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Review

Formulation and Evaluation of Thiochochicoside Loaded Trandermal Patches

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Abstract

The present study focuses on the formulation and evaluation of Thiocolchicoside-loaded transdermal patches aimed at providing sustained drug delivery, improving therapeutic efficacy, and enhancing patient compliance. Thiocolchicoside, a centrally acting muscle relaxant with poor oral bioavailability and gastrointestinal side effects, was incorporated into matrix-type transdermal patches using various polymers such as Hydroxypropyl methyl cellulose(mg), Sodium alginate(mg) and Sodium carboxymethyl cellulose(mg) along with suitable plasticizers.

The prepared patches were evaluated for their physicochemical properties including thickness, weight uniformity, folding endurance, moisture content, drug content, and surface pH. In-vitro drug release studies were conducted using Franz diffusion cells to assess the release profile of Thiocolchicoside over 12 hours. Among the various formulations, the optimized patch demonstrated satisfactory mechanical properties, high drug content uniformity, and a sustained drug release profile following like Higuchi or Korsmeyer-Peppas] kinetics.

The results suggest that transdermal delivery of Thiocolchicoside is a promising alternative to oral administration, potentially minimizing systemic side effects and improving patient adherence.

Keywords: Thiocolchicoside-loaded transdermal patches

1.INTRODUCTION.

The skin is the largest organ in the human body by mass, with an area of between 1.5 and 2.0 m 2 in adults. Drugs have been applied to the skin to treat superficial disorders, for the transdermal administration of therapeutics to manage systemic ailments and as cosmetics, dating back to the oldest existing medical records of man. For instance, the use of salves, ointments, potions and even patches, consisting of plant, animal or mineral extracts, was already popular in ancient Egypt and in Babylonian medicine (around 3000 BC) However, the routine use of transdermal delivery systems only became a common practice in the latter third of the 20th century when delivery technology was developed to enable precise and reproducible administration through the skin for systemic effects transdermal drug delivery is an alternative way of delivering drugs via the skin layer.[1]

The drug is carried through the skin into the bloodstream and circulates systemically in the body before reaching the target site.[2] The transdermal drug delivery method has several advantages over other routes of administration. Examples include the ability to deliver continuous doses of drugs over an extended period of time, the ability to bypass the digestive system, and the ability to avoid first-pass metabolism in the liver. Other drug administration routes, such as intravenous, can cause pain and increase the risk of infection. Nevertheless, the oral route is inefficient, and in the inhalation method, it is difficult in controlling the dosage. In view of its advantages over other routes, transdermal administration is commonly used to deliver drugs for conditions such as smoking cessation, chronic pain, and motion sickness, as well as hormone replacement therapy.[3]

Out of the many routes of administration available, the oral route remains the most popular dosage form among patients as it is easy to administer, carry around, formulation design flexibility, cost-effectiveness, causes minimal discomfort for many patients, and least sterility restrictions during manufacturing. Most of the newly discovered drugs are lipophilic in nature and have poor aqueous solubility, thereby posing problems in their formulation into delivery systems.[4]

Influence of human biology on performance of TDS

Percutaneous delivery of pharmaceutics is a technique that is used todeliver a drug into the systemic circulation across the skin .[5] Various factors such as age, gender, eth-nicity, skin hydration and metabolism affect the integrity and barrierproperties of the skin, resulting in variations in the amount of drug ab-sorbed. The main differences between male and female skin are poresize (sweat and sebaceous gland—men have larger skin pores sizes)and pH (pH of male skin is significantly lower than that of female skin).However, studies have shown no significant difference between thepermeation of nicotine across female and male skin under in vivo con-ditions to make any conclusions about gender-based variations. Ethnicity-based studies in permeation have demon-strated differences in skin structure observed between different races. One study compared the variation in skin per-meation of methyl nicotinate as a model drug between four differentethnic groups. It was found that the rank order of skin permeability wasAfro-Caribbean < Asians < Caucasians < Hispanics. Other studies have suggested a high lipid profile in the SCfor Afro-Caribbeans, in addition to a greater number of keratinocyte. ayers resulting in high cellular cohesion, and a lower water contentcompared with other races. Skin hydration isan important factor as water only accounts for 10%–20% of the SCunder physiological conditions, but after soaking in water or with cer-tain disease states (eczema, impetigo, psoriasis and icthyoses), this canchange, as well as in response to ambient humidity and temperature.Some research has suggested that excessivehydration causes swelling of keratinocytes, affecting lipid packing andresulting in an increase in the flux of some permeants. Difference inskin temperature could lead to increased or decreased flux across theskin, with permeability being directly proportional to skin temperature. The extent of the effects of heat exposure on invivo drug absorption and adverse events associated with transdermalsystems (TDS) are also functions of the physicochemical and pharma-cological properties of the drug(s) and their respective drug deliverysystem formulation design.[6]

Table 1.3 Microneedle types with their unique features.[7-10]

Solid Microneedles: These are the simplest type of microneedles, consisting of solid needles that penetrate the skin to create tiny channels. Solid microneedles are commonly used for drug delivery and cosmetic treatments.

