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FORMULATION AND INVITRO EVALUATION OF TAZAROTENE TOPICAL GEL

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Abstract:

Tazarotene is a member of the acetylenic class of retinoids. This medication is approved for treatment of psoriasis, acne, and sun damaged skin .In the present work an attempt was being made to formulate and evaluate topical gel containing antipsoriatics drug Tazarotene. Carbopol 971, Sodium CMC and carbopol 934 were selected as polymers.The drug and excipient compatability was studied by using FTIR Nine formulations of gels were prepared by taking different quantities of polymers .The prepared gel was subjected to various evaluation tests like pH, spreadability, viscosity, content uniformity and diffusion studies conducted upto 12hrs.All the results were with in the limits , by diffusion studies it was observed that formulation F7 shown maximum drug release of 97.62% which was considered as optimized formulation.

Key Words: *Tazarotene, Carbopol 971, Sodium CMC and carbopol 934*

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INTRODUCTION:

Transdermal drug delivery systems, Controlled release systems, Transmucosal delivery systems etc. has been developed. Transdermal delivery has been emerged as a novel tool over injectables and oral routes as it increases the patient compliance and avoids the first pass hepatic metabolism. In transdermal drug delivery system the drug is delivered in a controlled rate into systemic circulation through the skin . The intact skin is used as a port to administer a drug in transdermal gels but skin act as a barrier to ingress the material, it only allows a small material to penetrate over a period of time into systemic circulation. Gels are semisolid systems in which a liquid phase is constrained within a three dimensional polymeric matrix of natural or synthetic gums in which a high degree of physical or chemical cross linking has been established. Gels are defined as a substantially dilute cross-linked system, which exhibits no flow when in the steadystate . The USP defines gel as semisolid system consisting of either suspension of small inorganic particles or large organic molecules within the liquid.

MATERIALS AND METHODS:

Carbopol 971, Carbopol 934, Sodium CMC , Methanol, Water, Triethanolamine, Polyethylene glycol, Methyl parabben, all the chemicals used were lab grade.

Preparation of Tazarotene

Table 1 Composition of different emulgel formulations

Formulation (F)	Drug (mg)	Sodium CMC (mg)	Carbopol 934 (mg)	Carbopol 971 (mg)	Methanol (ml)	Triethanolamine(ml)	Polyethylene glycol (mg)	Methyl parabben (mg)	Water
F1	5	5	-	-	1	0.5	1	1	Q.s
F2	5	10	-	-	1	0.5	1	1	Q.s
F3	5	15	-	-	1	0.5	1	1	Q.s
F4	5	-	5	-	1	0.5	1	1	Q.s
F5	5	-	10	-	1	0.5	1	1	Q.s
F6	5	-	15	-	1	0.5	1	1	Q.s
F7	5	-	-	5	1	0.5	1	1	Q.s
F8	5	-	-	10	1	0.5	1	1	Q.s
F9	5	-	-	15	1	0.5	1	1	Q.s

Preparation of Tazarotene gel

Above mentioned quantity of carbopol 934, Carbopol 971 and sodium CMCwas soaked in water for a period of 2 hours. Carbopol was then neutralized with triethanolamine (TEA) with stirring. Then specified amount of drug was dissolved in appropriate and preweighted amounts of propylene glycol and ethanol. Solvent blend was transferred to carbopol container and agitated for additional 20 min. The dispersion was then allowed to hydrate and swell for 60 min, finally adjusted the pH with 98% TEA until the desired pH value was approximately reached (6.8-7). During pH adjustment, the mixture was stirred gently with a spatula until homogeneous gel was formed. All the samples were allowed to equilibrate for at least 24 hours at room temperature prior to performing rheological measurements.

Evaluation Of Prepared Gel Formulations

The prepared gels were evaluated for various evaluation parametrers like Percentage yield, pH measurement, spreadability, viscosity measurement, in-vitro diffusion study of the topical gel.

Calibration curve in water (make up with ph 6.8 phosphate buffer)

Standard solutions of different concentrations were prepared and their absorbance was measured at 270 nm (Table 2). Calibration curve was plotted against drug concentrations versus absorbance as given in the (Figure.1).

