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QUALITY CONTROL ANALYSIS AND ASSESSMENT OF DIFFERENT MARKET BRANDS OF CIPROFLOXACIN

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Abstract:

Dose structures are basically pharmaceutical items in the structure in which they are showcased for use, normally including a blend of dynamic medication parts and nondrug segments (excipients), alongside other non-reusable material that may not be considered either fixing or bundling, (for example, a container shell, for instance). The term unit measurements can now and then envelop non-reusable bundling too (particularly when every medication item is exclusively packaged. Different measurements structures might exist for a solitary specific medication, since various medicinal conditions can warrant distinctive courses of organization. For instance, steady queasiness and heaving might make it hard to utilize an oral dose structure, and in such a case, it might be important to use a backup course of action, for example, inhalational, buccal, sublingual, nasal, suppository or parenteral. The primary objective was in vitro comparative study of 5 different brands of Ciprofloxacin Tablets available in markets of Pakistan by The in vitro comparative study of 5 different brands of Ciprofloxacin Tablets available in markets of Pakistan

Weight variation Test, Disintegration Test, Hardness Test, Chemical Assay and In vitro dissolution study was conducted. After conducting color, friability, weight variation, hardness test and disintegration tests of various brands of Ciprofloxacin, the results were found under the acceptance range. The hardness showed variation among the tablets of various brands but there was no significant variation of hardness among the tablets of same brand. The Axcin indicated maximum drug potency (102%) and (101%) respectively while minimum potency was 93.07%. The in-vitro evaluation of 5 different F.P.Ps of Ciprofloxacin HCl film coated tablets available in the pharmaceutical market of Pakistan showed that all of brands of Ciprofloxacin satisfied the USP potency specifications and showed evidences of satisfactory initial in-vitro dissolution behavior.

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INTRODUCTION:

The generic drugs are made available to health care system in many developing countries [1] That's to improve the healthcare drug availability and delivery in developing countries but in addition to benefits it also accompanied by a lot of issues among which substandard drugs distribution in crucial one [2]. The drugs monitoring includes all procedures performed in obtaining relatively more and more data regarding product after it has got authorization for marketing and made publicly available for use and these that gotten from different procedures can be used for making standards [3], regulations and for improvement in product [2]. As the regulatory authorities depends upon limited information that are obtained from trials (clinical) and from other literatures for allowing and it is very important to monitor the medicines (approved) for its therapeutic effectiveness and Quality of medicines that are used by large population [4]. The medication significance in increasing patient satisfaction and lowering mortality may not be overemphasized like as low-quality medicines are relatively unsafe and also increase in treatment cost due to the medication having low quality [5]. Therefore, testing the drugs in laboratory in routine basis is important to save health of public especially in countries that are developing. World Health organization has already issued guidelines for requirements, quality control and registration of generic drugs [6]. The innovator drug's efficacy, safety and quality standards must also be satisfied by generic drugs [2]. Poor practices of quality control and concerned regulatory authorities has allowed presence of low Quality medicines in market [7]. It may have many causes as decomposition of main ingredient from drug due to storage conditions like humidity and temperature and also poor quality assurance during drug manufacturing [8].

The objective of present study was analysis of Quality control and to assess different brands of Ciprofloxacin that are available in market.

MATERIAL AND METHODS:

Five different brands of ciprofloxacin HCl (Axcin, Mytil, Nafcin, Oxirase And Quash) film coated tablets in which one brand is innovator (Axcin) and other four brands are generics, each of 500 mg available in Pakistani pharmaceutical market were evaluated.

UV-Visible Spectrophotometer (Model No. 1601, Schimadzu, Japan), Mosanto tablet hardness tester (Mosanto UK), Erweka disintegrating chamber, Orion Research analogue pH meter model 301, Siliconizad glass test tubes, Digital analytical balance (Model No. Ax-200. Schimadzu Japan.), Volumetric flasks, Conical flasks, glass funnels, test tubes (Pyer glass, scott), Sterile (pyrogen free disposable syringes(Otsuka), Pharma Test Dissolution Apparatus, PTWS – 11/P, TPT (Germany), Stability Chamber, Oven Memert Model U-30, 854 Schwabach (Germany).