Hollow Microneedles: These microneedles have a hollow core that allows for the delivery of fluids or drugs into the skin. Hollow microneedles are often used for transdermal drug delivery and sampling of interstitial fluid.

Coated Microneedles: These microneedles have a coating that dissolves upon penetration of the skin, allowing for the release of drugs or other substances. Coated microneedles are often used for transdermal drug delivery.

Dissolving Microneedles: These microneedles are made of materials that dissolve in the skin, allowing for the controlled release of drugs or other substances. Dissolving microneedles are often used for vaccines and other drug delivery applications.

LIST OF MATERIALS

Thiochochicoside Manufactured by Taj Pharmaceuticals, Provided by SURA LABS

Hydroxypropyl methyl cellulose(mg) Merck Specialities Pvt Ltd, Mumbai, India

Sodium alginate(mg) Merck Specialities Pvt Ltd, Mumbai, India

Sodium carboxymethyl cellulose(mg) Merck Specialities Pvt Ltd, Mumbai, India

Glycerin (ml) Merck Specialities Pvt Ltd, Mumbai, India

Ethanol (ml) Merck Specialities Pvt Ltd, Mumbai, India

EQUIPMENT USED

Double beam UV Visible Spectrophotometer Lab India UV 3000

Digital weigh balance Sartourious

FTIR Spectrophotometer Bruker

Magnetic Stirrer 2MLH Remi Equipments,Mumbai, India.

Franz diffusion cell

METHODOLOGY:

Formulation of transdermal patches

Preparation of blank patches:

Polymers of single or in combination were accurately weighed and dissolved in respective solvent and then casted in a Petri-dish with mercury as the plain surface. The films were allowed to dry overnight at room temperature.

Formulation of Drug Incorporated Transdermal Patches:

The matrix-type transdermal patches containing Thiochochicoside were prepared using different concentrations of ethyl cellulose and Eudragit S 100. The polymers in different concentrations were dissolved in the respective solvents. Then the drug was added slowly in the polymeric solution and stirred on the magnetic stirrer to obtain a uniform solution. Propylene glycol was used as plasticizers. Ethanol was used as the penetration enhancer. Then the solution was poured on the Petri dish having surface area of 78 cm2 and dried at the room temperature. Then the patches were cut into 2x2 cm^2 patches. Drug incorporated for each 2x2 cm^2 patch was 8 mg. the formulation table is given in table no. 6.3.

Table :7.1 Formulation of Thiochochicoside Patches

Ingredients	F1	F2	F3	F4	F5	F6
Thiochochicoside (mg)	20	20	20	20	20	20
Hydroxypropyl methyl cellulose(mg)	500	300	-	-	-	-
Sodium alginate(mg)	-	-	500	600	-	-
Sodium carboxymethyl cellulose(mg)	-	-	-	-	400	500
Glycerin (ml)	1	1	1	1	1	1
Ethanol (ml)	1	1	1	1	1	1
DMSO (ml)	1	1	1	1	1	1
Water (ml)	1.5	1.5	1.5	1.5	1.5	1.5

***In-vitro* Drug Diffussion Study:**

The in vitro study of drug permeation through the semi permeable membrane was performed using a franz type glass diffusion cell. The modified cell having higher capacity (25 ml) is used to maintain sink condition. This membrane was mounted between the donor and receptor compartment of a diffusion cell. The transdermal patch was placed on the membrane and covered with aluminum foil. The receptor compartment of the diffusion cell was filled with isotonic phosphate buffer of pH 7.4. The hydrodynamics in the receptor compartment were maintained by stirring with a magnetic bead at constant rpm and the temperature was maintained at 37±0.5ºC. The diffusion was carried out

for 12 h and 1 ml sample was withdrawn at an interval of 1 h. The receptor phase was replenished with an equal volume of phosphate buffer at each sample withdrawal. The samples were analyzed for drug content spectrophotometrically at 254 nm

Drug release kinetics:

Diffusion data of above two methods was fitted in Zero order, First order and Higuchi equations. The mechanism of drug release was determined by using Higuchi equation.

Zero-Order Kinetics:

Zero order as cumulative amount of Percentage drug released vs time

$$C=K0t$$

Where K0 is the zero-order rate constant expressed in units of concentration/time and t is the time in hours. A graph of concentration vs time would yield a straight line with a slope equal to K0 and intercept the origin of the axes.

First order kinetics:

First order as log cumulative percentage of log (%) cumulative drug remaining vs time,

$$L o g C = L o g C o - k t / 2.303$$

Where C0 is the initial concentration of drug, k is the first order constant, and t is the time.

