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RESEARCH ARTICLE

QUALITY CONTROL TESTS OF DIFFERENT AVAILABLE BRANDS OF LEVOFLOXACIN AND OFLOXACIN IN THE MARKET OF QUETTA CITY

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ABSTRACT

Levofloxacin is a third generation fluoroquinolones antibiotic with a broad spectrum activity against different kinds of bacteria. It is very widely used antibiotic, Levofloxacin has activity that is to counter the production the bacteria by damaging the DNA gyrase enzyme responsible for the replication of the bacteria to avoid further multiplication of bacteria. Ofloxacin is widely used broad spectrum fluoroquinolones antibiotic used against variety of bacterial infections caused by gram negative and gram positive bacteria. Ofloxacin is an intermediate between ciprofloxacin and norfloxacin in activity against gram negative bacteria but it is comparable to or more potent than Ciprofloxacin for gram positive bacteria and certain anaerobes. Quality control is a system in which we make sure that the products are formulated and Quality control checked according the given standards. It will help in avoiding the risks involved in a Pharmaceutical industry that cannot be countered by simple testing of the product. Different brands of Ofloxacin and levofloxacin were collected from the market of Quetta Pakistan. Checked physiochemical properties of all collected brands of Levofloxacin and Ofloxacin and compared with each other according to the standard protocols. The physiochemical tests were performed weight variation, Hardness, Friability, Thickness, Disintegration and Dissolutions. The results showed that the all brands were within acceptable range including the dissolution of the both formulations tested. It is concluded that these type of research may be conducted in future to check the Quality control tests of available brands of different formulations. These types of research will contribute the community for the best selection of the medicine from the market and also help the prescriber to select a best drug among the available formulations.

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INTRODUCTION

Levofloxacin is a third generation fluoroquinolones antibiotic with a broad spectrum activity against different kinds of bacteria. It is very widely used antibiotic, Levofloxacin has activity that is to counter the production the bacteria by damaging the DNA gyrase enzyme responsible for the replication of the bacteria to avoid further multiplication of bacteria 1. Levofloxacin can be used in infection of sinuses, skin lungs, ears, bones and joints caused by susceptible bacteria. It also can counter infections of prostate, it helps in treating diarrhea caused by Ecoli 2. Levofloxacin has shown very good activity against penicillin resistant streptococcus pneumonia and also effective against mycobacterium tuberculosis.

It is very effective against many infections with clinical efficacy of 80 to 90 percent 3.Levofloxacin is active against most aerobic gram positive and gram negative bacteria and have moderate activity against anaerobes. Penetration of levofloxacin in body tissues and fluids is more rapid and wide spread when given orally. Levofloxacin has lesser resistance in just 5 days of therapy. Various studies for chronic bacterial prostatitis have shown that mean duration of the drug administration is 40 days 4. Clinical cure is at 8 weeks which is 88.9 percent. Bacteriological eradication rate is 79 percent. Levofloxacin well suited for the treatment of skin structure infections of diabetics caused by susceptible organisms. The degree of penetration of an antibiotic into the infected site is very essential determinant of therapeutic success. Levofloxacin is used in the treatment of serious bone and synovial tissue infections as the concentration of levofloxacin is achieved in cancellous and cortical bone tissue and synovial tissue is are

greater than the breakpoint for susceptible organisms 5. Levofloxacin targets the DNA gyrase it inhibits the DNA gyrase an enzyme required for the replication of the bacterial DNA its transcription, repair and recombination of the bacteria. It has wide range of in vitro activity many aerobic gram negative bacteria though some strains may show moderate susceptibility or resistance. Levofloxacin is common with other fluoroquinolones that have moderate activity against anaerobes 6. Levofloxacin is mostly used orally most of the studies have suggested dose of 100mg thrice a day for 5 to 10 days for the treatment of different kinds of infections. It is well tolerated with these 7. Ofloxacin is widely used broad spectrum fluoroquinolones antibiotic used against variety of bacterial infections caused by gram negative and gram positive bacteria. Ofloxacin is an intermediate between ciprofloxacin and norfloxacin in activity against gram negative bacteria but it is comparable to or more potent than ciprofloxacin for gram positive bacteria and certain anaerobes 8.It is certainly suitable in chronic bronchitis and other respiratory and ENT infections. Bioavailability in the tablets is around 98 percent with maximum concentration after two or three hours after oral administration. Ofloxacin can be given in variety of infections such as urinary tract infections, respiratory tract infections, sexually transmitted diseases and infections by salmonella. Bioavailability of Ofloxacin is approximately 98 percent with half-life of 9 hours. After many clinical trials it is proved that the efficacy of Ofloxacin in the treatment of lower respiratory tract infections and urinary tract infections 9.