Table 2 Determination of $\lambda_{max}$of Tazarotene in methanol-- λ_{max}= 270 nm

Concentration (µg /ml)	Absorbance
0	0
0.5	0.126
1	0.248
1.5	0.362
2	0.487
2.5	0.599
3	0.723

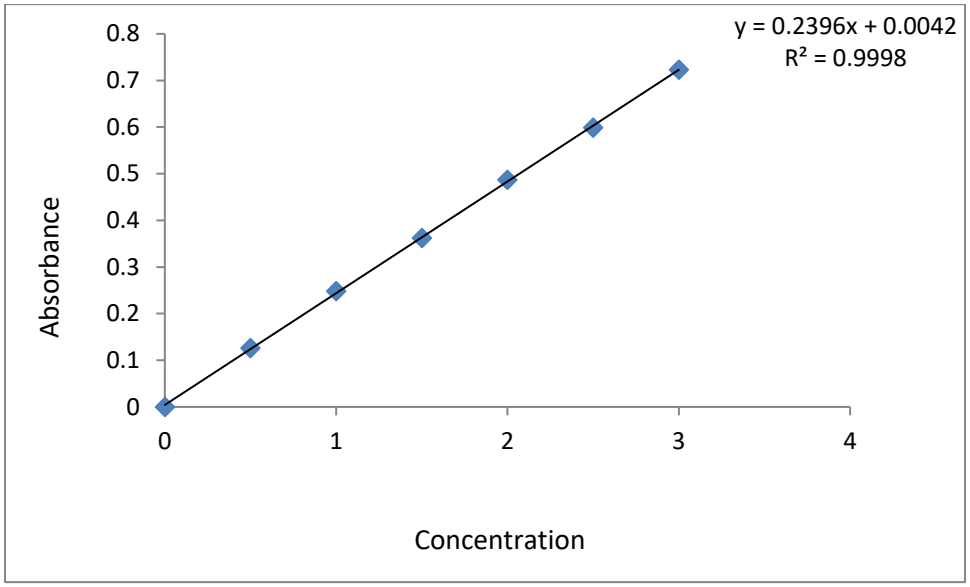

Figure 1: Standard graph of Tazarotene

Since the physical characterization is meant for physical integrity of the dosage form, the results were pooled at one place. Discussion on the results, described for gel formulation under the same heading.

Percentage yield

Sl.no	Formulation	Percentage yield
1	F1	91.23
2	F2	93.41
3	F3	92.36
4	F4	91.38
5	F5	94.15
6	F6	95.78
7	F7	93.42
8	F8	94.19
9	F9	90.32

Table 3: Percentage yield of gel formulations

Drug content

Sl.no	Formulation	Drug content
1	F1	94
2	F2	93
3	F3	94
4	F4	92
5	F5	97
6	F6	94
7	F7	93
8	F8	96
9	F9	95

Table 4: Drug content of gel formulations

Viscosity

Sl.no	Formulation	Viscosity (cps)
1	F1	78,320.08
2	F2	84,645.04
3	F3	92,643.26
4	F4	1,26,002.06
5	F5	1,19,628.20
6	F6	69,541.01
7	F7	95,765.04
8	F8	1,37,018.09
9	F9	97,489.04

Table 5: Viscosity of gel formulations

pH measurement

Sl.no	Formulation	pH
1	F1	6.6
2	F2	6.9
3	F3	6.8
4	F4	6.4
5	F5	6.7
6	F6	7.2
7	F7	6.9
8	F8	6.5
9	F9	6.8

Table 6: pH of gel formulations

Spreadability studies

Sl.no	Formulation	Spreadability gm.cm^2
1	F1	10.07
2	F2	11.76
3	F3	11.54
4	F4	11.88
5	F5	11.46
6	F6	11.10
7	F7	11.76
8	F8	11.69
9	F9	11.91