Higuchi Model:

Higuchi's model as cumulative percentage of drug released vs square root of time

$$Q = K t 1/2$$

Where K is the constant reflecting the design variables of the system and t is the time in hours. Hence, drug release rate is proportional to the reciprocal of the square root of time.

Kors meyer Peppas equations:

Korsmeyer peppas equation used to determine the mechanism of drug release form the polymer matrix of the tablet. Log cumulative percentage of drug released VS Log time, and the exponent n was calculated through the slope of the straight line.

$$Mt/M\infty=Ktn$$

Where $Mt/M\infty$ is the fractional solute release, t is the release time, K is a kinetic constant characteristic of the drug/polymer system, and n is an exponent that characterizes the mechanism of release of tracers. For cylindrical matrix tablets, if the exponent $n = 0.45$, then the drug release mechanism is Fickian diffusion, and if $0.45 < n < 0.89$, then it is non-Fickian or anomalous diffusion. An exponent value of 0.89 is indicative of Case-II Transport or typical zero-order release.

8. RESULTS AND DISCUSSION

Initially the drug was tested by UV to know their significant absorption maximum which can be used for the diffusion study of the drug.

8.1. Analysis of drug:

A. UV scan:

The lambda max of Thiochochicoside was found to be 254 nm.

B. construction of calibration curve:

Table 8.1: Standard graph of Thiochochicoside

Concentration(µg/ml)	Absorbance (at 254 nm)
0	0
2	0.111
4	0.224
6	0.339
8	0.442
10	0.557

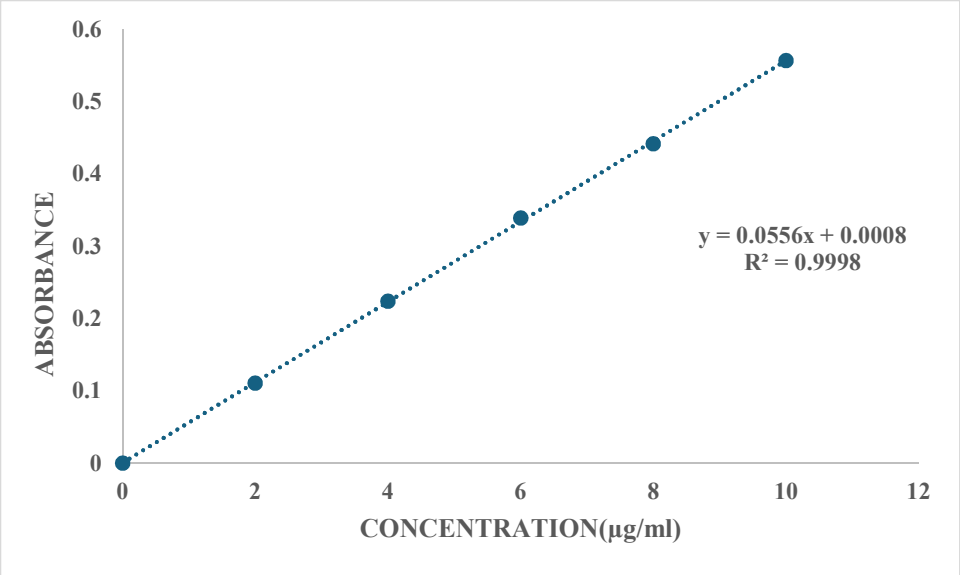


Figure 8.1: Standard calibration curve of Thiochochicoside

8.2. Pre formulation study

Totally, six formulation trials were done with the aim to achieve the successful matrix type Thiochochicoside transdermal patches. The blend trials prepared for the drug was evaluated for various physical parameters and content uniformity of drug by UV.

A. Colour, odour, taste and appearance

Table 8.2: Results of identification tests of drug

Parameter	Thiochochicoside
Color	White
Odor	Odorless
Taste	Bitter
Appearance	A white powder

B. Melting point determination:

Table 8.3: Results of melting point determination tests of drug

Drug	Reported melting point
Thiochochicoside	207 to 210.0^{0}c

C. Determination of solubility:

Table 8.4: Solubility Determination

Solvent	Drug solubility(mg/ml)
Distilled water	0.0403
Ph 7.4 phosphate buffer	78.3

8.3 Evaluation of Patch

The formulations F1 to F6 were varying in thickness when compared to other formulations which is due to the variation in the polymer concentration. Which shows the increase in polymer concentration increases the thickness of patch. For all other formulations it was found to be in between 0.031 ± 0.005 to 0.039±0.001 mm.

All formulations from F1 to F 6 shows weight variation in between 62±5.41 to 69±5.36 mg.

Folding endurance from formulations F1 to F6 was found to be in between 71 ± 0.12 to 78 ± 2.65 which can withstand the folding of the skin.

All formulations showed % drug content from 96.2 ± 3.67 to 99.11 ± 2.41.

