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Research Article

QUALITY CONTROL ANALYSIS AND ASSESSMENT OF DIFFERENT MARKET TABLET BRANDS OF FLURBIPROFEN

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Abstract:

Good manufacturing practice explain the procedures as well as quality control methods for better and satisfactory result, key methods to ensure the quality control of drugs has been followed during all research to maintain the required standard .Flurbiprofen is rapidly and almost completely absorbed following oral administration and used as analgesic and anti-inflammatory drug. The half-life of the Flurbiprofen is 0.5 - 4 hours after oral administration. Seven different brands of Flurbiprofen were selected to perform their Quality test. In this study, safest and most suitable brand among other available brands in Pakistan were selected. Several methods for quality control were done such as thickness, hardness, weight variation, disintegration, dissolution were performed according to the specifications. Drug release percentages of different brands were from 99.58, 98.52, 98.25, 100.0, 99.10, 99.12, and 99.85. The Quality control tests of all the different brands of Flurbiprofen which are tested are within the limits. All Physical tests and dissolution tests were done according to the specified specifications. All the test included hardness, thickness, weight variation, disintegration and dissolution were tested and the results were within acceptable range.

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Key Words: *Quality control, Flurbiprofen, Physical tests, Dissolution.*



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INTRODUCTION:

Good Manufacturing Practice often abbreviated as GMP and meant to safeguard the quality of the products by following a set of quality assurance guidelines [1, 2]. Quality assurance is a wide theory which contains all matters that exclusively or collectively effect on the quality of a Pharmaceutical product [3]. To managing the quality of raw ingredients, active materials and other related components, facilities connected during production, and its management, production and its examination processes. Quality control itself is concerned with the product sampling, its qualifications and its process of testing [4]. Quality controls also concern with organization, its documentation record and also release processes which confirms that the essential and related Ouality control tests are done [5]. Quality control itself is not only restricted to laboratory operations, it is involved in all the process where the quality of a product is directly concern [6]. The individuality of quality control is concern from the pharmaceutical production is considered as important fundamental to be the part of a satisfactory procedure of quality control [7]. Flurbiprofen is slightly yellow or a white powder of crystalline. It is freely soluble in mostly all polar solvents. The 244.26 is the molecular weight of the Flurbiprofen. It is a prostaglandin synthetic inhibitor. It is used to get rid of inflammation, swelling, stiffness and ache, caused by any infection or osteoarthritis and rheumatoid arthritis. Flurbiprofen is a part of NSAIDs class. It main function is to stop a substance which is responsible to cause pain in the body, cause fever in the body and inflammation in the body [8].

MATERIALS AND METHODS:

MATERIALS:

Drugs Used:

Flurbiprofen in powder form (Unitech Pharmaceuticals Pakistan)

Different seven national and multinational brands of Flurbiprofen tablets obtainable from the market of Quetta, Pakistan.

- 1. Froben (Abbott Labs Pakistan)
- 2. Synalgo (Platinum (pvt) Pakistan)
- 3. Ansaid (Park Davis Pharmaceuticals Pakistan)
- 4. Dulpro (Global Pharmaceutical Industries Pakistan)
- 5. Flurip (Unitech Pharmaceutical Pakistan)
- 6. Sanid (Stanley Pharma Industries Pakistan)
- 7. Inflamatix (Asian Continental Pharma industries Pakistan)

Equipment:

- 1. U.V Spectrophotometer
- 2. Stability Chamber
- 3. Analytical Balance

- 4. Dissolution apparatus
- 1. Pharma Test Disintegration Apparatus
- 2. Fribilator
- 3. Hardness Tester
- 4. Test Tubes, Beakers, Volumetric Flasks

Standard Curve:

To make standard curve, first of all phosphate buffer was prepared and after that stock solution was made. Five dilutions (different) were prepared from already prepared stock solution, after that the absorbance were noted from spectrophotometrically.

Spectrophotometric analysis:

These dilutions of Flurbiprofen were examined by the help of and use of UV-visible spectrophotometer, and then the absorbance values were noted at 247nm (λ_{max}) and drawn by using MS Excel format.

Physical Tests

Weight variation, Hardness

Six tablets of different brands were selected randomly of each brand, weighed and variations of weight were examined by the help of standard deviation.

Hardness of Tablets

Monsanto Hardness tester was used to check the hardness of different brands of Flurbiprofen in kg. Ten tablets of each brand were selected for hardness test.

Friability Test:

As per prescribed procedure ten tablets of each brand were selected randomly for physical test (friability). Friabilator was operated at 25 rounds per minutes for four minutes. % of Friability was calculated by using the formula.