Like other fluoroquinolones Ofloxacin inhibits the enzyme called DNA Gyrase I and topoisomerase that nicks the double stranded DNA, introduces negative super coils and then reseals the nicked ends. Ofloxacin binds to a subunit with high affinity and restricts its strand cutting and resealing function. Ofloxacin is bactericidal antibiotic by inhibiting or blocking the DNA gyrase enzyme which is responsible for untwisting required for multiplication of one DNA into double helix 10.Quality control is a system in which we make sure that the products are produced and controlled according the given standards. It will help in avoiding the risks involved in a pharmaceutical industry that cannot be countered by simple testing of the product. Good manufacturing practice is a set of principles and methods which should be followed by the manufacturer to produce quality drugs 11.It can be achieved only by having clear descriptions of the way in which the drugs should be manufactured. Good manufacturing specifically avoids the risk of cross contamination and mix up that which cannot be countered by testing of the final product. The risk of cross contamination and mix up can be controlled by having a proper management of working that takes them into account. The quality assurance system must be designed with these risks while manufacturing the drugs. Good manufacturing practice is that process in which we make sure that the products are consistently manufactured and controlled to the quality standards appropriate to their use. It is a set of principles and procedure followed by the manufacturer to make sure that the product is up to the mark. The basic aim of GMP is that quality cannot be tested into batch of product but it must be built into each batch of the product during all stages of the manufacturing process 12. Good manufacturing practice is to avoid some risks such as contamination of the products causing damage to the health of patient, to avoid incorrect labeling on the containers which means that patients are receiving wrong medicine. In some cases insufficient or too much active ingredients which could result ineffective treatment or adverse reaction. Good manufacturing important because a poor quality medicine may contain toxic substances that have been unintentionally added 13.

METHODOLOGY

Table No 1. Brands of Ofloxacin selected for this study

S.No	Brands	Manufacturer Name
1	Flovix	Bryon Pharma Pvt Ltd Peshawar
2	Xarvid	Axis Pharma Pvt Ltd Faisalabad
3	Quinox	Brookes Pharma Pvt Ltd Karachi
4	A vid	Allaince Pharma Pvt Ltd Peshawar
5	Ofloquin	Global Pharma Pvt Ltd Islamabad

Table No 2. Brands of Levofloxacin

S.No	Brands	Manufacturer Name
1	Levoflo	Mafins Pharma Pvt Ltd Karachi
2	Alovic	Allaince Pharma Pvt Ltd Peshawar
3	Lcord	Axis Pharma Pvt Ltd Faisalabad
4	Felix	Adamjee Pharma Pvt Ltd Karachi
5	Genlevo	Brookes Pharma Pvt Ltd Karachi

Glassware used: Beaker, Pipettes, Measuring cylinder, Funnels.

Equipments: Vernier calipers, Hardness tester Pharma Test, Friabilator FR 2000, Electric Balance Digital Balance, PH Meter Shimadzu, Disintegrator Pharma Test, Dissolution Apparatus Pharma test, Germany, UV spectrophotometer Shimadzu.

Collection of samples: Samples of different brands five different brands of each levofloxacin500mg and Ofloxacin 100mg were collected from local Quetta city on the basis of mostly prescribed.

Physical Evaluation of Levofloxacin: Tablets of the selected five brands of levofloxacin were evaluated for various physical tests which include weight variation, hardness, thickness, disintegration and dissolution.