Weight variation and disintegration test

Twenty tablets of each brand were weighed individually and calculated the average weight of tablet. Maximum and minimum values for weight were noted. USP limits for weight variation test were applied to evaluate the data.

USP specifications were applied for disintegration test with a constant frequency (speed) rate 32 c.p.m (speed limit is 29-32 c.p.m as per USP specification) at temperature of 37 C°. (Temperature limit is 35 C° -39 C°as per USP specifications). As the disintegration test was carried out for the film-coated tablets so it was performed in

two steps using following two different Medias.

1. Water: The tablets were first immersed in water for five minutes prior to disintegration to dissolve the film coat of the tablets.

2. 0.1 N HCl: After dissolving the coat of the tablet, it was placed in the disintegration apparatus using 0.1 N HCl as disintegration medium. Six tablets of each brand of Ciprofloxacin and were taken and the mean disintegration time (in minutes) was calculated. If the test was failed for these first six tablets then the test was performed for other twelve tablets of each brand of Ciprofloxacin in two rounds, six tablets in each round. USP tolerance was applied to evaluate the results obtained.

Hardness Test/Crushing Strength:
Twenty tablets of each brand were selected randomly and subjected to hardness test. The range of crushing strength was noted. The instrument showed the force of breaking in Newton, which were converted in Kg/cm2. After that the results obtained were evaluated using USP tolerance limits.

Chemical Assay of Ciprofloxacin Tablets:
The assay for the active ingredients in the Ciprofloxacin HCl film coated tablets was performed using UV-Visible spectrophotometer. The chemical assays were repeated three times and results are presented as the mean of three determinations.

Standard Preparation: Weight of the Ciprofloxacin HCl equivalent to 100 mg of Ciprofloxacin base were calculated as follow,

$$= \frac{\text{Molecular Weight of Ciprofloxacin Monohydric chloride Monohydrate}}{\text{Molecular weight of Ciprofloxacin base}} \times 100$$

So, 116.4 mg of Ciprofloxacin HCl equivalent to 100 mg of Ciprofloxacin base were calculated and were used during standard solution preparation for assay of the tablets.

The calculations were made on the basis of weight of Ciprofloxacin HCl equivalent to Ciprofloxacin base.

Powder of standard Ciprofloxacin HCl equivalent to 100 mg of Ciprofloxacin base were weighed accurately with the help of electronic balance. This amount of powder of respected drugs was transferred to 100 ml of volumetric flask in which small amount of 0.1 N HCl was added to dissolve Ciprofloxacin HCl powder. It was sonicated well for 20 minutes to get clear solution. The volume was made upto 100 ml with 0.1 N HCl in the volumetric flask and was mixed.

Sample Preparation: Twenty tablets of Ciprofloxacin 500mg were taken and crushed into powder form. Then these powders were sieved through 100 mesh and weighed accurately with the help of digital electronic balance .Average weight for a single tablet was determined by dividing the total weight of sieved powder by total number of tablets.

Weight for a single tablet equivalent to 100mg of active Ciprofloxacin was calculated as follows.

$$\text{Equivalent weight of tablet of Ciprofloxacin} = \frac{\text{Average weight of single tablet}}{\text{Total weight of active ingredient in tablet}} \times 100$$

Now powder equivalent to 100 mg of active (Ciprofloxacin as base) were weighed and taken in 100ml volumetric flask and then a small quantity of 0.1 N HCl solution was added to dissolve the given quantity of powder. After that the volume was made up to mark by adding 0.1 N HCl solution. The solution was stirred for 20 minutes to dissolve and mixed it completely. This

solution was filtered in conical flask. One ml of filtrate was taken in a 100 ml volumetric flask.
Analysis: Absorbance of sample solution and standard solution were measured at λmax.276nm on UV-Visible Spectrophotometer using 0.1 N HCl as blank.

