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IN-VITRO EVALUATION OF MARKETED DICLOFENAC SODIUM GEL

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ABSTRACT

The present research has been undertaken with aim to evaluate in vitro drug release through egg membrane using keishary chein diffusion cell. So, the diffusion of diclofenac Sodium by the diclofenac Sodium gel was evaluated through egg membrane. In number of cases it may be advantageous to use animal skin as alternative for membranes as human skin. Due to physiological and morphological similarities between human skin and egg membrane the in vitro diffusion study was carried out by using egg membrane. In present work the marketed diclofenac gel was evaluated *in vitro* using egg membrane into Phosphate buffer at 37°C, where the sample was collected at timed intervals after initial spreading of gel on membrane and replaced with phosphate buffer to maintain sink condition and the concentration of diclofenac was assayed using U.V. Spectrophotometer at 276nm. From the study, it was concluded that marketed Diclofenac gel containing Diclofenac exhibited better drug release.

KEYWORDS

Diclofenac Sodium, *In vitro* diffusion and Egg membrane.

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INTRODUCTON

Transdermal drug delivery is topically administered medications in the form of patches which when applied to the skin to deliver the drug through skin in controlled and predetermined manner in order to increase the therapeutic efficacy of drug and reduced side effect of drug. For effective transdermal drug delivery system, the drugs are easily able to penetrate the skin and easily reach the target site. TDDS increase patient compliance and reduces the load as compared to the oral route. FDA approved the first Transdermal system Transdermal-SCOP in 1979¹.

Diclofenac Sodium is a Non-steroidal Anti-inflammatory drug. It is widely used to reduce inflammation and pain in conditions such as Rheumatoid arthritis, menstrual pain, Dysmenorrhoeal fever, Osteoarthritis or Acute injury.

Diclofenac sodium is class 2 drugs of BCS classification which has high permeability and low solubility it has potent anti-inflammatory action but it does not penetrate well through skin and cannot reach effective concentration at the site of action after transdermal application. Because of this the current research was carried out with intension to determine where the drug diffuses as desired or not^{2,3}.

Diclofenac Sodium is soluble in water, ethanol, methanol and DMF. Molecular Formula of Diclofenac Sodium is $C_{14}H_{10}Cl_2NNaO_2$ and Molecular Weight is 318.129gm/mol. And its melting point is 288-290°C. Chemical name of Diclofenac Sodium is Sodium; 2-[2-(2, 6-Dichloroanilino) phenyl] acetate⁴.

MATERIAL AND METHODS

Materials

Diclofenac Sodium drug was taken from Ozone International Mumbai; Marketed diclofenac gel was taken from Ranbaxy Labs Pvt. Ltd. Goa, India, Potassium Dihydrogen Phosphate was taken Ozone International Mumbai.

Instrumentation

UV Visible Spectrophotometer (Systronic119), Magnetic Stirrer (Remi).

METHODOLOGY

Preparation of Phosphate Buffer

50ml of 0.2M potassium¹ dihydrogen phosphate in 200ml of volumetric flask. Add 39.1ml of 0.2M NaOH. Add water to adjust 200ml.

Preparation of Potassium Dihydrogen Phosphate, 0.2m

Dissolve 27.218gm of potassium dihydrogen phosphate in water and dilute with water to 1000ml.

PROCEDURE

Preparation of Egg membrane from Eggs⁵

Place fresh egg in distilled water. Pour conc. HCl on it; keep it for 3-4 Hrs so that outer thick layer precipitates and is converted into thin membrane. Remove the yellowish material by making a small cut on the membrane. Soak this membrane for a period of 24 Hrs in Phosphate Buffer pH7.4.

In Vitro Diffusion Procedure

1. Fill the receptor compartment with diffusion media (phosphate buffer pH 7.4)
2. Place the prepared egg membrane above the receptor compartment, no bubble should form between the fluid and the egg membrane.
3. Weigh accurately marketed gel containing 10mg diclofenac and spread carefully on the membrane side towards the donor compartment.
4. Stir the diffusion fluid by using a magnetic stirrer.
5. Remove 0.5ml sample from receptor compartment through the sampling port with the help of 1ml syringe at 1 to 24 Hrs.
6. Replace with the 0.5ml fresh phosphate Buffer pH 7.4 to maintain sink condition.
7. Dilute the withdrawn 0.5ml sample with phosphate buffer pH 7.4 up to 10ml in 10ml volumetric flask.
8. Measure the absorbance at 276nm by UV Spectrophotometer and determine the percent cumulative drug absorbed by using equation of standard calibration curve.