Table 8.5: Evaluation of patches

Formulation Code	Average weight(mg)	Thickness (mm)	Folding endurance	Flatness (%)	Flatness (%)	% Drug Content
F1	65±1.05	0.031 ± 0.005	73 ± 1.25	98	Transparent	96.2 ± 3.67
F2	69±5.36	0.035±0.006	78 ± 2.65	96	Transparent	99.11 ± 2.41
F3	67±2.84	0.039±0.001	71 ± 0.12	99	Transparent	98.10 ± 3.29
F4	62±5.41	0.033±0.007	78 ± 1.41	97	Transparent	97.32 ± 1.64
F5	66±9.18	0.036±0.002	75 ± 2.32	100	Transparent	98.42 ± 4.35
F6	63±4.69	0.032±0.005	77 ± 1.14	99	Transparent	97.24 ± 2.15

***In vitro* diffusion study:**

All the formulation *in vitro* diffusion study was carried out by using Franz type diffusion cell under specific condition such as temp maintained at 32 ± 0.5 °C. The diffusion was carried out for 12 h and 5 ml sample was withdrawn at an interval of 1 h.

Table 8.6: *In vitro* drug permeation of Thiochochicoside containing different concentrations of Hydroxypropyl methyl cellulose

Time (Hrs)	F1	F2
0	0	0
1	19.34	16.52
2	22.13	21.89
3	28.55	24.41
4	33.93	29.43
5	42.23	36.17
6	53.46	42.46
7	59.14	48.71

8	66.92	54.86
9	73.73	62.92
10	79.65	74.24
11	83.41	89.72
12	89.53	94.19

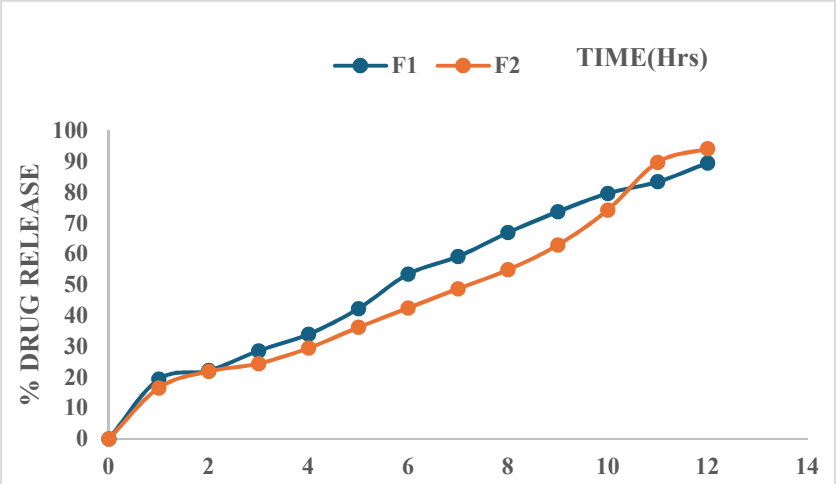


Figure: 8.2 Cumulative % drug permeation of Thiochochicoside patch (F1, F2)

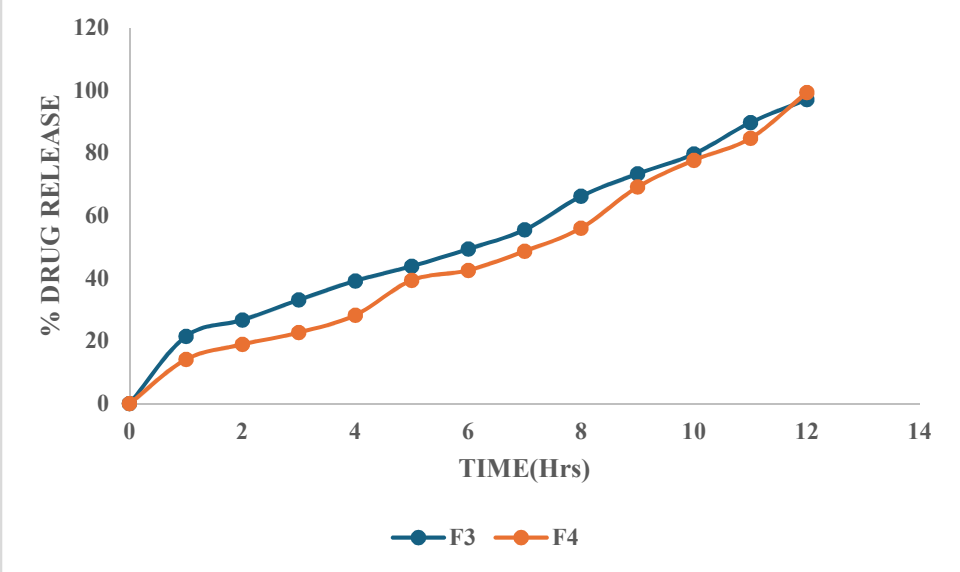
The formulations F1 to F2 were prepared by different concentrations of Hydroxypropyl methyl cellulose (500 and 300mg) the drug release or drug permeation from the patch was dependence on the concentration of polymer in the matrix. At low polymer concentration the drug permeation is more within 12 hours it was total amount of drug was permeated. The 500mg concentration of polymer was showed maximum drug released at 12 hrs 94.19 %. The 300mg