***In vitro* dissolution study:**
Dissolution of tablets of Ciprofloxacin were carried in the following two Medias.

1. Distilled Water

2. 0.1 N HCl Solution
0.1 N HCl was also used as a dissolution medium for dissolution tests to determine the influence of tropical climate storage conditions on the quality of tablets which is a major part of my current project.

Calibration curve for Ciprofloxacin HCl in Distilled water: forty mg of standard grade Ciprofloxacin HCl powder were accurately weighed with the help of digital electronic balance and after weighing transferred to 100 ml volumetric flasks. It was dissolved in small quantity of distilled water and then sonicated for 20 minutes to get a stock clear solution .This solution was diluted with addition of distilled water in sufficient quantity to make the volume up to the mark. So aqueous solution of Ciprofloxacin having 0.4 mg/ml concentration was prepared which was used as stock solution .Different volumes of stock solution were taken in 100 ml flask and each volume this solution was diluted by making the volume up to 100 ml with corresponding dissolution medium (Distilled water) to get solutions of Ciprofloxacin HCl of 0.008, 0.01, 0.012, 0.014, 0.016, 0.018 and 0.02 mg/ml. These solutions were analyzed with UV-Visible Spectrophotometer at λ_{max} 276nm while using distilled water as blank solution. Three readings were noticed for each dilution and mean of these three readings was calculated for the respective concentration. A calibration curve was constructed by plotting absorbance versus concentrations which gave an equation of y= 87.597×-0.0079 with coefficient of variation (R^2) of 0.9999 (n=7).

Calibration curve for Ciprofloxacin HCl in 0.1 N HCl: Calibration curve for Ciprofloxacin HCl was also constructed in 0.1 N HCl solutions by following the same procedure
As described above for calibration curve of Ciprofloxacin HCl in Distilled Water except 0.1N HCl was used as solvent in this case. The equation obtained was y= 122.49 ×+0.0004 with a coefficient of variation (R^2) 0.9997 in this case. Unknown concentrations of Ciprofloxacin HCl were determined using regression equation.
Y=MC+B

Where Y= absorbance of solution containing Ciprofloxacin HCl at λ_{max} 276nm.
M= Slope of Ciprofloxacin HCl Standard curve of Known concentrations.
C= concentration to Calculate
B= Intercept of curve
After rearranging the above equation we got:
C= (Y-B)/M

Dissolution tests for Ciprofloxacin HCl were performed using the USP paddle method (Apparatus II) at speed of 50rpm. The volume of dissolution medium in each vessel was 900 ml, maintained at a temperature of 37.0 ±0.5 C°. Aliquots (5ml) of the dissolution medium were withdrawn at interval of 5,15,30,45 and 60 minutes. The samples were withdrawn manually using a 5ml syringe from each vessel of the dissolution apparatus. After each sampling equal volume of dissolution medium was added to each vessel as replacement solution. The dissolution samples were diluted with the dissolution medium (1:50) so as to get absorbance in the linear range of the Lambert-Beer Law and were analyzed by UV-Visible spectrophotometer at λ_{max} 276nm. After calculating the results for dissolution profiles of the finished pharmaceutical products of Ciprofloxacin in both of the dissolution media (D/W and 0.1 N HCl) these were also compared with each other.

Statistical Calculation: The profiles of formulations that met these requirements were further evaluated using Weilbur function

models, a Model Independent Approach using a Similarity Factor (f_2) as recommended by the FDA for the comparison of the dissolution profiles of immediate release dosage forms .[87] In this study ,the dissolution profile of the test formulation obtained was compared with the dissolution characteristics of the reference formulation *(innovator brand Axcin) obtained. As the dissolution studies were performed in two different media hence the f2 was calculated for the tablet dissolution profiles in both media. The f2 values thus obtained from dissolution in D/W was compared with obtained from the tablet dissolution in 0.1 N HCl to determine the similarity of their dissolution behavior in the corresponding medium .The similarity factor was computed using the equation by Moore and Flanner recommended by the FDA(51).

$$f2 = 50\log\left\{\left(1+\frac{1}{n}\sum_{t=1}^{n}(R_t - T_t)^2\right)^{-0,5}\times 100\right\}$$

Where R_t and T_t are the percentages of drug dissolved at time t (for t=1, 2, …..n), of the reference and test formulation respectively. The measurements at each time point were weighed according to its importance in the dissolution curve using wt as an optional weight factor. As all time points were equal so wt was assigned value 1. The profiles of F.P.Ps were considered similar/pharmaceutically equivalent showing less than 10% average difference at any sample time point, corresponding to a similarity factor (f2) greater or equal to 50.