Table 7: Spreadability values of gel formulations

In-Vitro Drug Permeation Studies

In-vitro skin permeation study or in-vitro diffusion study has been extensively studied, developed and used as an indirect measurement of drug solubility, especially in preliminary assessment of formulation factors and manufacturing methods that are likely to influence bioavailability. The objectives in the development of in-vitro diffusion tests are to show the release rate and extent of drug from the dosage form. The in-vitro drug permeation study of Tazarotene from gel formulation was studied using Franz diffusion cell and the method described in methodology chapter. The release data was obtained for all the gel formulations. Spectrometric results were obtained and given consideration to sampling loss, to calculate actual cumulative drug diffused was calculated since the volume of receptor cell was only 20 ml (table-8). The obtained diffused amount of drug was extrapolated to diffusion by unit surface area of semi permeable membrane.

In-Vitro Release Studies

Table 8 In-vitro cumulative % drug release profile for Tazarotene

	Cumulative % drug release								
Time	F_1	F_2	F_3	**F_4**	F_5	F_6	F_7	F_8	**F_9**
0	0	0	0	0	0	0	0	0	**0**
30min	2.58	3.53	4.1	5.1	4.45	6.01	6.25	4.13	6.5
1hr	11.56	12.54	10.28	13.52	13.24	8.12	13.63	12.16	13.19
2hr	17.87	19.3	19.23	18.45	19.25	19.33	18.73	21.25	18.59
3hr	25.23	28.52	27.72	28.45	24.15	28.7	24.35	28.59	24.2
4hr	35.28	36.83	36.24	42.35	36.25	32.72	38.3	36.46	38.8
5hr	42.63	45.34	48.09	51.56	46.32	48.62	49.27	48.25	49.73
6hr	51.73	54.52	52.05	60.45	54.32	56.33	58.92	57.79	54.79
7hr	60.25	63.33	61.09	65.25	62.33	61.66	64.44	66.24	65.39
8hr	64.46	67.93	67.52	71.75	68.86	66.34	69.88	72.75	73.56
9hr	69.52	71.09	69.45	74.48	71.35	71.35	75.54	78.69	76.3
10hr	74.05	76.43	73.35	79.38	75.25	74.09	79.59	83.59	80.22
11hr	77.53	80.25	75.65	88.39	80.72	78.34	82.45	93.19	82.34
12hr	79.97	83.43	79.57	89.45	**84.09**	82.25	86.32	97.62	87.71