Weight variation: Weight variations of all the different brands were done by using electrical balance. Twenty tablets were tested individually tested to check the deviation from the given protocol. If weight of the tablets is more than the acceptable value then patient may suffer from over medication. If the weight is of active medicaments is less than the acceptable range then patient may be under medication. The tablets of five different brands of levofloxacin and Ofloxacin were weighed and the results were tabulated 14.

Hardness Test: Hardness was measured by using hardness tester. Hardness of tablets is checked to measure the strength of tablets towards breakage. In hardness tester tablets are crushed to measure the strength of tablets. The method of shipment is determined by checking hardness of those tablets. Tablets of five different brands of levofloxacin and Ofloxacin placed one by one in the hardness tester to measure hardness of the selected tablets 14.

Friability Test: Friction and shock are the forces that most often cause the tablets to chop or break. The friability test is closely related to tablet hardness and is designed to evaluate the

ability of the tablet to withstand abrasion in packaging, handling and shipping. Tablets get chip chop or break is due to the friction and shock are the forces mostly causes during friability. The value is stated as a percentage. A maximum weight loss of not more than 1% of the weight of the tablets being tested during the friability test is considered generally acceptable and any broken or cracked tablets are not picked up 14.

Thickness: Thickness was measured by using Vernier calipers. All the selected tablets of the five different brands of levofloxacin and Ofloxacin were measured one by one by Vernier calipers and the results were noted 14.

Disintegration Test: The disintegration test is done to find out the time it takes for a solid oral dosage form like a tablet or capsule to completely disintegrate. The time of the disintegration is the measurement of the quality of the tablet. Disintegration time was measured by disintegration tester. The tablets of the selected five brands of levofloxacin and Ofloxacin were tested in the disintegration tester to measure the disintegration time of the tablets 14.

Dissolution Test: Dissolution was test was carried out by dissolution apparatus by using dissolution media according to USP and BP. The dissolution rate of all the different brands of both Ofloxacin and levofloxacin tablets were determined by using the dissolution test apparatus USP. Dissolution test for each brand was set up separately using 900ml of 0.1NHCL as a medium and the temperature was kept at 37 ± 0.5ºC. The speed was kept at 100 revolution per minute. The samples were collected at different time intervals i.e. 5, 10, 15, 20, 25, 30, 35, 40, and 45minutes and check on the absorbance were set for Ofloxacin at 294 nm and for Levofloxacin at 292 nm. All the selected tablets of five different brands of levofloxacin and Ofloxacin were placed in the dissolution apparatus to check the dissolution time 15.

RESULTS

Table No 3. Weight variation of different brands of levofloxacin gms

S No	Levoflo gm	Alovic gm	Lcord gm	Felix gm	Genlevo gm
1	4.0	3.8	3.9	4.2	4.0
2	4.2	3.9	3.9	4.1	4.1
3	4.2	4.0	3.8	4.1	4.2
4	4.1	4.1	3.9	3.8	4.2
5	4.1	3.9	4.1	3.8	4.1
6	4.2	3.8	4.0	3.9	3.9
7	3.9	3.8	3.9	4.1	4.0
8	4.2	4.1	4.2	3.9	4.2
9	3.9	3.8	4.1	4.0	4.1
10	4.0	3.9	4.0	4.2	4.2
11	4.1	4.2	3.9	3.9	4.0
12	4.2	4.2	3.8	3.9	4.1
13	4.1	4.1	3.9	3.8	4.2
14	4.1	3.8	4.0	4.2	3.9
15	3.9	3.9	3.9	4.2	4.0
16	3.9	3.8	4.0	3.8	4.1
17	4.2	4.0	4.0	3.8	4.2
18	4.1	3.9	4.1	3.8	4.2
19	4.2	3.8	3.9	3.8	3.9
20	4.1	3.9	4.0	3.9	4.0

All the brands of Levofloxacin were checked their weight variation found slight different but all those brands were within acceptable range according to the specification.

