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A Review: Analytical Methods For Determination Of Diclofenac In Pharmaceutical Samples

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Abstract: ***Diclofenac is NSAID'S drugs which is available in different dosage form like Tablet, Capsule, Syrup, Cream. This article reviews the analytical methods for identification and quantitative determination of Diclofenac in sample. The most commonly adapted method for determination of Diclofenac in sample on UV- Spectrometry (Spectroflurometry, Colorimetry), Chromatography like High profile liquid chromatography (HPLC), Gas chromatography with mass spectrometry and High performance thin layer chromatography (HPTLC).***

Keywords: Diclofenac, Ibuprofen, colorimetric, HPLC, HPTLC and Gas chromatography

I. INTRODUCTION

Non steroidal antiinflamentry drugs (NSAID'S) have analgesic, antiinflamentry, antipyretic properties. The NSAID'S act by blocking of enzyme cycloxygenase i.e. COX and hence there is inhibition of formation of prostaglandin from arachidonic acid which is part of phospholipids. NSAID'S have small or no effect on lipoxygenase which are convert leukoteriene from arachidonic acid. Both prostaglandin and leukotriene have effect in inflammation process, NSAID'S inhibit synthesis of prostaglandins within central nervous system which exert antinociceptine action and it also act by blocking platelet cycloxygenase, which inhibit formation of thromboxane A_2, known as aggregating agent e.g. Aspirin.

II. CLASSIFICATION OF NSAID'S DRUG

The classification NSAID'S based upon clinical pharmacological characters, half life, chemical classification.

- ✓ Salicylic acid derivatives: Aspirin, Sodium salicylate, Olsalazine, Diflunisal, Salicylsalicylic acid and Sulfasalazine
- ✓ Para-aminophenol derivatives: Acetaminophen
- ✓ Pyrazolone derivatives: Metamizol
- ✓ Non steroidal anti-inflammatory drugs-
  - Indoleacetic acid: Indomethacin, etodolac, and Zomepirac
  - Benzothiazide or Oxicam derivatives: Tenoxicam, Piroxicam and Meloxicam
  - Pyrrole acetic acid derivatives: Alclofenac, Diclofenac, Bromfenac and Ketorolac
  - Propionic acid derivatives: Ibuprofen, fenoprofen, Ketoprofen and Suprofen
  - Arylalkanoic acid derivatives: Nabumetone
  - Benzothiazide or oxicam derivatives: Piroxicam, Meloxicam and Meloxicam
  - COX-2 selective inhibitors: Rofecoxib, Celecoxib and Nimesulide
- ✓ Gold compound:Auranofin, Gold sodium thiomalate
- ✓ Antigout drugs: Colchicine, Probancid, Sulfinpyrazone

III. ADVERSE EFFECT OF NSAID'S

CNS- Headache, Vertigo, Dizziness, Hyperventilation, Confusion

CVS-Myocardial infarction, Closure of ductusarteriosus

Hypersensitivity- Asthma, Shock, Urticaria, Hypotension, Flushing

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Platelets-Increased risk of haemorrhage, Inhibited platelet activation

GI-Nausea, Anorexia, Abdominal pain, Ulcer, Diarrhoea

Renal- Hyperkalemia, Salt and retention, Decreased urate excretion, Decreased effectiveness of diuretic medications

Uterus-Inhibition of labour, Prolongation of gestation

IV. DICLOFENAC

The Diclofenac is Aryl acetic derivatives. The chemical name of Diclofenac is 2 [2,6dichlorophenylamino] benzene acetic acid. It is white to slightly yellowish crystalline powder, sparingly soluble in water, freely soluble in ethanol, methanol. It is An analgesic, antipyretic, antiinflamentry drug, which act by inhibition of prostaglandin synthesis by selecting COX-2.

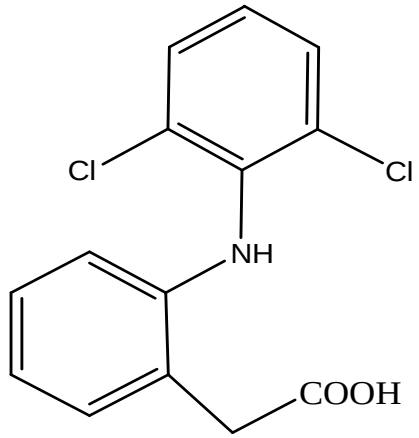

Figure 1: Chemical structure of Diclofenac

A. PHARMACOKINETICS

Diclofenac is mostly absorbed orally. It is protein bound 99% metabolized and excreted in urine and bile. It is also found in synovial fluid is maintained for 3 times longer period than in plasma.

B. USES

Diclofenac is used in rheumatoid, osteoarthritis and dysmenorrhoea, bursitis, relief pain and wound oedema. It is used in treatment of spondylitis.

C. DOSE

50 mg, 100mg of enteric coated tab. And S.R. tab. respectively with brand name VOVERAN, DICLONAC, MOVONAC and 25 mg/ml in 3ml amp. For i.m. inj.

