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“Studies on Dissolution Rate of Marketed Preparation of Enteric Coated Diclofenic-Sodium Tablets.”

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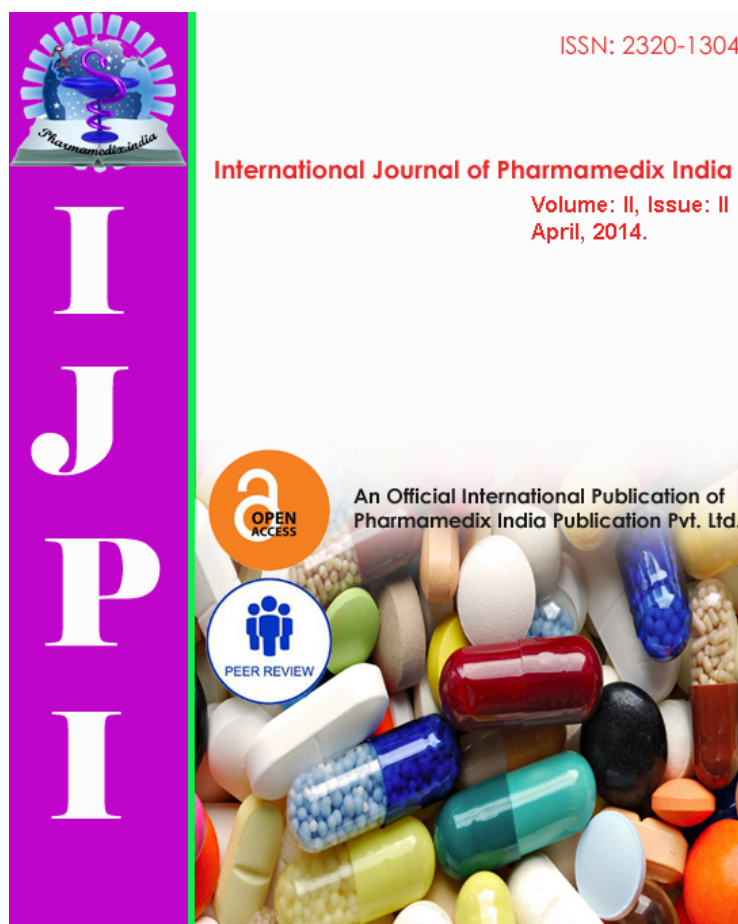
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Abstract:

The present study was performed to illustrate the effect of pH on dissolution profile of diclofenac sodium tablets. Diclofenac sodium has analgesic, antipyretic and anti-inflammatory activities. The in vitro dissolution profiles were found to be varying for each tablet, but within the prescribed limit. In vitro dissolution tests can be used to guide formulation developments, identify critical manufacturing variables, monitor formulation quality from batch to batch, predict the in vivo performances and also serve as a surrogate for bioavailability and bioequivalence. The coating with any system is an easy and economical approach for preparing stable diclofenac sodium coat. Diclofenac sodium enteric coated tablets in order to prevent its release in the stomach and facilitate immediate release of the drug in the duodenum.

Keyword: Dissolution profiles, pH, Coating, Bioavailability and bioequivalence.

Introduction

Diclofenac, as the sodium salt, is a benzeneacetic acid derivative, designated chemically as mentioned in standards 2-[(2,6-dichlorophenyl)amino] benzeneacetic acid, monosodium salt. Diclofenac, as the sodium salt, is a faintly yellowish white to light beige, virtually odorless, slightly hygroscopic crystalline powder. It is freely soluble in methanol, soluble in ethanol, and practically insoluble in chloroform and in dilute acid. Diclofenac sodium is sparingly soluble in water. Diclofenac sodium extended-release tablets are a non-steroidal anti-inflammatory drug (NSAID) that exhibits anti-inflammatory, analgesic, and antipyretic activities in animal models. The mechanism of action of diclofenac sodium, like that of other NSAIDs, is not completely understood

but may be related to prostaglandin synthetase inhibition. Film coating is the more contemporary and thus commonly used process for coating oral dosage forms.). It consists of the deposition of a thin layer of a polymer formulation to the surface of an oral solid dosage form. This will confer specific benefits that broadly range from: (i) improving the visual qualities of the dosage form, (ii) masking unpleasant organoleptic properties, (iii) easing ingestion, (iv) improving product stability and (v) modifying the release profile of the drug.^[1,3,6]

MATERIALS AND METHODS

A double-beam Shimadzu-1800 UV- Visible spectrophotometer is used as required, with spectral bandwidth of 2 nm, wavelength accuracy ± 0.5 nm and a pair of 1-cm matched

quartz cells was used to measure absorbance of the resulting solution. In vitro dissolution of Diclofenic-sodium tablet was carried out by using the USP electrolab dissolution test apparatus. Chemicals which are used in the analysis are ; Diclofenic sodium tablet, Pottassium di-hydrogen phosphate, Distilled water, Hydrochloric acid (conc), Disodium hydrogen phosphate.