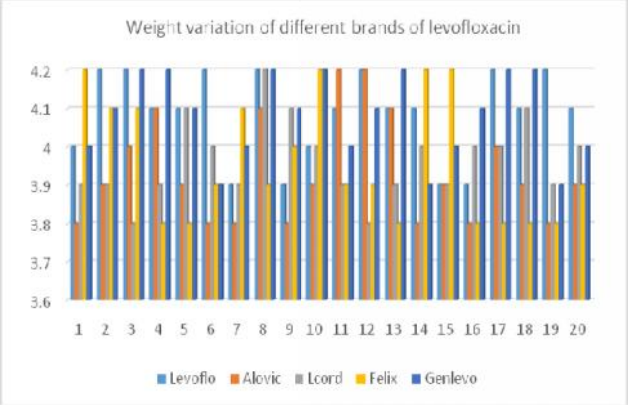

Figure No 1. Weight variation of different brands of levofloxacin

Table No 4. Hardness of five different Brands of Levofloxacin 500mg

S. NO	Levoflo Kp	Alovic Kp	Lcord Kp	Felix Kp	Genlevo Kp
1	14.8	11.6	10.0	12.1	10.5
2	14.0	12.2	11.2	12.0	10.5
3	14.9	10.9	10.4	13.0	11.0
4	15.0	11.6	11.3	11.4	9.4
5	15.0	12.0	10.3	11.4	9.9
6	14.0	13.0	11.7	11.9	10.2
7	14.8	10.2	10.9	12.6	11.1
8	15.3	11.0	11.2	12.0	10.3
9	14.8	10.9	10.7	11.8	11.5
10	14.9	10.8	10.0	11.9	9.8

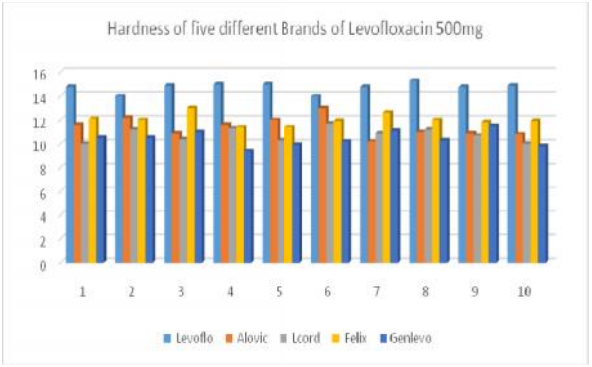

Figure No 2. Hardness of five different Brands of Levofloxacin 500mg

Discussion of hardness of five different brands of levofloxacin: The hardness of five different brands of levofloxacin was tested accordingly and the results showed minimum hardness of Levoflo was 14 KP and maximum hardness of Levoflo measured on the hardness tester was 15.3 KP. Hardness of Alovic was measured accordingly and minimum hardness noted on the hardness tester was 10.2 KP and maximum hardness of Alovic was 13.0 KP. Lcord of was measured accordingly on hardness tester which was measured as 10.0 and maximum hardness was measured as 11.7 KP. Felix was measured on hardness tester minimum hardness measured was noted as 11.4 KP and maximum hardness noted was 13.0. Genlevo measured on hardness tester minimum hardness measured was 9.4 KP and maximum hardness was 11.5 KP.

Table No 5. Thickness of levofloxacin

S.NO	Levoflo mm	Alovic mm	Lcord mm	Felix mm	Genlevo mm
1	6.03	5.88	6.23	5.90	6.11
2	6.16	5.89	6.12	5.78	6.09
3	6.17	5.85	6.01	5.93	6.12
4	6.05	5.90	6.05	5.88	6.11
5	6.13	5.93	6.03	5.94	6.15
6	6.12	5.92	6.10	5.89	6.05
7	6.12	5.96	6.20	5.88	6.12
8	6.10	5.78	6.03	5.97	6.10
9	6.21	5.79	6.11	5.98	6.03
10	6.21	5.95	6.03	5.87	6.11

