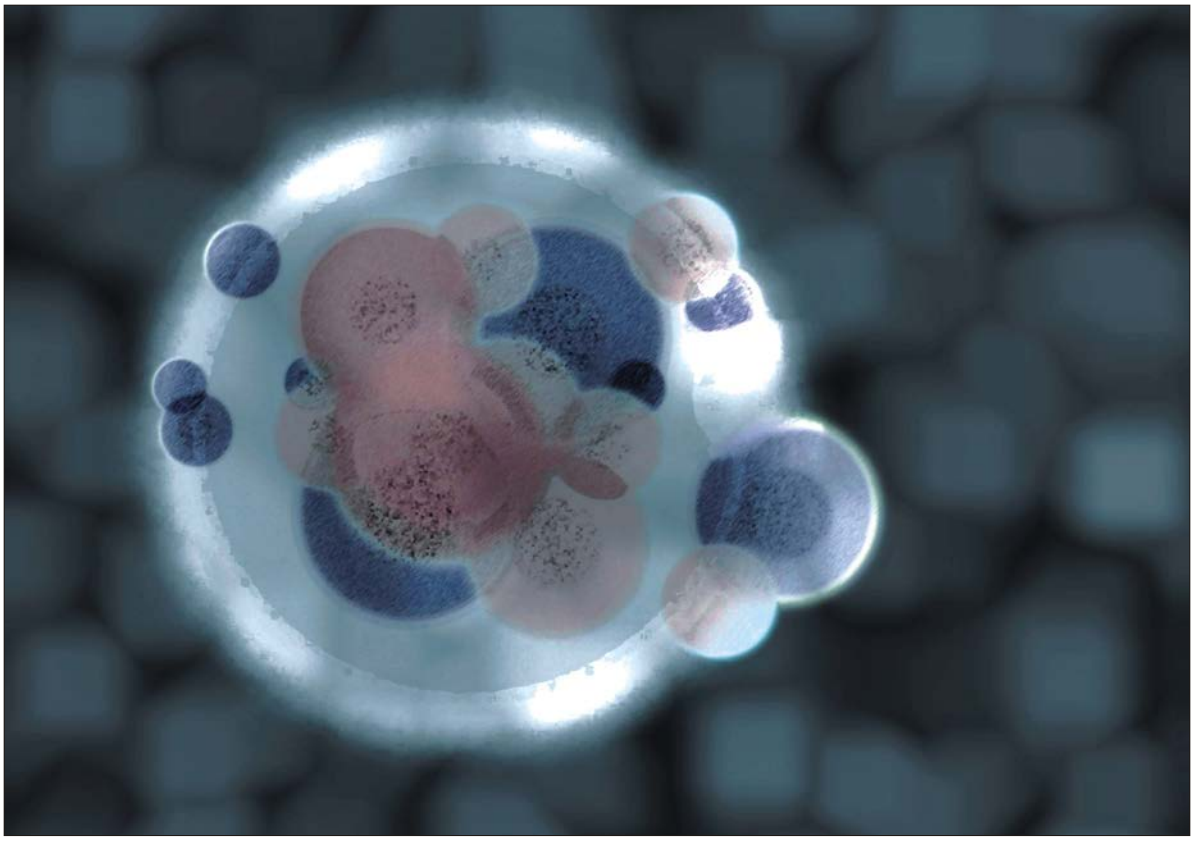

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Quality Assurance of Fluoroquinolones in Commercial Pharmaceutical Formulations

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Abstract: Fluoroquinolones are broad spectrum synthetic antibiotics and are used for the treatment of many types of systematic infections. The drugs given to the patient would not show the required result, if the appropriate amount is not available to the body. A total of forty nine commercial pharmaceutical formulations including Ciprofloxacin, Norfloxacin, Ofloxacin and Pefloxacin were analyzed by UV and colorimetric methods for their active ingredient. The results shows that 5 sample contained the higher amount as claimed, 3 samples contained the same amount while all remaining samples contained the lower amount as claimed by the manufacturers. The amount of fluroquinolone differ in the range of +12 to -11%. However, these amounts lie in the therapeutic window and will not affect their therapeutic action. The results obtained by the colorimetric method were comparable with the result of the UV spectrophotometric method.