Table: 8.7 *In vitro* drug permeation of Thiochochicoside containing different concentrations of Sodium alginate

Time (Hrs)	F3	F4
0	0	0
1	21.51	14.13
2	26.73	18.92
3	33.17	22.74
4	39.23	28.29

5	43.92	39.43
6	49.41	42.61
7	55.57	48.74
8	66.26	56.12
9	73.43	69.23
10	79.79	77.79
11	89.82	84.82
12	97.14	99.43

Figure:8.3 Cumulative % drug permeation of Thiochochicoside patch (F3, F4)

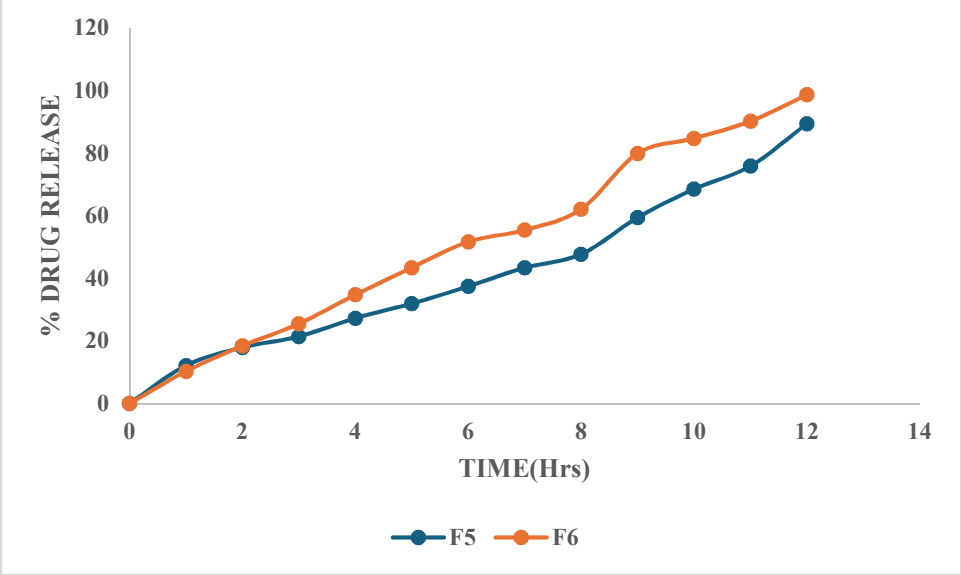


The formulations F3 to F4 were prepared by different concentrations of Sodium alginate (500,600 mg), the drug release or drug permeation from the patch was dependence on the concentration of polymer in the matrix. The 600 mg (F4) concentration of polymer was showed maximum drug release 99.43% within 12 hours .

Table: 8.8 *In vitro* drug permeation of Thiochochicoside containing different concentrations of Sodium carboxymethyl cellulose

Time (Hrs)	F5	F6
0	0	0
1	12.14	10.29
2	17.92	18.43
3	21.43	25.51
4	27.25	34.76
5	31.94	43.42
6	37.43	51.67
7	43.37	55.43
8	47.73	62.15
9	59.41	79.93
10	68.52	84.74
11	75.89	90.21
12	89.41	98.68

Figure:8.4 Cumulative % drug permeation of Thiochochicoside patch



The formulations F5 to F6 were prepared by different concentrations of Sodium carboxymethyl cellulose (400,500 mg), the drug release or drug permeation from the patch was dependence on the concentration of polymer in the matrix. The 400mg (F5) concentration of polymer was showed maximum drug released at 12 hors 89.41%. The 500mg (F6) concentration of polymer was showed less drug release 98.68at 12 h.

Among all 6 formulations F4 formulation showed good drug permeation from the patch.
Among all *in vitro* evaluation parameters F4 formulation passed all evaluation parameters.

8.4 Kinetic models for Thiochochicoside

Various models were tested for explaining the kinetics of drug release. To analyze the mechanism of the drug release rate kinetics of the dosage form, the obtained data were fitted into zero-order, first order, Higuchi, and Korsmeyer-Peppas release model.

