, comparison, formulations.

INTRODUCTION

Atenolol is a Beta blocker that falls into two categories one of which is non selective beta receptor antagonist that is able to block both B1 and B2 receptors and the other is selective beta blocker also termed as cardio selective beta blocker which produces effects by blocking B1 receptor and Atenolol is the latter [1]. Atenolol is a beta blocker cardiovascular drug that helps to control hypertension (high blood pressure) and chest pain (angina), myocardial infarction and migraine also [2]. It does not cure high blood pressure for good rather helps in managing it if taken properly without skipping doses. Atenolol lowers the blood pressure by its beta adrenergic blocking effect which does not let adrenergic drugs such as epinephrine or adrenaline to produce their effect on the nerves of sympathetic nervous system whose stimulation leads to the increased heart beat. Atenolol by being a beta adrenergic blocking agent, lowers the cardiac output and abnormal cardiac rhythms. Reducing the force of contraction of heart muscle reduces the blood pressure and all of which ultimately minimizes the oxygen need of the body that is required to relief angina pain [3]. Elimination of atenolol takes place in the unchanged form via urine [4]. Patients with impaired renal function require dose reduction whereas the usual dose of atenolol does not interfere the patients with liver diseases. Atenolol is also elucidated as Benzeneacetamide, 4-[2-hydroxy-3-[(1-methylethyl) amino]propoxy]-2-[p-[2-Hydroxy-3-(isopropylamino)propoxy]-phenyl]acetamide [5].



We have done these types of study on different drugs which is very useful for selection of drug for pharmacist and doctors [6-8]. This study is important because dispensing of right drugs is important tool for pharmacy [9].

METHADODOLOGY

4 brands of Atenolol 100 mg tablets have been evaluated using some quality control parameters, such as weight variation, thickness, friability test, hardness test, disintegration and dissolution test with the aim to assess the comparative studies with the brand leader of ateneol.

- Weight Variation Test - The weight variation test has been performed on each brand of Atenolol by taking 20

tablets and weighed individually on AND Electronic Balance FX-400, taking their average and comparing the weight of each tablet with the average weight calculated.

- Thickness test - Vernier Calliper has been used to determine tablet thickness, performed on 20 tablets of each brand of Atenolol. Tablet thickness is of great importance for the tablet packaging.
- Friability test - Friability test has been performed on 10 tablets of each brand of Atenolol by subjecting to a uniform tumbling motion for specified period of time in on FB - 1004 Curio Company and the weight loss is determined. Friability test is done to check if a tablet abrades during transportation by taking initial and final weight and determining the weight loss.
- Hardness test - Hardness test has been performed on 10 tablets of each brand of Atenolol on MH-1, hardness tester of Galvano Scientific by diametrically crushing the tablets and applying the compression force that fractured it.
- Disintegration Test - Disintegration test has been performed on 6 tablets of each brand of Atenolol on Curro model no DS-0702 to measure the time taken by the tablets to disintegrate when placed in a liquid medium and body temperature i.e., 37 C and under the specified experimental conditions.
- Dissolution Test - The amount of active ingredient released from the oral dosage form (tablets) was determined by dissolution test on model no. GDT-7L of Galvano Scientific using medium with known volume. Dissolution test helps to determine the bioavailability of a drug.

RESULTS AND DISCUSSION

The physicochemical parameters of available brands of atenolol were analyzed and specification given in table 1. The results of thickness are given in table 4. Hardness result are given in table 5 and 6 and friability is given in table 7. Disintegration Test shows following results for TEN, BLOK, ATEN and CARDIO and they disintegrate in 12, 7,6 and 14 minutes respectively shown in Table 8.

DISCUSSION

The aim of this study is to evaluate and compare the quality of commercially available brands of atenolol (TEN, BLOK, ATEN and CARDIO) in Karachi, Pakistan. For comparatively study, physicochemical parameter such as weight variation test,

thickness, hardness test, friability and disintegration test were performed. Disintegration and Uniformity of weight are compendial standards to analyse the quality of tablets. The weight variation values of (TEN, BLOK, ATEN and CARDIO) are given in Table 2,3. According to USP the requirements of weight variation hardness and thickness are met when out of 20 tablets of each brand the weight, hardness and thickness of drugs not more than 2 tablets differs from the average weight, hardness and thickness. Disintegration Test shows following results for (TEN, BLOK, ATEN and CARDIO) and they disintegrate in 12, 7,6 and 14 minutes respectively shown in Table 8.