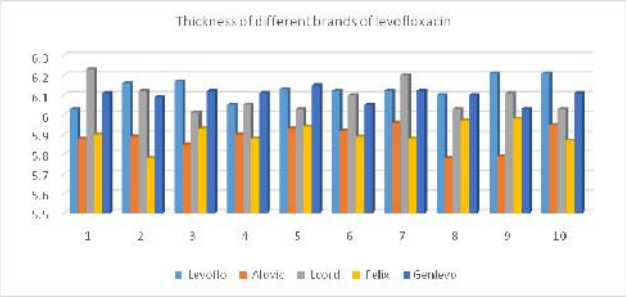

Figure No 3. Thickness of different brands of levofloxacin

Table No 6. Friability test of ten tablets of five different brands of Levofloxacin 500mg

Weight (gm)	Levoflo	Alovic	Lcord	Felix	Genlevo
Weight before friability	4.0	3.9	3.8	3.9	4.0
Weight after friability	3.9	3.8	3.7	3.8	3.9
Variance	0.1	0.1	0.1	0.1	0.1
%age	1%	1%	1%	1%	1%

Table No 7.Disintegration of five different brands of Levofloxacin

Product	Time/Minutes
Levoflo	5.8
Alovic	5.9
Lcord	5.3
Felix	5.0
Genlevo	5.2

Table No 8.Dissolution test of five different Brands of levofloxacin 500mg

S. No	Brands name	Dissolution %age
01	Levoflo	98.2 %
02	Alovic	99.0 %
03	Lcord	97.0 %
04	Felix	98.1 %
05	Genlevo	98.0 %

Discussion of Thickness Test of different brands of Levofloxacin 500mg: All the brands were performed thickness according to the official procedure and it is concluded that minor difference found with each other but it was found that all the different brands were within the limits as per specified standards.

Discussion of Friability Test: Friability of Levoflo brand was tested result was 1 %. Friability of Alovic brand was tested result was 1 %, Friability of Lcord brand was tested the result was 1%, Friability of Felix brand was tested result was 1 % and the Friability of Genlevo was tested and the result was 1 %. It is concluded that all the brands of Levofloxacin were tested friability and found within the acceptable range according to the specified standards.

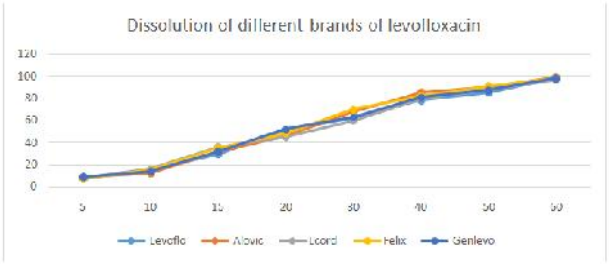

Figure No 4. Dissolution of different brands of levofloxacin

Discussion of Disintegration of different brands of Levofloxacin 500mg: Disintegration time of Levoflo brand of levofloxacin was 5.8 minutes, Disintegration time of Alovic was 5.9 minute, Disintegration time of Lcord was noted 5.3 minutes, Felix was disintegrated in 5.0 minutes and Genlevo was disintegrated in 5.2 minutes. It is concluded that all the brands of Levofloxacin were tested Disintegration test accordingly and found within the acceptable range according to the specified standards i.e. less than 15 minutes.

Table No 9. Hardness of five Different Brands of Ofloxacin

S. NO	Flovix	Xarvid	Quinox	A vid	Ofloquin
1	11.8	10.2	6.2	8.9	7.5
2	11.2	8.9	6.0	8.0	7.0
3	12.0	9.9	6.5	9.2	8.2
4	10.8	9.5	6.8	9.5	8.5
5	11.5	8.9	7.2	9.0	8.4
6	11.0	8.7	6.7	8.7	8.7
7	10.9	10.6	6.9	9.6	8.0
8	10.2	8.0	6.2	9.0	7.9
9	11.6	10.3	7.1	8.9	7.2
10	12.1	8.8	6.0	10.0	9.0