RESULTS AND DISCUSSION

The given marketed diclofenac gel showed 159.8% cumulative drug diffusion of diclofenac from the gel through egg membrane into receptor compartment.

**For Standard
Observation table**

Table No.1: Results of Dissolution

S.No	Interval time	Absorbance
1	15minutes	0.007
2	30minutes	0.065
3	1hrs	0.145
4	2hrs	0.291
5	3hrs	0.383

For Observation

Table No.2: Calculation for % CDD

Time (hrs)	Absorbance	Concentration (µg/ml)	Concentration (µg/10ml)	Concentration (mg/0.5ml)	Concentration (mg/20ml)	CDD	%CDD 0.5
0.5	A	a	a×10	(a×10)/1000=L	L×40=T	T	(T×100)/10
1	B	B	b×10	(b×10)/1000=M	M×40=U	U+L=UL	(UL×100)/10
2	C	C	c×10	(c×10)/1000=N	N×40=V	V+L+M=VM	(VM×100)/10
4	D	D	d×10	(d×10)/1000=O	O×40=W	W+L+M+N=WN	(WN×100)/10
8	E	E	e×10	(e×10)/1000=P	P×40=X	X+L+M+N+O=XO	(XO×100)/10
12	F	F	f×10	(f×10)/1000=Q	Q×40=Y	Y+L+M+N+O+P=YP	(YP×100)/10
24	G	G	g×10	(g×10)/1000=R	R×40=Z	Z+L+M+N+O+P+Q=ZQ	(ZQ×100)/10

Table No.3: Calculation for % CDA

Time (Min.)	Absorbance	Concentration (µg/ml)	Concentration (µg/10ml)	Concentration (mg/0.5ml)	Concentration (mg/20ml)	CDA	%CDA
12	0.007	0.434	4.34	0.0434	0.868	0.868	8.68
30	0.065	0.572	5.72	0.0572	2.288	3.156	31.56
60	0.145	0.763	7.63	0.0763	3.052	6.208	62.08
120	0.291	1.112	11.12	0.112	4.448	10.656	106.56
180	0.383	1.331	13.31	0.1331	5.324	15.98	159.8