Key words: Fluoroquinolones, Quality assurance

Introduction

Fluoroquinolones are synthetic broad spectrum 4-quinolone derivatives with bactericidal activity against a wide range of gram negative and gram positive organism. The antibacterial action of fluoroquinolones is due to their ability to inhibit bactericidal enzyme DNA gyrase. Which is required for DNA replication and transcription (Shen and Pernet, 1985). The enzyme binds to two segments of DNA creating a node of positive (+) superhelix. The enzyme then introduces a double stand break in the DNA and passes the front segment through the break. The break is then resealed creating a negative (-) supercoil. Quinolones inhibit both the nicking and closing activity of the gyrase (Hooper and Wolfson, 1988).

Fluoroquinolones are less toxic than other quinolone with better activity and effectiveness against obligate intra cellar pathogens.

Fluoroquinolones are used in oral and injectable dosage forms in a wide variety of infections. These have proven an effective treatment for many types of system infections as well as for both acute and chronic infections of urinary tract (Campoli-Richards *et al*., 1988). The effect of overdose and under-dose are manifold. Inadequate concentration resulting from low dose leads to bacterial resistance (Paton and Reeves, 1991). Overdoses has different adverse effects like drozziness, headache, abdominal discomfort and allergic reactions like rashes and pruritus. (Schacht sp. *et al*., 1988; Nix *et al*., 1992).

Due to improper packing and storage of drug, decomposition by environmental factors and malpractice in drug manufacturing, the claimed amount is usually not present in the marketed drug. Present project was designed to assess the quality in commercially available fluoroquinolone formulations by spectrophotometric methods.

Materials and Methods

The commercially available pharmaceutical preparations of fluoroquinolines were procured from local medicine market of Faisalabad being sold under different trade names in the form of tablets. A total of forty nine samples of fluoroquinolones including (Ciprofloxacin 21, 7 Norfloxacin, 15 Ofloxacin and 6% Pefloxacin) were analyzed by UV and colorimetric method. In UV method standard solutions of pure fluoroquinolones and formulation were prepared. The amount of fluoroquinolones was determined at the wavelength of maximum absorbance (λmax = 276, 276, 285 and 255 nm, respectively) thus amount of fluoroquinolones so determined was compared with the amount described by manufacturers (Bauer *et al*., 1990). In colorimetric method standard fluoroqunolones solutions were prepared in 0.1 N HCl solution. To 5 ml of the standard solution added 1 ml freshly prepared solution of 1% ferric chloride and made volume upto 50 ml. Similarly samples solutions were made. Blank solution was prepared by adding 1 ml of ferric chloride in 50 ml 0.1 N HCl solution and measured the absorbance of both standard and sample preparations at λmax = 438 by using spectronic UV 2001 Hitachi Japan) (Chowdary and Prasad, 1994).

Results and Discussion

The analysis of 49 pharmaceutical preparations containing fluoroquinolones by UV method revealed that five samples contained higher concentration, three samples contained the same while all remaining contained lower amount of fluoroquinolone than claimed. From 21 samples of ciprofloxacin, 3 samples contained higher as claimed, 2 sample contained same while 16 sample contained lower concentration than claimed as given in Table 1. From 7 samples of norfloxacin, all samples contained lower concentration of fluraqualine in claim (Table 2). From 15 sample of ofloxacin, only one sample contained higher concentration, one sample contained the same while 13 samples contained lower concentration of loxacin as claimed as given in Table 3. From 6 samples of pefloxacin 1 sample contained higher concentration while 5 samples contained lower concentration as claimed (Table 4).