RESULTS AND DISCUSSION:

Table 1. Shows the results of quality control tests of all the selected brands of finished pharmaceutical products Ciprofloxacin. After conducting colour, friability, weight variation, hardness test and disintegration tests of various brands of Ciprofloxacin, the results were found under the acceptance range. The hardness showed variation among the tablets of various brands but there was no significant variation of hardness among the tablets of same brand. The maximum hardness was observed for MYTIL While NAFCIN Showed minimum hardness among all the formulations of Ciprofloxacin. The disintegration time test showed appreciable differences for different brands of Ciprofloxacin. No co-relation was observed between hardness and disintegration time of the formulations. The divergence in the hardness, weight and disintegration time test values may due to differences in the manufacturing procedure or in the quantity and quality of the materials used in the formulations.

Table: 1- Quality control tests of Five F.P.Ps of Ciprofloxacin

Room temperature							
F.P.P	**Time**	**Colour**	**Hardness**	**Friability**	**Weight variation**	**Disintegration**	**assay**
AXCIN	0 month	White	8.4	0.1	740.98	10	102.320%
	3 month	White	8.4	0.1	740.70	10	101.200
	6 month	White	8.3	0.1	739.70	10	100.127
MYTIL	0 month	White	5.4	0.4	803.10	12	100.789
	3 month	White	5.2	0.4	802.92	12	100.140
	6 month	White	5.1	0.4	802.95	13	99.124
NAFCIN	0 month	White	10.17	0.31	780.75	18	97.281
	3 month	White	10.2	0.39	779.95	18	96.200
	6 month	White	10.4	0.38	779.40	19	96.142
OXIRASE	0 month	White	7.9	0.53	723.16	11	99.035
	3 month	White	7.4	0.54	722.75	11	98.765
	6 month	White	7.3	0.55	721.62	12	97.576
QUASH	0 month	White	6.53	0.42	777.52	25	96.930
	3 month	White	6.43	0.40	780.08	25	96.132
	6 month	White	6.21	0.43	775.65	25	95.768
Accelerated Temperature							
FPP	**TIME**	**Color**	**Hardness**	**Friability**	**Weight variation**	**disintegration**	**Assay**
AXCIN	0 month	White	8.37	0.1	740.70	10	101.920%
	3 month	White	8.23	0.1	740.40	10	101.143
	6 month	White	8.20	0.1	740.34	10	100.045
MYTIL	0 month	White	5.36	0.38	801.65	12	99.978
	3 month	White	4.95	0.37	801.80	12	99.041
	6 month	White	4.90	0.36	801.25	13	98.980
NAFCIN	0 month	White	10.1	0.3	775.54	19	97.045
	3 month	White	10.3	0.29	774.87	20	96.013
	6 month	White	10.27	0.27	774.25	25	95.897
OXIRASE	0 month	White	7.6	0.57	721.65	11	98.934
	3 month	White	7.2	0.58	720.54	12	98.254
	6 month	White	7.19	0.52	720.20	12	97.890
QUASH	0 month	White	6.6	0.39	772.65	25	96.340
	3 month	White	6.36	0.42	773.54	26	96.043
	6 month	White	6.25	0.42	773.20	26	95.740

Table: 2

Table 2 describes the results of the drug potency of different brands of Ciprofloxacin. All the selected brands met USP 24 requirements in spite of the appreciable differences among the % drug potency of various formulations. The Axcin indicated maximum drug potency (102%) and (101%) respectively while minimum potency was 93.07% which was shown by OXIRASE.The differences among the results showing the the drug potency may be due to the following reasons.