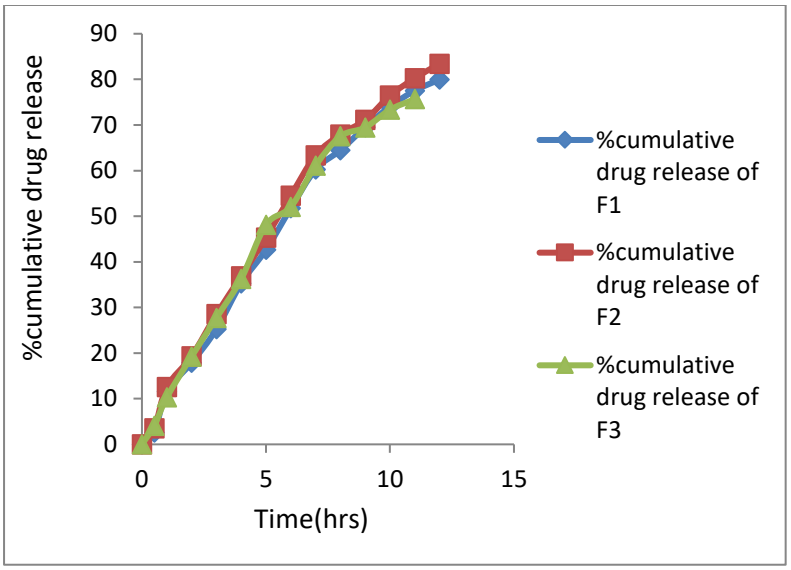

Figure :2. Dissolution graphs for the formulations F1,F2,F3

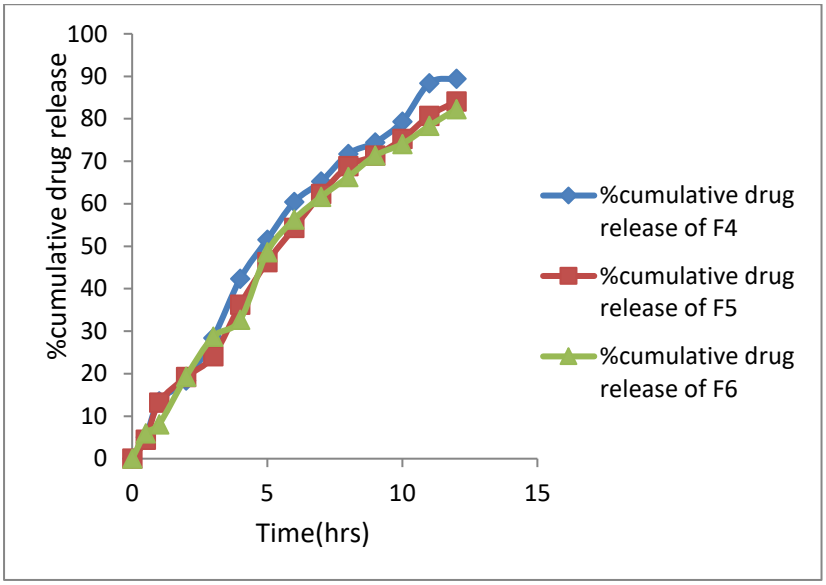

Figure :3 Dissolution graphs for the formulations F4,F5,F6

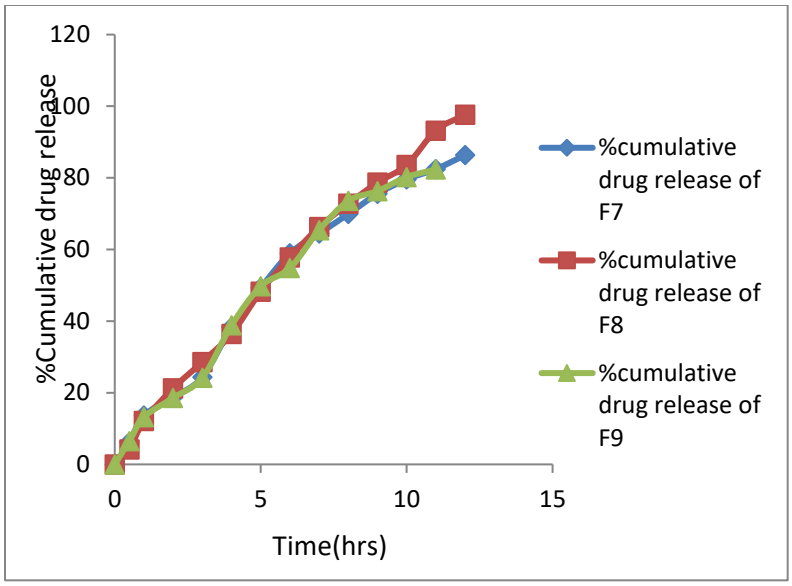

Figure :4 Dissolution graphs for the formulations F7,F8,F9

Table :9 Release kinetics

CUMULATIVE (%) RELEASE Q	TIME (T)	ROOT (T)	LOG(%) RELEASE	LOG (T)	LOG (%) REMAIN
	0	0			2.000
4.13	**0.5**	0.000	0.616	0.000	1.982
12.16	1	1.000	1.085	0.000	1.944
21.25	2	1.000	1.327	0.000	1.896
28.59	3	1.414	1.456	0.301	1.854
36.46	4	1.732	1.562	0.477	1.803
48.25	5	2.000	1.683	0.602	1.714
57.79	6	2.236	1.762	0.699	1.625
66.24	7	2.449	1.821	0.778	1.528
72.75	8	2.646	1.862	0.845	1.435
78.69	9	2.828	1.896	0.903	1.329
83.59	10	3.000	1.922	0.954	1.215
93.19	11	3.162	1.969	1.000	0.833
97.62	12	3.317	1.990	1.041	0.377