Colorimetric analysis revealed that four samples contained more concentration of fluoroquinolone than claimed. Three samples contained the same concentration as the claimed while all remaining tablets contained lower amount of fluoroquinolone than claimed. From 21 sample of ciprofloxacin 2 samples contained higher amount of ciprofloxacin as claimed 2 samples contained same amount and 17 sample contained lower amount of ciprofloxacin as claimed as given (Table 1). From 7 samples of norfloxacin, all samples contained lower amount as claimed (Table 2). From 15 samples of ofloxacin one sample contained higher concentration as claimed. One sample contained same while 13 samples contained less

Table 1: Showing the Ciprofloxacin contents in various formulations estimated by UV and colorimetric methods

Commercial name	Observed by	
	UV (mg)	Colorimetry (mg)
Algocin	220	224
Alproxen	240	231
Ciplox	222	226
Ciprocide	253	249
Ciprocil	221	222
Ciprocin	234	226
Ciprok	230	223
Cipromen	228	238
Ciproquine*	496	499
Ciprox	222	229
Ciproxin	233	229
Hipro	222	227
Lucid*	500	484
Mytil	234	241
Neofloxin*	468	453
Novidate	273	258
Proflox	221	231
Roxin	234	224
Seprosaydin*	516	514
Suprox	235	239
Viloc	221	224

Labeled = 250 mg, *Labeled = 500 mg

Table 2: Showing the Norfloxin contents in various formulations estimated by UV and colorimetric methods

Commercial Name	Observed by	
	UV (mg)	Colorimetry (mg)
Floxin	383	382
Nolicin	391	388
Norfax	386	386
Noroxin	387	383
Uracin	397	394
Uritac	398	395
Utinor	379	376

Labeled = 400 mg

Table 3: Showing the ofloxacin contents in various formulations estimated by UV and colorimetric

Commercial	Observed by	
	UV (mg)	Colorimetry (mg)
Adiflox	196	195
Bactacin	189	186
Ciof	181	180
Cracin	224	219
Flovix	185	183
Floxy	193	188
Gyrasid	182	181
Loxat	198	196
Oflox	195	191
Ofloxbid	184	181
Oxil	200	200
Ofloxin	189	187
Quinox	196	190
Rutrix	193	188
Wiloxin	196	198

Labeled = 200 mg

Table 4: Showing the pefloxacin contents in various formulations estimated by UV and colorimetric methods

Commercial name	Observed by UV (mg)	Colorimetry (mg)
Abaktal	402	409
Eyphen	379	385
Peflacine	373	372
Peflox	387	384
Pelox	360	362
Pipro	372	367

Labeled = 400 mg

amount as claimed as given in Table 3. From 6 samples of pefloxacin only one sample contained higher amount as claimed while 5 samples contained less amount of pefloxacin as claimed by manufacturer as given in Table 4. A comparison of UV and colorimetric method of analysis revealed a difference of less than 5% indicating that both the methods are equally useful for the analysis of fluoroquinolones in tablet formulations. The amount of fluoroquinolones differ from labeled in the range of +12 to -11% (Table 1-4). However, these amounts lie in the therapeutic window and will not affect their therapeutic action.

When lower dose of fluoroquinolone is given to the patients, the Minimum Inhibitory Concentration (MIC) required to kill bacteria can not be achieved, so the required therapeutic level is not obtained (Paton and Reeves, 1991).

Higher dose of fluoroquinolone may caused digestive disorder, gastric pain, nausea, dizziness and vomiting (Lauwers *et al*., 1986).

From the present study it is concluded that there should be a drug quality assessment system as an integral part of a national drug control system to prevent the production, export, import and distribution of ineffective, harmful or poor quality drugs. Such a system must be based on appropriate legislation and be supervised by a suitably qualified and properly empowered authority, supported by inspection and laboratory services.

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