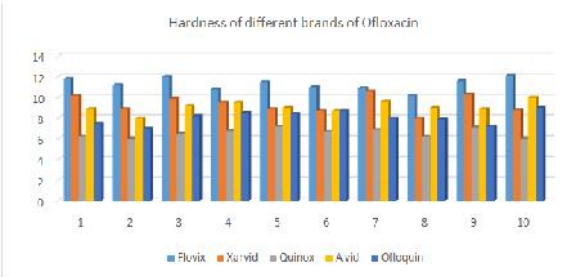

Figure No 5. Hardness of different brands of Ofloxacin

Discussion for Dissolution Test different brands of levofloxacin: Dissolution test of Levoflo was 98.2 %. Dissolution test of Alovic was 99.0 %. Lcord was tested and the result was 97.0 %, Felix was tested and the result was 98.1 %, Genlevo dissolution test was 98.0 %, all the five brands of Levofloxacin have passed the dissolution test. It is concluded that all the brands of Levofloxacin were tested Dissolution according and found within the acceptable range according to the specified standards.

Table No 10. Thickness of different brands of Ofloxacin

S. NO	Flovix (gm)	Xarvid (gm)	Quinox (gm)	A vid (gm)	Ofloquin (gm)
1	6.12	6.00	6.21	6.01	5.88
2	6.02	6.01	6.22	6.03	5.85
3	6.03	5.96	6.21	6.05	5.89
4	6.15	5.92	6.23	6.02	5.90
5	6.11	5.98	6.25	6.12	5.85
6	6.15	5.98	6.22	6.06	5.87
7	6.12	5.85	6.25	6.09	5.98
8	6.16	5.88	6.29	6.05	5.90
9	6.19	5.92	6.20	6.11	5.98
10	6.10	5.96	6.23	6.02	5.86

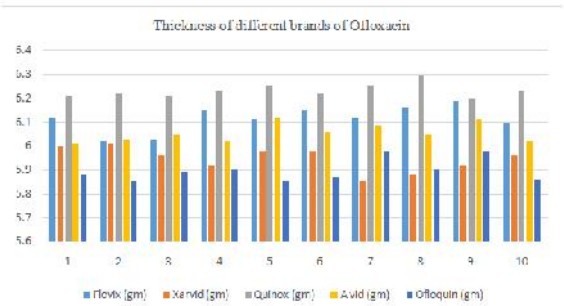

Figure No 6. Thickness of different brands of Ofloxacin

Table No 11. Weight variation of different brands of Ofloxacin

S. NO	Flovix (gm)	Xarvid (gm)	Quinox (gm)	A vid (gm)	Ofloquin (gm)
1	4.6	4.5	4.4	4.8	4.3
2	4.7	4.5	4.3	4.8	4.5
3	4.4	4.5	4.3	4.7	4.8
4	4.3	4.5	4.5	4.8	4.8
5	4.4	4.8	4.3	4.6	4.2
6	4.7	4.5	4.6	4.6	4.2
7	4.5	4.5	4.3	4.7	4.6
8	4.6	4.7	4.3	4.8	4.3
9	4.8	4.7	4.4	4.5	4.3
10	4.6	4.6	4.4	4.8	4.3
11	4.4	4.5	4.3	4.8	4.2
12	4.5	4.6	4.4	4.7	4.3
13	4.5	4.5	4.6	4.7	4.2
14	4.6	4.6	4.7	4.8	4.3
15	4.7	4.5	4.4	4.5	4.2
16	4.5	4.6	4.4	4.8	4.7
17	4.6	4.5	4.5	4.8	4.3
18	4.4	4.6	4.3	4.7	4.2
19	4.5	4.5	4.4	4.7	4.3
20	4.6	4.5	4.3	4.8	4.3