Method:

Preparation Of Phosphate Buffer Ph-6.8:

According to IP specifications, Dissolve 3.40 gm. of Pottassium di-hydrogen phosphate and 3.55 gm. of Disodium hydrogen phosphate in distilled water. Make the volume upto 1000 ml with the help of distilled water.^[4]

Preparation Of 0.1N Hydrochloric acid:

According to IP specifications, Take 8.33 ml of concentrate hydrochloric acid with the help of dropper very carefully. And dilute it upto 1000 ml with the help of distilled water.^[4]

Procedure

In vitro dissolution of Diclofenic-sodium tablet was carried out using the USP dissolution test apparatus. At first 900 ml of dissolution medium was placed in bath container. The tablet was introduced in to the bath container, the paddle was rotated up to 2 hr at $37 \pm 0.5^\circ\text{C}$. Electrolab dissolution tester with a rotating paddle at 50 RPM was used. The dissolution was started with 0.1N HCl for 2 hours and samples were withdrawn at 15 minutes intervals. Bath volume was maintained at 900 ml. After 2 hours the

product was transferred to pH 6.8 phosphate buffer medium and again electrolab dissolution tester with a rotating paddle at 50 RPM was used. Dissolution was carried out for 50 minutes at $37 \pm 0.5^\circ\text{C}$ and the samples were withdrawn at 5 minutes intervals. Bath volume was maintained at 900 ml. The absorbance of each sample was observed by U.V. visible spectrophotometer at 276 nm against blank reagent and then calculations and graphs are plotted.^[2,6,8]

RESULT AND CONCLUSION

The Dissolution test of marketed preparation of diclofenic-sodium (50mg) has been carried out and it is found to be average 65 %. The result was found that the formulation showed very low drug release in 0.1N hydrochloric acid buffer (pH 1.2). This was due to the low solubility of Diclofenac Sodium at pH 1.2, but complete release was displayed by formulation in Phosphate buffer (pH 6.8). Thus it can be concluded, that drug dissolution was a function of drug solubility, at various pH ranges. Indian pharmacopeia (IP 2007) According to the monographs in Indian Pharmacopoeia, for each of the tablets tested for dissolution, the amount of active ingredient in solution is not less than 70% of the prescribed or stated amount. The results obtained from the study revealed that the formulation passed the IP general specifications standard for dissolution rate test for enteric coated diclofenic-sodium marketed tablet (50 mg).

Table-1 Dissolution test of Diclofenic-sodium market preparation (Enteric coated 50 mg)
at pH 1.2 or 0.1 N Hcl in acidic medium

Time	Sq. rt. of time	Log time	Absorbance	Conc. (mg)	Conc. (µg)	Conc. In 900 ml	Cumulative drug release	% Cumulative drug release	% Cumulative drug retain	Log % Cumulative drug retain	(m/m ⁰⁰) x 1000	log(m/m ⁰⁰) x 1000
0	0	0	0	0	0.0000	0.000	0	0	100	2	0	0
15	3.872983	1.176091	0.087	2.667	0.0027	2.400	2.400	4.8000	95.2000	1.9786	479.041	2.68037
30	5.477226	1.477121	0.088	2.700	0.0027	2.430	2.430	4.8600	95.1400	1.9784	485.029	2.68576
45	6.708204	1.653213	0.089	2.733	0.0027	2.460	2.460	4.9200	95.0800	1.9781	491.017	2.69109
60	7.745967	1.778151	0.096	2.967	0.0030	2.670	2.670	5.3400	94.6600	1.9762	532.934	2.72667
75	8.660254	1.875061	0.099	3.067	0.0031	2.760	2.760	5.5200	94.4800	1.9753	550.898	2.74107
90	9.486833	1.954243	0.111	3.467	0.0035	3.120	3.120	6.2400	93.7600	1.9720	622.754	2.79431
105	10.24695	2.021189	0.119	3.733	0.0037	3.360	3.360	6.7200	93.2800	1.9698	670.658	2.82650
120	10.95445	2.079181	0.142	4.500	0.0045	4.050	4.050	8.1000	91.9000	1.9633	808.3832	2.90761
135	11.61895	2.130334	0.174	5.567	0.0056	5.010	5.010	10.0200	89.9800	1.9541	1000	3

Table-2 Dissolution test of Diclofenic-sodium market preparation (Enteric coated 50 mg)
at pH 6.8 phosphate buffer in basic medium