(a) Manufacturing process variations.
(b) Use of various quality and quantity of formulation materials and
(c) Use of poor quality of raw materials

Table 2: Chemical Assay of Ciprofloxacin tablets

FPP	Absorbance (Mean)		
	Sample	Standard	%Q
Axcin	1.178	1.17	102.320
MYTIL	1.105	1.17	96.134
NAFCIN	1.116	1.17	97.865
OXIRASE	1.061	1.17	93.07
QUASH	1.129	1.17	99.03

Table 3 And Fig 1 to 3 show the results of the calibration curves of Ciprofloxacin HCl in D/W and in 0.1 N HCl. A prominent difference in the dissolution and solubility of Ciprofloxacin in D/W and 0.1 N HCl is obvious from the comparison of both the calibration curves, obtained from analysis of the similar concentrations of Ciprofloxacin HCl in D/W and in 0.1 N HCl solvents under similar conditions. Greater absorbance was observed for the concentration of Ciprofloxacin in 0.1 N HCl (solvent) as compared to the absorbance of the same concentration in D/W at same λmax (276nm).this confirms that dissolution and solubility of Ciprofloxacin in 0.1 N HCl (at pH 1.2) is greater than D/W. This difference was also demonstrated by the dissolution profiles of selected brands of Ciprofloxacin HCl in both the dissolution media (D/W and 0.1 N HCl

Table 3: Conc. Vs peak areas of Ciprofloxacin in D/W and 0.1N HCl

Sr.#	Stock Soln(ml)	Dilutions mg/ml	Absorbance in D/W	Absorbance In 0.1N HCl
1	2.0	0.008	0.686	0.980
2	2.5	0.010	0.863	1.218
3	3	0.012	1.040	1.470
4	3.5	0.014	1.217	1.708
5	4	0.016	1.394	1.991
6	4.5	0.018	1.572	2.208
7	5	0.020	1.749	2.432