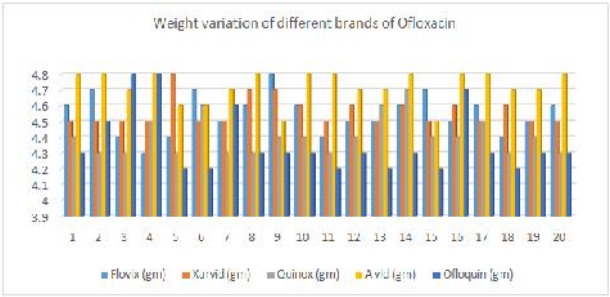

Figure No 7. Weight variation of different brands of Ofloxacin

Table No 12.Friability test of tablets of five different Brands of Ofloxacin

Weight	Flovix (%)	Xarvid (%)	Quinox (%)	A vid (%)	Ofloquin (%)
Weight before friability	4.7	4.5	4.3	4.8	4.5
Weight after friability	4.5	4.3	4.1	4.7	4.4
Variance	0.2	0.2	0.2	0.1	0.1
%age	2%	2%	2%	1%	1%

Physiochemical results of different brands of Ofloxacin

Discussion of Hardness of different brands of Ofloxacin

The hardness of five different brands of Ofloxacin was tested accordingly and the results showed the hardness of Flovix ranged from10.2 to 12.1 KP, Xarvid ranged from 8.0 to 10.3 KP, Quinox ranged from 6.0 to 7.2 KP, Avid ranged from 8.0 to 10.0 KP and Ofloquin ranged from 7.0 to 9.0 KP. All the brands were slight different with each other but within acceptable range.

Table No 13. Disintegration of five different brands of Ofloxacin

Product	Time/Minutes
Flovix	6.5
Xarvid	6.3
Quinox	6.0
Avid	5.9
Ofloquin	5.5

Table No 14. Dissolution test of five different Brands of Ofloxacin

S. No	Brands Name	Dissolution %age
01	Flovix	96.20 %
02	Xarvid	95.70 %
03	Quinox	97.90 %
04	Avid	98.1 %
05	Ofloquin	96.52 %

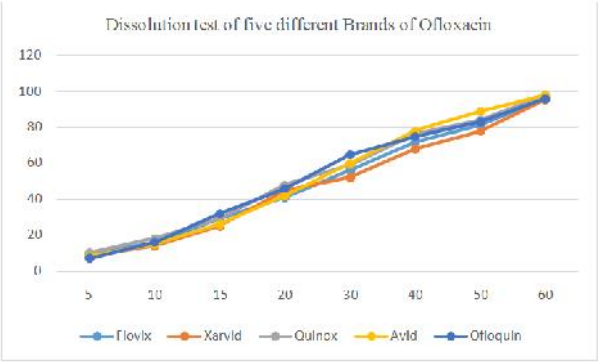

Figure No 7. Dissolution test of five different Brands of Ofloxacin

Discussion of Friability Test: Friability of Flovix was tested result was 2 %, Xarvid was 2 %, Quinox was 2%, Avid was 1 % and friability of Ofloquin was 1 %, all of the above brands were tested, results were in acceptable limit which indicates that that all the above manufacturers are following the standards.

Discussion of Disintegration: Disintegration time of Flovix was 6.5 minutes. Disintegration time of Xarvid was 6.3 minutes. Disintegration time of Quinox was noted 6.0 minutes. Avid was disintegrated in 5.9 minutes and Ofloquin was disintegrated in 5.5 minutes.

Discussion of dissolution of Ofloxacin: Dissolution of all the brands of Ofloxacin were checked with the help of dissolution apparatus Pharma test, Germany. Dissolution test of Flovix was 96.2 %, Xavid was 95.70 %, Quinox was 97.90 %, Avid was 98.1 % and Ofloquin was 96.52 %. All five brands of Ofloxacin were acceptable range. It is concluded that all the brands of Ofloxacin were tested Dissolution accordingly and found within the acceptable range according to the specified standards.

CONCLUSION

Two different antibiotics were selected for this research work Levofloxacin and Ofloxacin. Five different brands of each formulation were collected from the market of Quetta, Pakistan on the basis of prescription.

The results showed after compilation that all the brands of levofloxacin and Ofloxacin tested their Physiochemical properties and compared with each were within the specified limits, which indicates that the manufacturers are fallowing the standards accordingly. It is concluded that these types of research may be conducted in future to check the Quality control tests of available brands of different formulations. These types of research will contribute the community for the best selection of the medicine from the market and also help the prescriber to select a best drug among the available formulations.

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