Time	Sq. rt. of time	Log time	Absorbance	Conc. (mg)	Conc. (µg)	Conc. In 900 ml	Cumulative drug release	% Cumulative drug release	% Cumulative drug retain	Log % Cumulative drug retain	(m/m ⁰⁰) x 1000	log(m/m ⁰⁰) x 1000
0	0	0	0	0	0	0	0	0	100	2	0	0
5	2.236	0.699	0.269	8.733	0.0087	7.86	7.86	15.72	84.28	1.926	447.0199	2.6504
10	3.162	1.00	0.307	10.0	0.01	9.0	9.0	18	82	1.914	511.9454	2.7092
15	3.872	1.176	0.382	12.5	0.0125	11.25	11.25	22.5	77.5	1.889	639.9317	2.8692
20	4.472	1.301	0.416	13.63	0.0136	12.27	12.27	24.54	75.46	1.8777	697.9522	2.8438
25	5.00	1.3979	0.483	15.2	0.0152	13.68	13.68	27.36	72.64	1.8861	778.1570	2.8911
30	5.477	1.477	0.508	16.7	0.0167	15.03	15.03	30.06	69.94	1.8447	854.9488	2.9319
35	5.916	1.544	0.528	17.36	0.017	15.63	15.63	31.26	68.74	1.837	889.0785	2.9489
40	6.324	1.602	0.568	18.7	0.0187	16.83	16.83	33.66	66.34	1.822	957.3379	2.9810

45	6.708	1.653	0.581	19.13	0.0191	17.22	17.22	34.44	65.56	1.817	979.5222	2.9910
50	7.071	1.698	0.593	19.53	0.0195	17.58	17.58	35.16	64.84	1.812	1000	3.000

Graphs according to their drug release (Acidic Medium) :