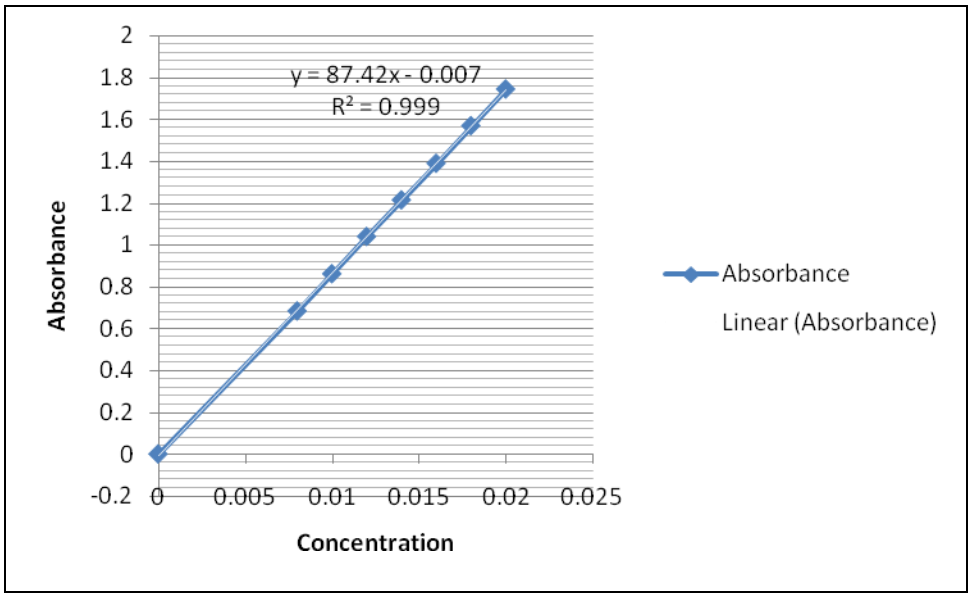

Fig.1: Calibration curve of Ciprofloxacin HCl in D/W

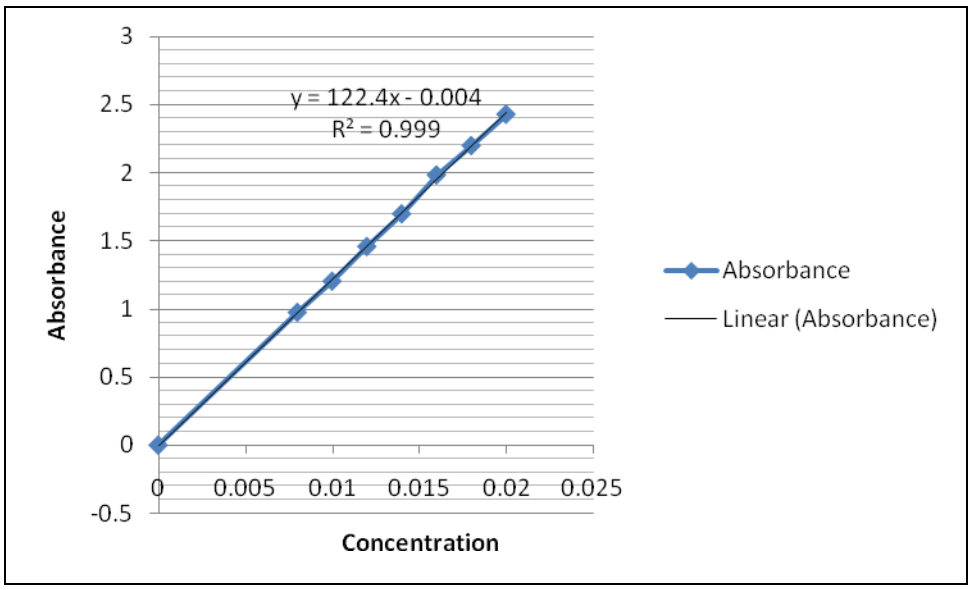

Fig.2: Calibration curve of Ciprofloxacin HCl in 0.1N HCl

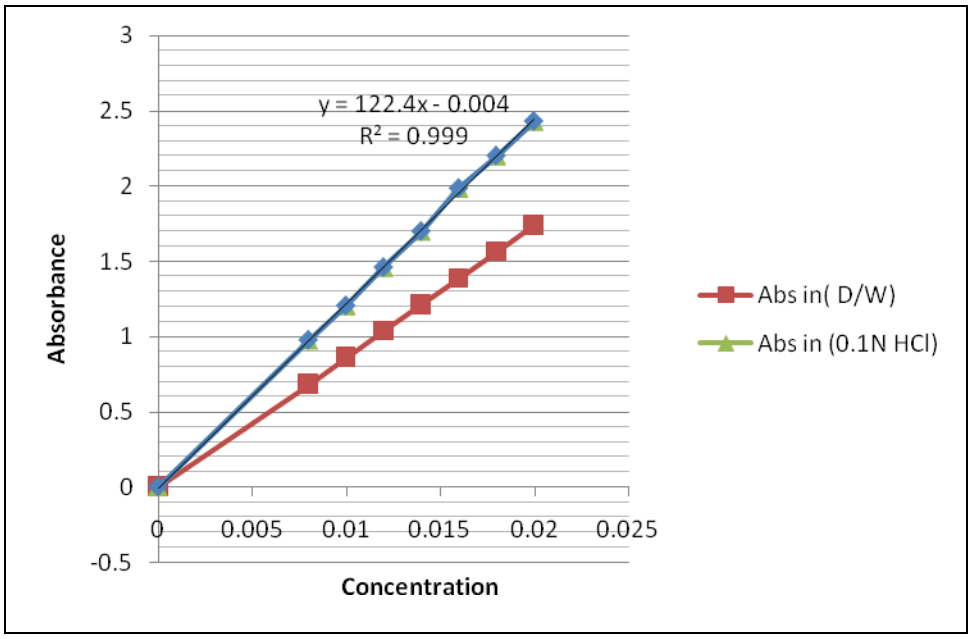

Fig.3: Comparison b/w calibration curves of Ciprofloxacin HCl in D/W and 0.1 N HCl.