Table:8.8 Kinetics data of F4 Thiochochicoside patch

CUMULATIVE (%) RELEASE Q	TIME (T)	ROOT (T)	LOG (%) RELEASE	LOG (T)	LOG (%) REMAIN	RELEASE RATE (CUMULATIVE % RELEASE / t)	1/CUM% RELEASE	PEPPAS log Q/100	% Drug Remaining	Q01/3	Qt1/3	Q01/3-Qt1/3
0	0	0			2.000				100	4.642	4.642	0.000
14.13	1	1.000	1.124	0.000	1.938	13.310	0.0751	-0.876	86.69	4.642	4.426	0.216
18.92	2	1.414	1.212	0.301	1.923	8.145	0.0614	-0.788	83.71	4.642	4.374	0.267
22.74	3	1.732	1.352	0.477	1.889	7.490	0.0445	-0.648	77.53	4.642	4.264	0.378
28.29	4	2.000	1.430	0.602	1.864	6.730	0.0371	-0.570	73.08	4.642	4.181	0.461
39.43	5	2.236	1.595	0.699	1.783	7.868	0.0254	-0.405	60.66	4.642	3.929	0.712
42.61	6	2.449	1.625	0.778	1.762	7.027	0.0237	-0.375	57.84	4.642	3.867	0.774
48.74	7	2.646	1.685	0.845	1.712	6.924	0.0206	-0.315	51.53	4.642	3.721	0.920
56.12	8	2.828	1.742	0.903	1.651	6.901	0.0181	-0.258	44.79	4.642	3.551	1.090
69.23	9	3.000	1.835	0.954	1.501	7.591	0.0146	-0.165	31.68	4.642	3.164	1.477
77.79	10	3.162	1.886	1.000	1.362	7.697	0.0130	-0.114	23.03	4.642	2.845	1.796
84.82	11	3.317	1.921	1.041	1.223	7.571	0.0120	-0.079	16.72	4.642	2.557	2.085
99.43	12	3.464	1.997	1.079	-0.180	8.278	0.0101	-0.003	0.66	4.642	0.871	3.771