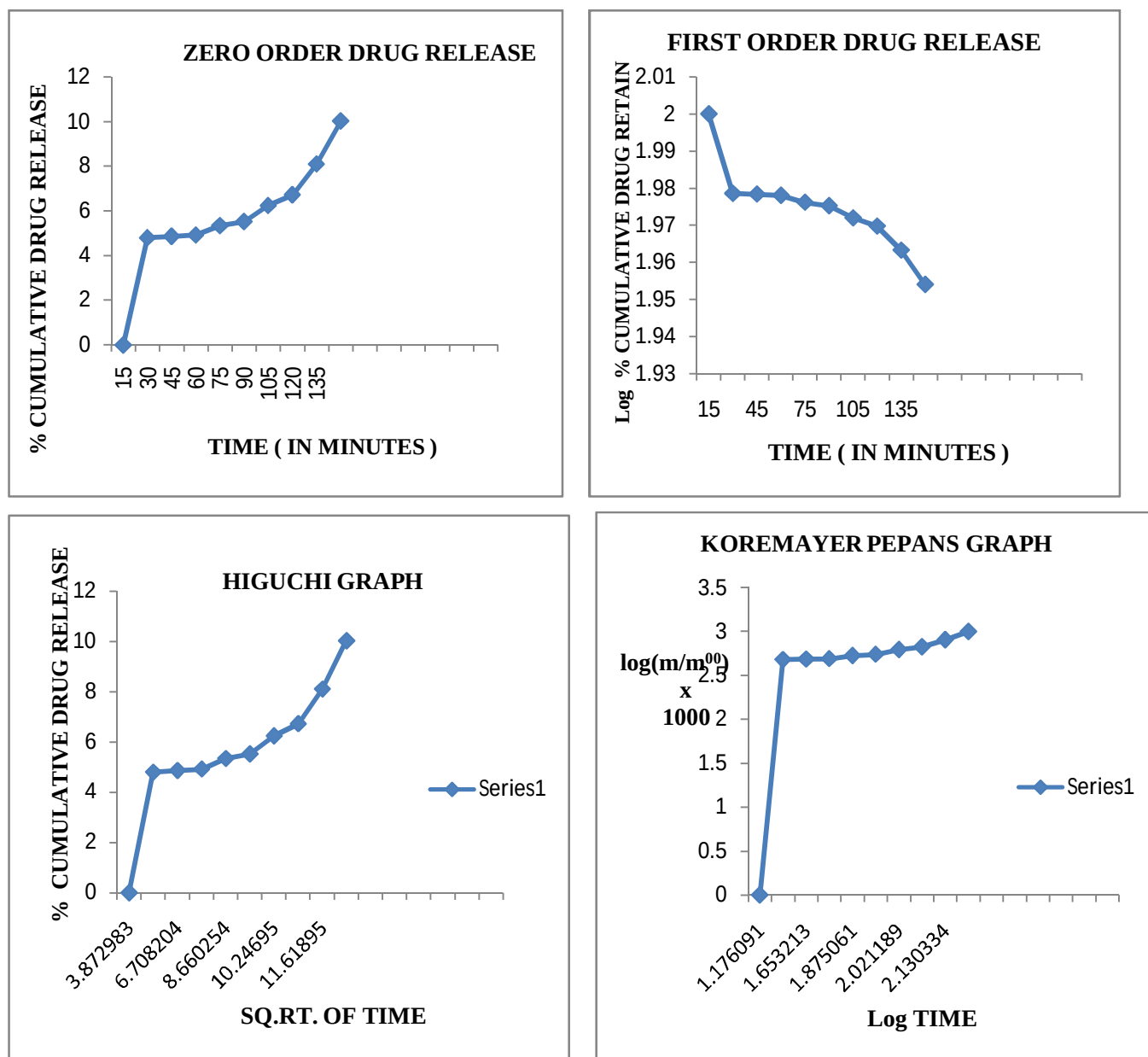


Figure 1 Graphs of Drug release in 0.1 N Hcl acidic medium

Graphs according to their drug release (Basic Medium)

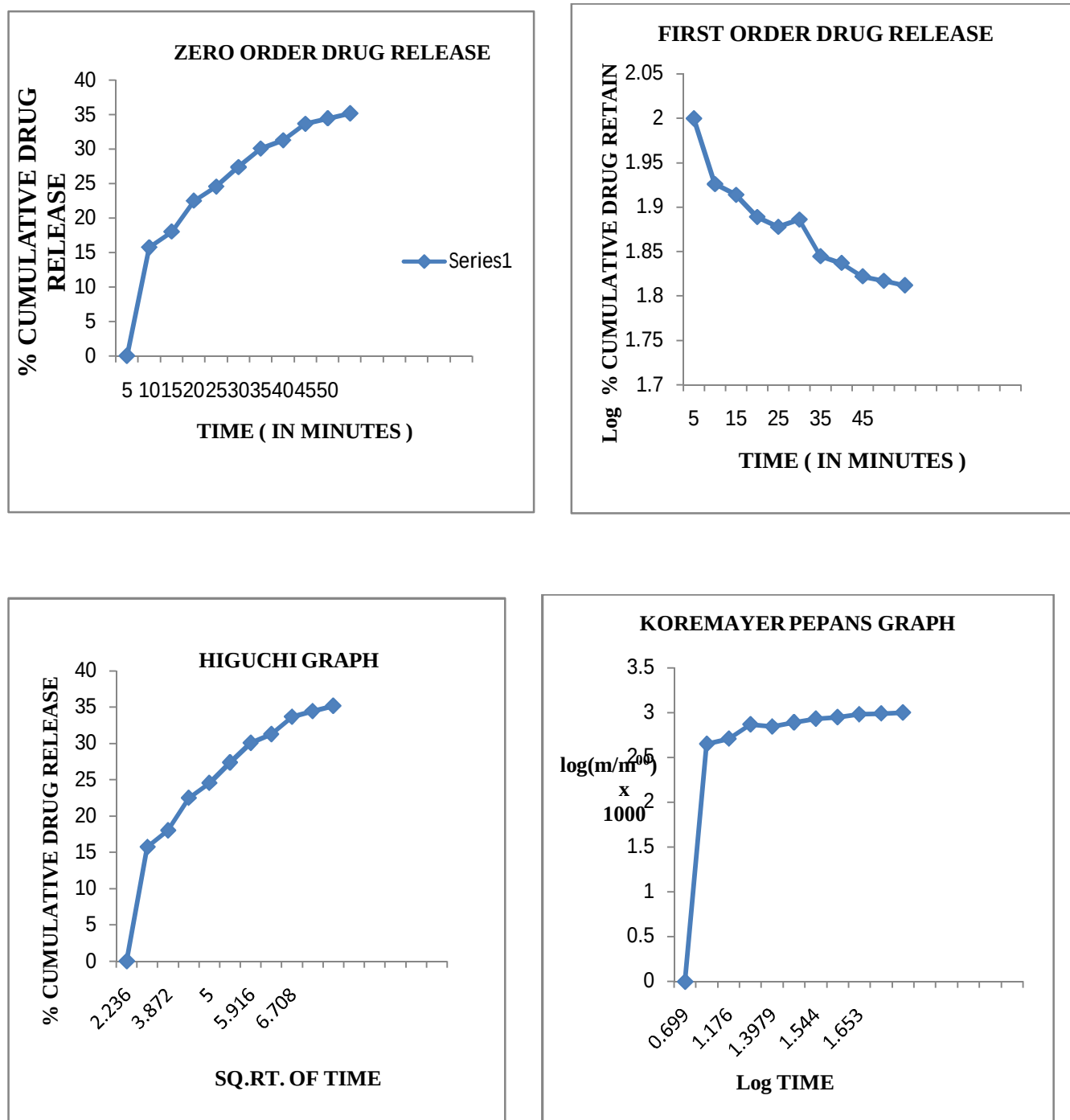


Figure 2 Graphs of Drug release in phosphate buffer pH-6.8 basic medium

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