The table 4 shows the results of the comparative dissolution of individual brands of Ciprofloxacin in D/W and 0.1 N HCl. All the formulations dissolution profiles were found within the USP 24 recommended range, in both the dissolution media with discernible variations among their profiles. Dissimilarity among the different formulations dissolution profiles within the same dissolution media were found. Two of the Five (40% sampled) brands of Ciprofloxacin (Axcin, Mytil,) and one out of the Five (20% sampled) brands showed very rapidly dissolving immediate release profile by exhibiting >85% drug release within first 15 minutes in 0.1 N HCl while this was accomplished by one of Five (20%) brands of Ciprofloxacin (Axcin) in D/W. All other formulations of v showed comparatively weak dissolution profile.

Table 4: Dissolution Data of Axcin at room temperature

DW			
	0 month	3 month	6 month
5 min	71.3719	71.3809	71.7645
15 min	79.8957	80.9431	81.0321
30 min	95.1005	95.2410	95.8965
45 min	95.2053	95.8954	95.9785
60 min	95.0717	95.9732	96.0132
0.1 HCl			
	0 month	3 month	6 month
5 min	80.8935	80.9785	81.0216
15 min	88.9758	89.0214	89.1340
30 min	97.4255	97.6532	97.7543
45 min	97.9643	97.9865	98.0021
60 min	97.6049	98.0145	98.1325

The disintegration profiles acquired from all brands after capacity at mimicked tropical conditions were found inside of the USP prescribed reach for in-vitro drug discharge .Moreover all the F.P.Ps showed a checked lessening with abnormal state of varieties among their in-vitro drug discharge profiles amid capacity at recreated tropical conditions. Which clarify the estimations of f2 for the disintegration information of individual brands furthermore indicate examination among the closeness component (f2) of chose definitions at 3 months and 6 months at reenacted tropical capacity conditions. The f2 values computed for Mytil, Nafacin and OXIRASE were 67.2, 65.3, 62.95 individually following 3 and 6 months stockpiling showing noticeable similitude in their disintegration profiles with the standard medication.Therefore disintegration qualities of these plans were considered pharmaceutically proportionate medication discharge profiles of standard medication (87).

After capacity at reproduced tropical conditions for 6 months under both conditions, all plans demonstrated similitude (f2 >50) in the disintegration profile with that of the standard medication Axcin. The base contrast in the profile were watched for Oxrase (f2=36.61) individually. In addition, the varieties in the profile were an excess of higher after capacity at 40 °C ±2° RH:75%±5% when contrasted with that of the outcomes after capacity at 25 °C ±2°C/RH :60% ±5% for 6 months. It unmistakably clarifies the more conspicuous impact of expansion temperature and relative stickiness amount in nature upon the soundness of the Ciprofloxacin (88).

As it has been seen by Pecol et al. in 1999(89) that the nature of medications turns out to be less sure especially for poor populaces why should charmed lower evaluated drugs in an unregulated situation .For this situation, it is imperative that the medication administrative power ought to take the fundamental measure to guarantee that the medications accessible in the pharma business sector are persistently of good quality. The substance examine results on the substance of the API outlined this point of confinement was inside of the procurement prescribed by the USP for all F.P.Ps. The discoveries are like those delivered Abdi et al. in 1995 (90) on the nature of chloroquine tablets accessible on the pharma business sector of Tanzania, where all inspected F.P.Ps from 10 distinct makers were found inside of the scope of USP particulars of the concoction examine test. However a report was presented by Kibwage et al. in 1992 (91) delineated that roughly 45% of all the F.P.Ps inspected from the pharmaceutical business sector of Kenyan and dissected at the quality control lab of Daru were found of substandard quality as far as the substance of the API. Additionally another study was led by Shakoor et al. in 1997 (92) pointed on the vicinity of both fake and substandard medications on the pharma markets of Thai and Nigerai where 32 % of 89 tests did not go along the USP details of synthetic examine. These varieties in results can't be explained, taking into account the continuance of a fruitful medication control and observing framework. As it has been seen in numerous reports concerning the nature of medications in the creating nations. (93)