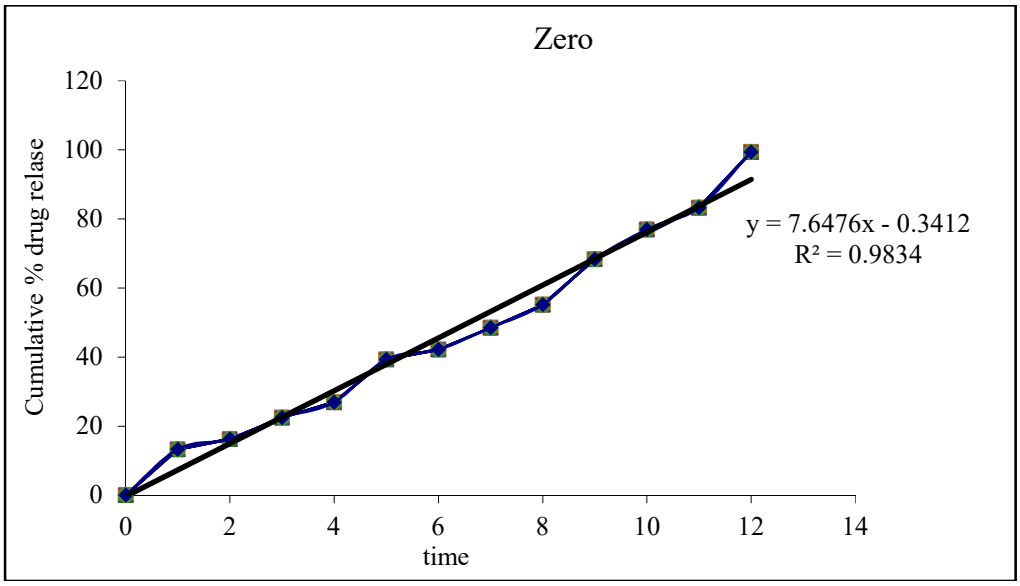


Figure: 8.4 Graph of Zero order kinetics

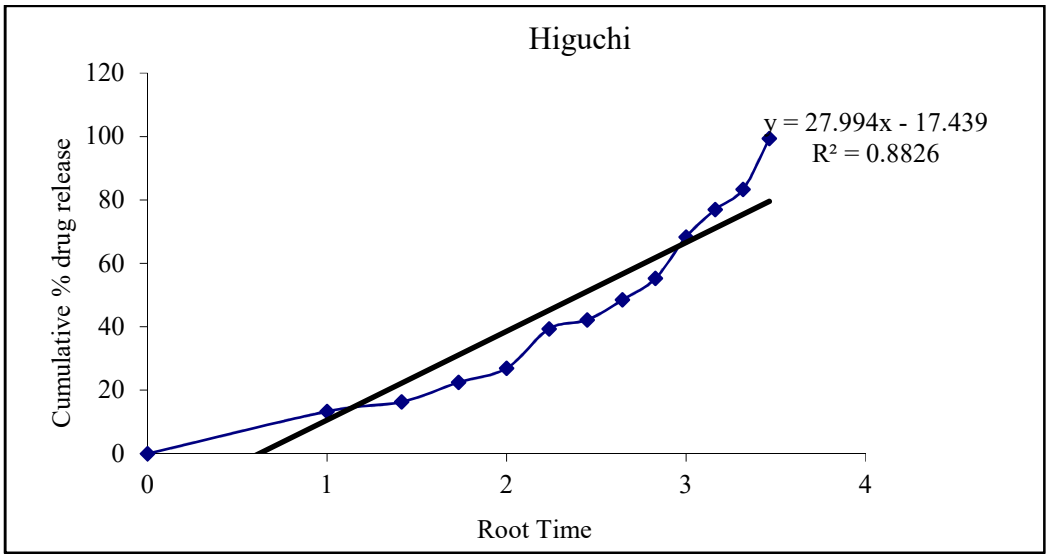


Figure: 8.5 Graph of Higuchi release kinetics

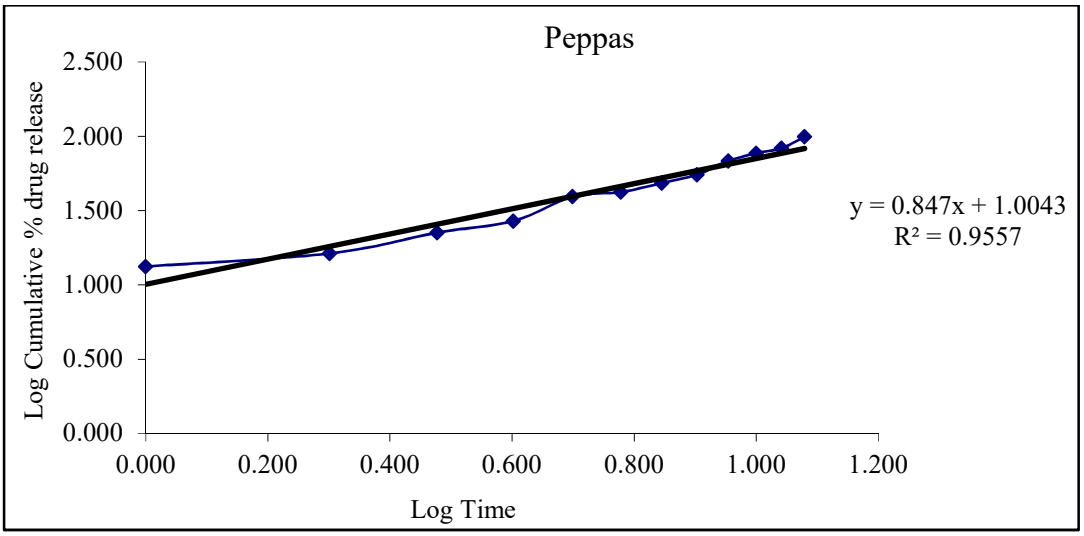


Figure :8.6 Graph of peppas release kinetics

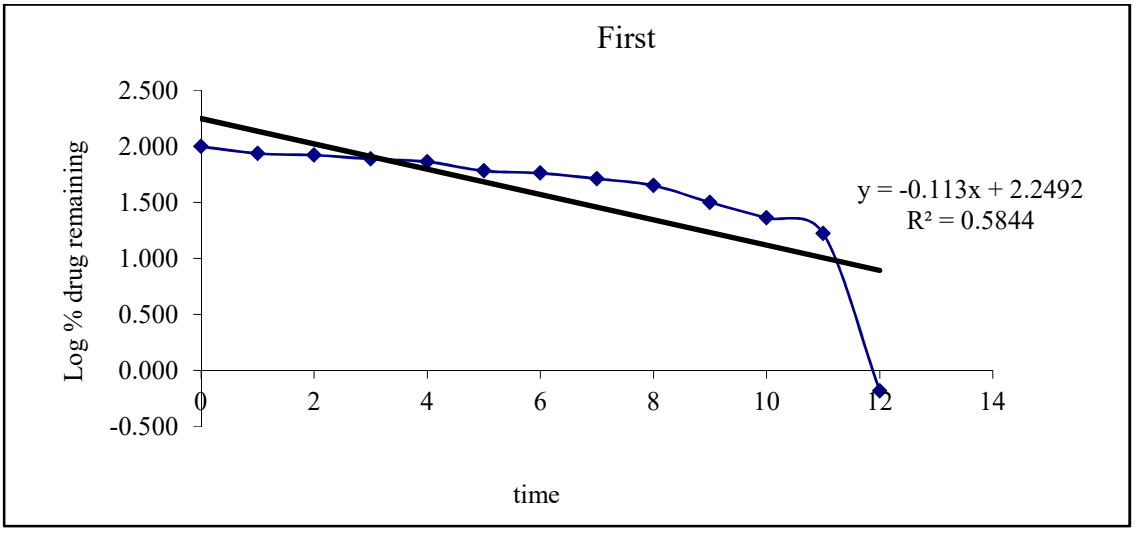


Figure: 8.7 Graph of First order release kinetics

From the above data the optimized formulation followed Zero order kinetics model rule.