Table 1: General Table

No.	NAME OF PRODUCT	S.NO	CODE NO.	BATCH NO.
1	TENORMIN	TEN	4396	572
2	BLOKIUUM 100	BLOK	8835	131530
3	ATENOLOL	ATEN	9727	149
4	CARDIOLYTE	CARDIO	12169	F142

Table 2: Statistical Weight Variation Table

S.NO	CODE NO.	BATCH NO.	AV.WT	SD	UCL	LCL
TEN	4396	572	283	212	319	247
BLOK	8835	131530	331	2	337	325
ATEN	9727	149	283	12	319	247
CARDIO	12169	F142	409	5.6	426	392

Table 3: Official Limits And Results For Weight Variation Test

No.	S.No.	CODE No.	Batch No.	Results in (gm)	BP/USP Specs	Deviation From BP/USP
1	TEN	4396	572	0.283	7.50%	All Passed
2	BLOK	8835	131530	0.331	7.50%	All Passed
3	ATEN	9727	149	0.283	7.50%	All Passed
4	CARDIO	12169	F142	0.409	7.50%	All Passed

Table 4: Statistical Thickness Variation Table

S.NO	CODE NO.	BATCH	AV.THIC KNESS	SD	UCL	LCL
TEN	4396	572	5	0.06	5.18	4.82
BLOK	8835	131530	5	2	5.6	4.4
ATEN	9727	149	4.4	0.2	5	3.8
CARDIO	12169	F142	4	0.03	4.09	3.91

Table 5: Statistical Hardness Variation Table

S.NO	CODE NO.	BATCH	HARDNESS	SD	UCL	LCL
TEN	4396	572	7.8	0.6	9.6	6
BLOK	8835	131530	5	0.7	7	3
ATEN	9727	149	3	0.8	5.4	0.6
CARDIO	12169	F142	5.6	0.6	7.4	3.8

Table 6: Calculation for Hardness Test

	Tb.1	Tb.2	Tb.3	Tb.4	Tb.5	Tb.6	Tb.7	Tb.8	Tb.9	Tb.10
TENORMIN										
Hardness (kg)	8	7.5	7.3	9	8	6.8	8	7.4	8.4	7.9
Mean	7.8	7.8	7.8	7.8	7.8	7.8	7.8	7.8	7.8	7.8
SD	0.6	0.6	0.6	0.6	0.6	0.6	0.6	0.6	0.6	0.6
UCL	9.6	9.6	9.6	9.6	9.6	9.6	9.6	9.6	9.6	9.6
LCL	6	6	6	6	6	6	6	6	6	6
BLOKIUUM 100										
Hardness (kg)	6	4.4	5.9	5.7	4.9	4.4	4.9	4.1	4.9	4.5
Mean	5	5	5	5	5	5	5	5	5	5
SD	0.7	0.7	0.7	0.7	0.7	0.7	0.7	0.7	0.7	0.7
UCL	7	7	7	7	7	7	7	7	7	7
LCL	3	3	3	3	3	3	3	3	3	3
ATENOLOL										
Hardness (kg)	2.7	1.9	2.3	3.1	4	4.4	3.3	3.7	2.7	2.9
Mean	3	3	3	3	3	3	3	3	3	3
SD	0.8	0.8	0.8	0.8	0.8	0.8	0.8	0.8	0.8	0.8
UCL	5.4	5.4	5.4	5.4	5.4	5.4	5.4	5.4	5.4	5.4
LCL	0.6	0.6	0.6	0.6	0.6	0.6	0.6	0.6	0.6	0.6
CARDIOLYTE										
Hardness (kg)	4.5	6	6.4	6	5.1	5.9	5.9	5.2	5.6	5
Mean	5.6	5.6	5.6	5.6	5.6	5.6	5.6	5.6	5.6	5.6
SD	0.6	0.6	0.6	0.6	0.6	0.6	0.6	0.6	0.6	0.6
UCL	7.4	7.4	7.4	7.4	7.4	7.4	7.4	7.4	7.4	7.4
LCL	3.8	3.8	3.8	3.8	3.8	3.8	3.8	3.8	3.8	3.8

Table 7: Friability of all Brands

No.	S.NO	CODE NO.	BATCH NO.	FRIABILITY	LIMITS	COMMENTS
1	TEN	4396	572	0%	Less than 1%	Within Limits
2	BLOK	8835	131530	0%	Less than 1%	Within Limits
3	ATEN	9727	149	0%	Less than 1%	Within Limits
4	CARDIO	12169	F142	0%	Less than 1%	Within Limits

Table 8: Disintegration Time for All Brands

No.	S.NO	DISINTEGRATION TIME	LIMITS	COMMENTS
1	TEN	12 min	Not More than 30 Min	Within Limits
2	BLOK	7 min	Not More than 15 Min	Within Limits
3	ATEN	6 min	Not More than 15 Min	Within Limits
4	CARDIO	14 min	Not More than 15 Min	Within Limits

CONCLUSION

It is concluded that the results of all the tests (weight variation test, thickness, hardness test, friability and disintegration test) of selected brands of atenolol (100 mg) exhibits some difference but these variations are in specified limits.

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