Friability (%)=W1-W2W1×100 (1)

Where W1 is the initial weight and W2 is final weight after dusting

In Vitro Dissolution Studies of Flurbiprofen different Brands

In vitro studies regarding dissolution will be completed according to USP (Basket) method 1, used the dissolution apparatus (8-station) Pharma Test (Hunburg, Germany). Each and every station or flask was filled up to 900ml with (PH 7. 4) phosphate buffer 0.2M which was used as dissolution medium to examine the release pattern of the active ingredient from each kind of tablets at 100 rounds per minutes and the temperature was kept at $37\pm2~^{0}$ C. At determined different time intervals (10min, 15min, 30min, 45min, and 60 minutes). 05 ml of samples were taken out with the help of syringe and after each sample equivalent amount was added to make the medium up to the mark. Samples were examined by

spectrophotometrically at detected wave length of 247nm from the help of UV- Visible Spectrophotometer UV-1601 (Shimadzu, Japan). The UV absorbance values were combined in Flurbiprofen standard curve after that the percent drug release of the drug was calculated.

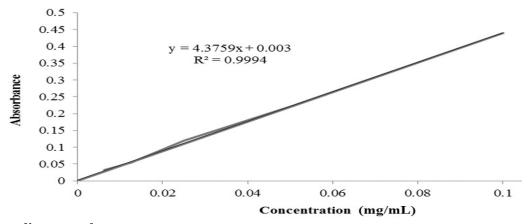
Result of analytical curve

The results indicated that there was linear relationship between concentration and absorbance and resulted R², value was 0.9994 and the resultant regression equation was y = 4.3759x + 0.003 as given in the Table 1 and Fig. 1.

RESULTS AND DISCUSSIONS:

Table 1: Results of flurbiprofen analytical curve.

Conc. (mg/mL)	Abs (1)	Abs (2)	Abs (3)	Mean abs
0.00626	0.01	0.03	0.032	0.022
0.025	0.05	0.04	0.05	0.064
0.05	0.10	0.10	0.131	0.120
0.05	0.20	0.30	0.21	0.230
0.1	0.40	0.40	0.440	0.450



Physical quality control tests:

Table No 2: Thickness, Diameter and Friability tests.

Brand Name	Thickness	Diameter	Friability
Froben	3.93 ± 0.05	14.23 ± 0.03	0.32 ± 0.05
Sgoynalgo	3.96± 0.04	13.98 ± 0.02	0.41 ± 0.05
Ansaid	4.11 ± 0.05	14.52 ± 0.05	0.43 ± 0.03
Dulpro	4.03 ± 0.06	14.23 ± 0.03	0.39 ± 0.04
Flurip	4.12 ± 0.07	14.56 ± 0.04	0.23 ± 0.05
Inflamatix	4.23 ± 0.03	15.01 ± 0.06	0.36 ± 0.02

Table 3: Hardness, Weight variation and Disintegration tests.

Brand name	Hardness	Weight variation	Disintegration
Froben	9 ± 0.06	432.4 ± 0.081	12 ± 0.87
Synalgo	11 ± 0.04	389.2 ± 0.058	11 ± 0.23
Ansaid	10 ± 0.05	387.6 ± 0.041	14 ± 0.32
Dulpro	11 ± 0.08	397.2 ± 0.052	13 ± 0.51
Flurip	9 ± 0.03	407.3 ± 0.022	12 ± 0.62
Inflamatix	12 ± 0.04	30745 ± 0.031	11 ± 0.78

Table 4: Drug %age Release

S.No	Brand name	Manufacturer	%age release
01	Sanid	Stanley Pharma Pakistan	99.58
02	Flurip	Unitech Pharmaceutical Pakistan	98.52
03	Dulpro	Global Pharmaceutical Pakistan	98.25
04	Nsaid	Park Davis Pakistan	100.0
05	Synalgo	Platinum Pakistan	99.1
06	Froben	Abbott Laboratory Pakistan	99.12
07	Inflamatix	Asian Continental Pharma Pakistan	99.85

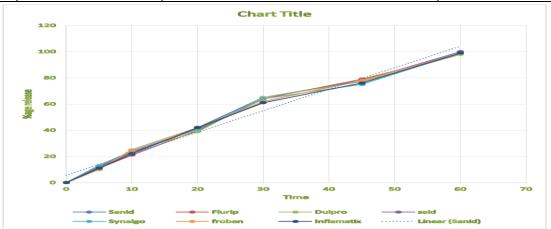


Fig 2: %age Release of different brands of Flurbiprofen

Drug Release profiles

The pattern of the release profile of all the brands of Flurbiprofen were within 60-65 minutes, at zero time when started the dissolution procedure. The results showed that the release %age of the drug were as described in figure 2. All the results were shown they were within the acceptable range. The percentage relese of all of these brands were sanid 99.58%, Flurip 98.52%, Dpro 98.25%, Nsaid 100.0%, Synalgo 99.1%, Froben 99.12 %, and Inflamatix 99.85%. It shows that all the brands were in the range of acceptable.

CONCLUSION:

The Quality control test of all the different brands of Flurbiprofen which are tested are within the limits. All Physical tests and dissolution tests were done according to the specified specifications. All the test included hardness, thickness, weight variation, disintegration and dissolution were tested and the results were confirms the author.

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