A few studies have been portrayed in the writing audit on the soundness of the pharmaceutical measurement shapes under honest to goodness stockpiling environment in the tropics (94, 95, 96). Every one of these reports have pointed on the substance strength of the medication. It is perceived that under states of hot moist temperature, the API might encounter polymorphic or precious stone changes, which reduce its characteristic solvency. In addition, there is probability of collaborations between excipient-excipient or excipient-drug connections to happen affected by hot sticky temperature, which understudy diminish the disintegration rate of a pharmaceutical dose shapes containing a synthetically stable medication (96). In the present study sensational changes in the disintegration conduct of a few definitions have been watched. The medication definition that fizzled the soundness test had a more than 40% decrease in the measure of medication discharged following 3 and 6 months of security testing. It was unrealistic to distinguish the reason for the disappointment in disintegration of the plans, as the careful arrangement of the details was not accessible. It is realized that the unexpected communications among the elements of the measurement structure

occurring for a medication plan put away at high temperature and stickiness conditions are mind boggling and definition subordinate. (97)

The F.P.Ps might have for instance disintegrants, which can detached its ability to swell on maturing or on revelation to high mugginess/temperature (98). For the details that did not go along the USP determinations of the disintegration test, no firm choice might be tackled its bioavailability profile. (97)

Since numerous reports have portrayed on the instances of trial details with an essentially decreased in-vitro drug discharge attributes after maturing, however offering comparable bioavailability profiles to new definitions .Such cases have been watched for matured Nitrofurantoin cases (99). Conversely different studies directed with the outcomes that Nitrofurantioin tablet definitions upon introduction to stretch conditions offered a noteworthy reduction in-vitro drug discharge profiles furthermore an impressive decrease in their rate of retention (100). The inability to follow the USP disintegration details might be considered as a notice of an imminent bioavailability issue.

The disintegration tests were skillful to separate low quality F.P.Ps amongst the examples that had surrendered the concoction test tests. Albeit all the F.P.Ps showed compound corruption after maturing yet a percentage of the details displayed maturing reduction in their disintegration conduct when contrasted with pioneer/standard references brand (Axcin).This impact was high up at high temperature and abnormal state of stickiness proportion (40 °C±2°/RH; 75%±5%) while at states of 25 °C±2°/RH;60%±5% it was moderately less lively. At first 62.5%(3/5) of the chose brands indicated disintegration profile like the standard detailing i.e f2 esteem ≥50 or near 50 however upon introduction to reenacted tropical capacity conditions, this proportion was drastically decreased to 12.5%. This as well as one of the brands fizzled the disintegration test subsequent to being subjected to a dependability test at reproduced tropical conditions which affirms that increment in temperature and stickiness improve the rate of synthetic response (102). As identified with the administrative perspectives ,the WHO encourage a quickened soundness test under zone IV climatic conditions to be executed for all pharmaceutical measurements frames made arrangements for bringing into the worldwide pharmaceutical market(Matthews)(101) A steadiness test is proposed as a quality control apparatus that might be utilized to affirm if a dose structure/definition and the assembling process don't impact the adequacy and wellbeing of the item under the appropriation and capacity conditions .The breakdown of a few details to guarantee disintegration's standard particulars subsequent to being subjected to a dependability test at mimicked tropical capacity conditions guess that the medication plans are confused for promoting in nations with tropical atmosphere conditions, for example, Pakistan. Standard examining and observation of the quality and security in tropical states of the details on business sector by the administrative power ought to be idealistic as method for keeping the passageway to the business sector of pharma with

CONCLUSION:

During the collection of the samples, it was appeared that there are huge disparity between the price of innovator brand and their generic equivalents. It is very important to take essential measures aimed at to control and monitor the quality of the medicines, available in the phrma market. The in-vitro evaluation of 5 different F.P.Ps of Ciprofloxacin HCl film coated tablets available in the pharmaceutical market of Pakistan showed that all of brands of Ciprofloxacin satisfied the USP potency specifications and showed evidences of satisfactory initial in-vitro dissolution behavior. However, the dissolution characteristics after storage at simulated tropical conditions for 6 months, 2 of these F.P.Ps were not acceptable. The evaluation of the bioavailability of these formulations is optional to expound the effect of poor dissolution on its bioavailability

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