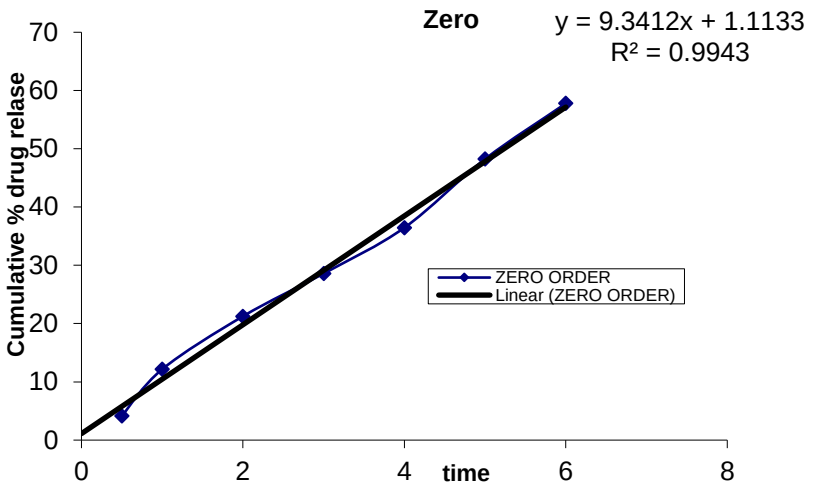

Figure: 5 kinetic model Zero order

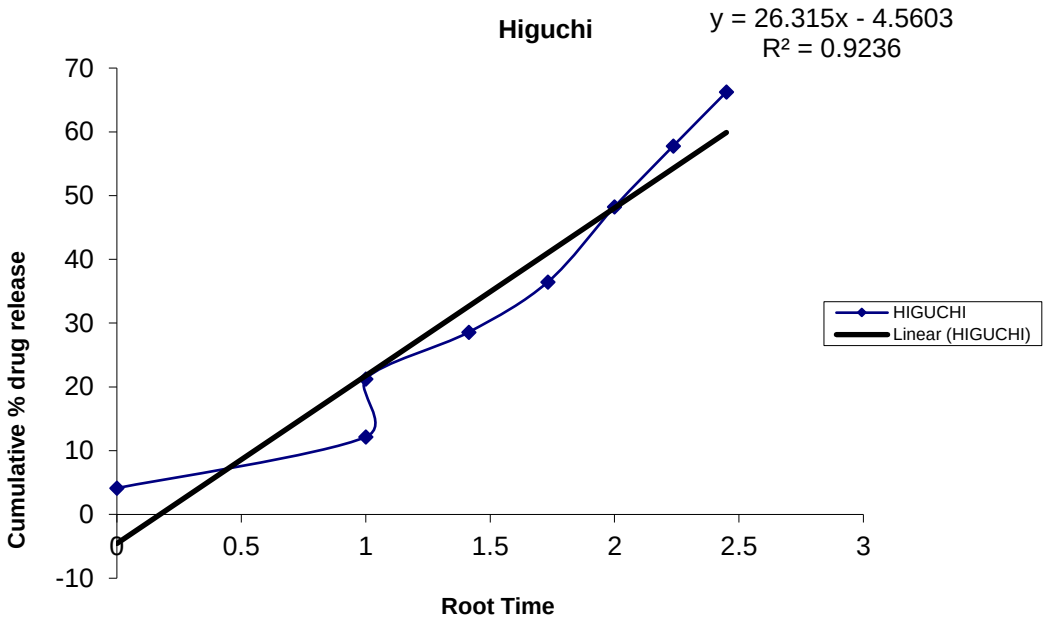

Figure :6 kinetic model-higuchi

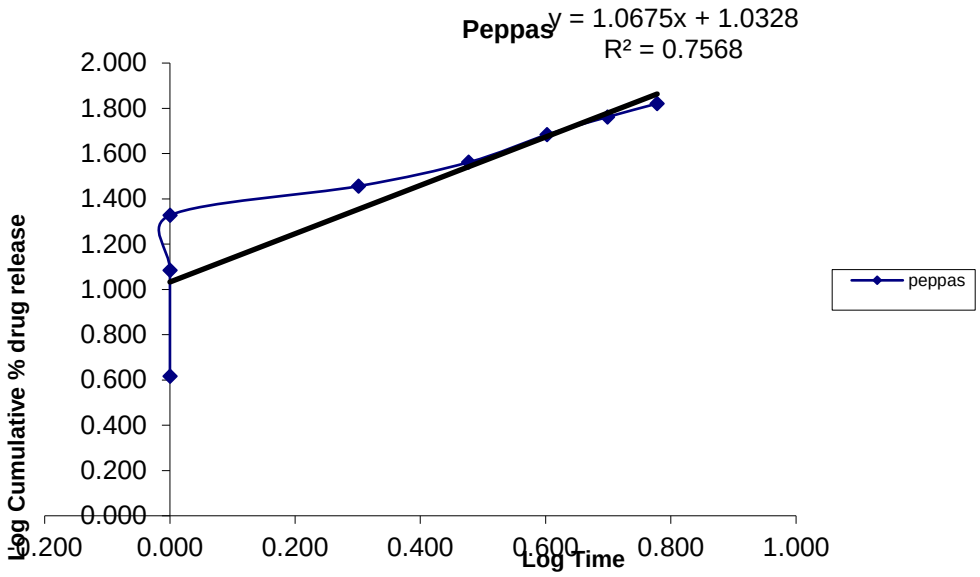

Figure : 7 kinetic model-peppas

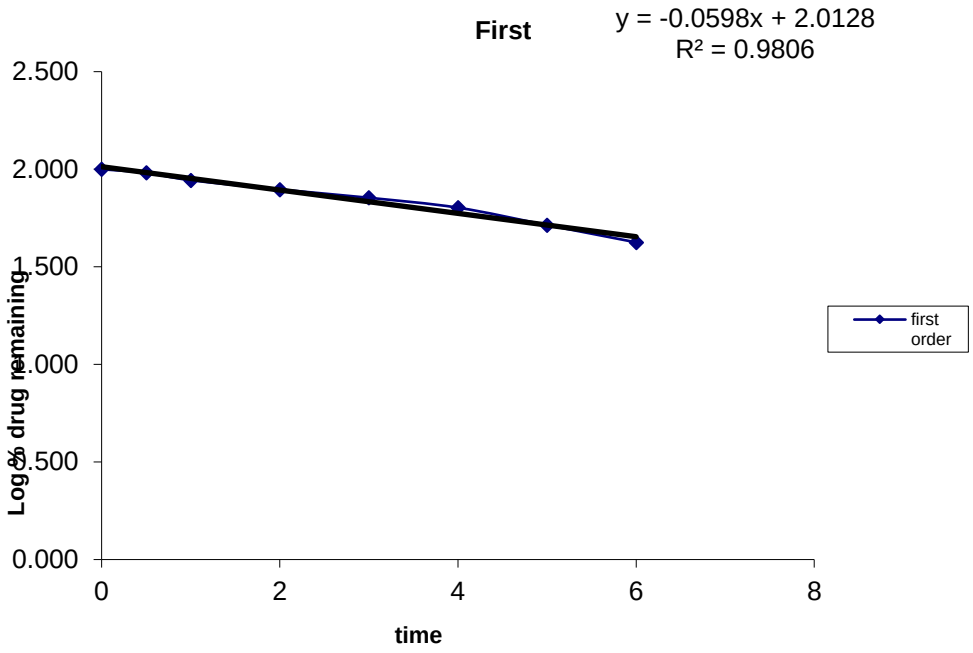

Figure :8 Kinetic model First order

CONCLUSION:

In the present work an attempt was being made to formulate and evaluate topical gel containing antipsoriatics drug Tazarotene. Carbopol 971, Sodium CMC and carbopol 934 were selected as polymers.The drug and excipient compatability was studied by using FTIR Nine formulations of gels were prepared by taking different quantities of

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