8.2. Compatibility studies:

IR SPECTROSCOPY:

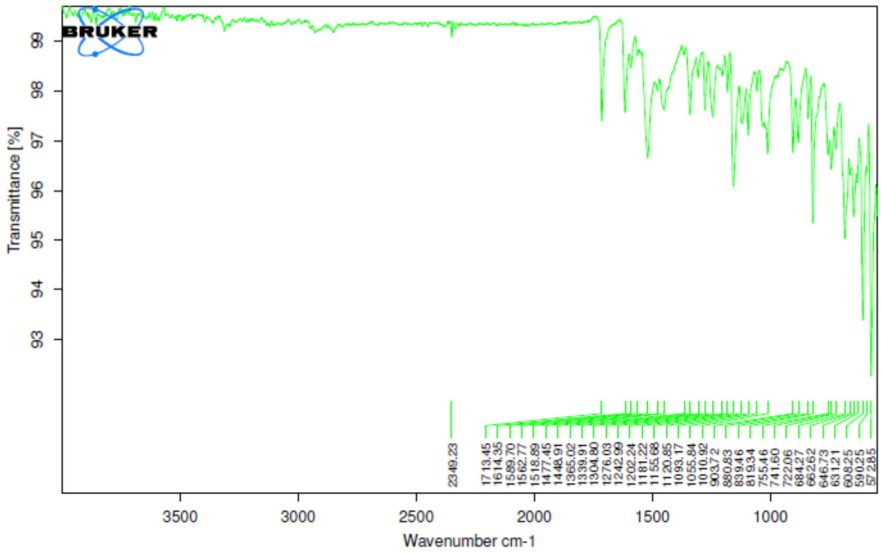


Figure 8.8: FTIR Spectrum of pure Thiochochicoside drug

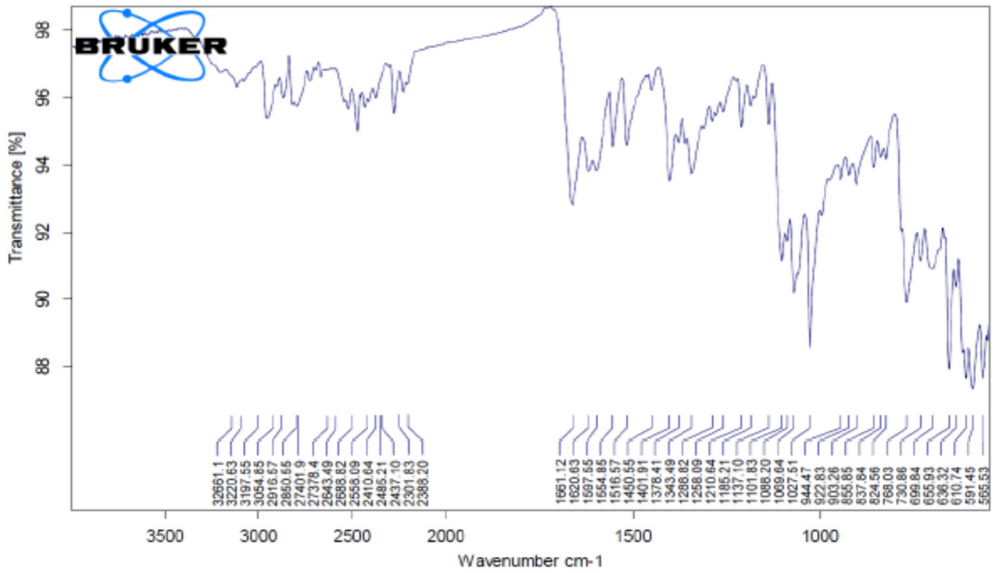


Figure 8.9: FTIR of Optimized formulation

The compatibility studies of the drug with excipients indicate no characteristic visual changes and no additional peaks were observed during FT-IR studies.

CONCLUSION

The present study successfully formulated and evaluated Thiocolchicoside-loaded transdermal patches using various polymers and plasticizers with the objective of achieving sustained drug delivery and enhanced patient compliance. Among the different formulations developed, the optimized patch exhibited desirable physicochemical characteristics including uniform drug content, adequate thickness, flexibility, folding endurance, and excellent adhesive properties.

In-vitro drug release studies revealed a sustained and controlled release profile of Thiocolchicoside over 12hours, indicating the potential of the transdermal route in reducing dosing frequency and minimizing gastrointestinal side effects commonly associated with oral administration. The optimized formulation followed [mention kinetic model, e.g., Higuchi or

Korsmeyer-Peppas] release kinetics, suggesting diffusion-controlled or matrix-mediated drug release.

Overall, the study concludes that Thiocolchicoside-loaded transdermal patches represent a promising alternative drug delivery system for muscle relaxant therapy, offering better therapeutic efficacy, patient convenience, and controlled release characteristics.

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