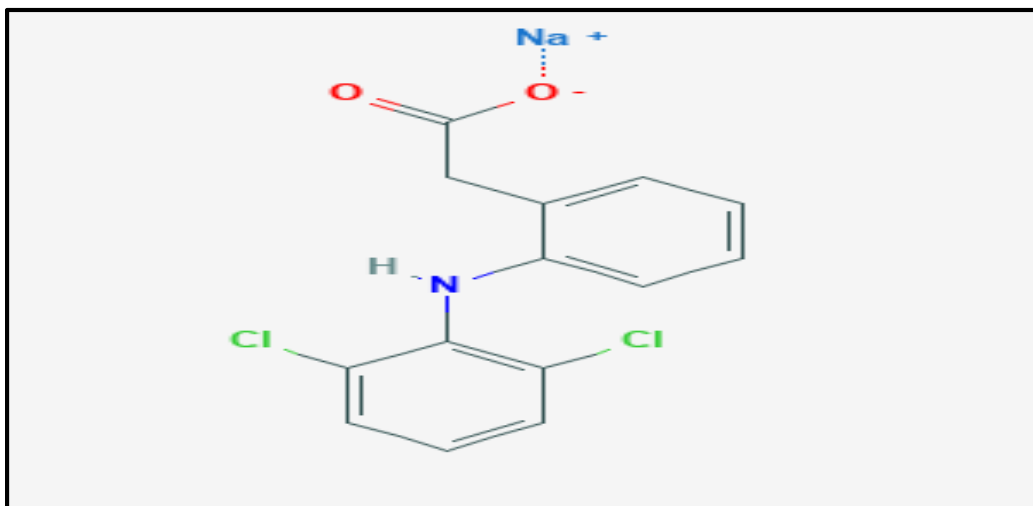


Figure No.1: Structure of Diclofenac Sodium Observations

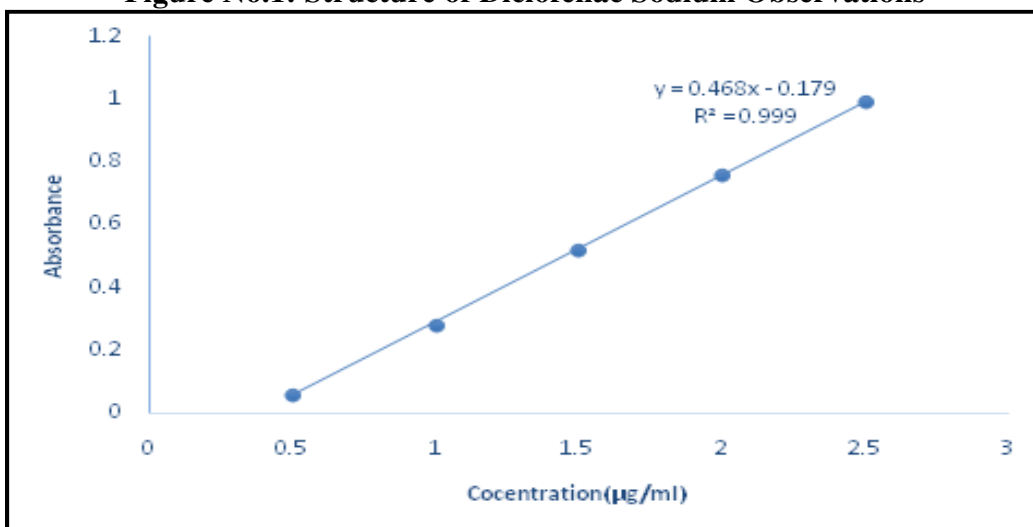


Figure No.2: Standard calibration curve of diclofenac sodium in phosphate buffer pH 7.4

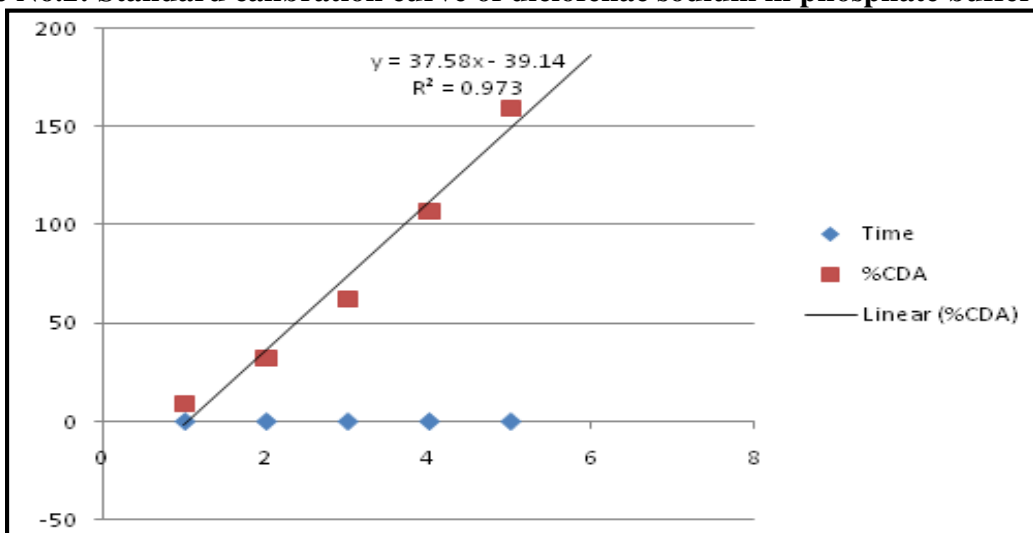


Figure No.3: Calibration curve of %CDA

CONCLUSION

From the study it was concluded that marketed diclofenac gel containing diclofenac exhibited better drug release.

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CONFLICT OF INTEREST

We declare that we have no conflict of interest.

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