V. METHODS FOR DETERMINATION OF DICLOFENAC

- ✓ Spectrometry
- ✓ Spectroflurometry
- ✓ Colorimetry
- ✓ Chromatography

A. SPECTROMETRY

max	Sample matrix	Solvent	Linearity	Accuracy	Precession	References
230-276 nm	Diclofenac, Serratiopeptidase	Distilled water	0.9999	99.81-100.2	0.0979	[6]
220-350 nm	Diclofenac Potassium, Metaxalone	Methanol	7.5	100.14-101.98	0.01-1	[7]
252-330 nm	Diclofenac Potassium, Paracetamol, Serratiopeptidase	Methanol: Distil water(40:60)	2-30	98.22-102.76	1.42	[8]
277-222 nm	Diclofenac	Methanol	0.9992	97.017-98.339	0.4801-1.472	[9]
253-287 nm	Diclofenac ,Famotidine	Methanol	0.9999	98.26-101.16	0.6255	[10]
247-276 nm	Paracetamol, Diclofenac	0.1M Urea	0.9991	0.6-0.613	0.177-0.361	[11]
249-246 nm	Diclofenac Sodium, Thiocolchicoside	Methanol	4-36	99.02-99.46	0.76-1.81	[12]
566.2 nm	Diclofenac	Toluene	0.6-10	82.6-94.3		[13]

Table 1: Condition for UV-Spectrometry analysis for Diclofenac in samples

B. SPECTROFLUROMETRIC METHOD

Spectroflurometric method of determination of Diclofenac Sodium in pharmaceutical tablet and ointment using Shimadzu RF-5301 PC. Spectroflurometer equipped with a 150W Xenon arc Lamp, using 1.00cm quartz cells. The fluorescence intensity of Diclofenac in acid solution (HCl 0.01 M) It exciting at 289 nm and obtaining fluorescence emission at 362 nm.

C. COLORIMETRIC METHOD

A simple and precise colorimetric method was developed for determination of Diclofenac Sodium in tablets dosage form, using newly developed 4-Carboxyl-2,6dinitrobenzediazonium ion (CDNBD) as chromatogenic derivatizing reagent with azo dye. Diclofenac exhibit absorbance at 470 nm and obeyed linearity in concentration range 1.35-10.8 g/ml. The LOQ and LOD were found to be 0.81 and 0.27 g/ml respectively. This method has advent of speed, simplicity, sensitivity and affordable instrumentation.

D. CHROMATOGRAPHY

a. HPLC

Detector type	Samples Matrix	Chromatographic column	Mobile phase	Reference
UV at 243 nm	Diclosodium, Benzocaine	ZodiacC-18 (1504.6mm)i.d.5m	0.1%Glacial acetic acid and Water :Acetonitrile,(35:65)	[16]
Electro chemical detector	Diclofenac	C-18(2504.6mm/d),5m	Acetonitrile & Glacial acetic acid(50:50)(v/v)	[17]
UV at 240 nm	Sparfloxacin & NSAID	STARC-18(2504.6mm), 5m	Methanol: Water(90:10)(v/v)	[18]
UV Visible SPD 10A VPSERIES at 262nm	Diclofenac Sodium, Serratipeptidase	WATERS XTERRA RP8(4.6150)5	O-Phosphoric acid buffer: Methanol(70:30)(v/v)	[19]

Table 2: Condition for HPLC analysis for Diclofenac in sample

b. HPTLC

Scanning/ Detector	Samples Matrix	Stationary phase	Mobile phase	Reference
Camag TLC	Diclofenac Sodium, Famotidine	Aluminum 200 layer of Silica gel 60RP $18F_{254}$	Methanol:Water: Triethylamine(7:5:3:5:0.5)	[20]
Camag TLC	Diclofenac HCL& Tolperisone	Silica gel $60F_{254}$	Tolune : Ethyl acetate: Methanol(4:4:2ml v/v/v)	[21]
Camag TLC	Diclofenac Sodium, Thiocolchicoside	Silica gel $60F_{254}$	Tolune:Ethyl acetate: Methanol(5:3:2 v/v/v)	[22]
Camag TLC Scanner-3	Diclofenac Potassium, Paracetamol, Chlorzoxazone	Silica gel $G60F_{254}$	Tolune:Ethyl acetate (55:45 v/v)	[23]
Camag TLC Scanner-3	Tramadol, Diclofenac	Merck TLC Aluminum Silica gel $60F_{254}$	Methanol:Ethyl acetate: Chloroform:Tolune (4:2:2:2v/v/v/v)	[24]

Table 3: Condition for HPTLC analysis for Diclofenac in sample

c. GAS CHROMATOGRAPHY

The rapid, sensitive and specific methods were developed for determination of Diclofenac in pharmaceutical preparation by gas chromatography with mass spectrometry. The linearity was established over concentration range 0.25-5g/ml. The intra- and inter-day relative standard deviation (RSD) was less than 4.62%.The limits of quantification (LOQ) were determined as 0.15g/ml. This method is used for quality control of Diclofenac pharmaceutical dosage form to quantify drug and check formulation content uniformity.

VI. CONCLUSION

The presented systematic review discuss about various analytical method for the determination of Diclofenac in pharmaceutical dosage form samples. These analytical methods are important for qualitative and quantitative determination of Diclofenac in pharmaceutical dosage form.

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