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Development And Characterization Of Transdermal Patches Of Fluphenazine

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Abstract: *The bulk of small molecule medications are often administered orally, making oral and parenteral routes the most popular drug delivery methods. Predetermined dosages, mobility, and patient self-administration are the benefits of the oral route. Because of these factors, the oral route continues to be the most practical way to administer drugs. Therefore, injection is the main method of delivering macromolecules. However, this method has drawbacks, including the need for a professional administrator to give the injections, their intrusive character, which causes discomfort, and patients' decreased acceptability or compliance. It stands to reason that enhanced drug administration techniques like transdermal drug delivery (TDD) may be able to overcome the many inherent constraints of traditional medicine delivery methods. With methods like transdermal patches that adhere to a portion of the skin, we could be enhancing the therapeutic efficacy of medications. By arranging several penetration enhancers, the patch's strength of adhesion produces a strong penetration ability of TDDs.*
Keywords: *Topical drug delivery, TDDS, Antipsychotic drug, fluphenazine*

INTRODUCTION:

Topical remedies anointed, bandaged, rubbed or applied to the skin are likely to have been used since the origin of man, with the practices becoming evident with the appearance of written records, such as on the clay tablets used by the Sumerians [1]. Indeed, it has been suggested that a liquefied ochre-rich mixture, made some 100 000 years ago and found at the Blombos Cave in South Africa, may have been used for decoration and skin protection. Ancient Egyptians used oil (e.g. castor, olive and sesame), fats (mainly animals), perfumes (e.g. bitter almond, peppermint and rosemary) and other ingredients to make their cosmetic and dermatological products (unguents, creams, pomades, rouges, powders, and eye and nail paints). The mineral ores of copper (malachite: green) and lead (galena: dark grey) were used to prepare kohl, a paste used to paint the eyes [2]. Red ochre was used as a lip or face paint, and a mixture of powdered lime and oil was used as a cleansing cream. The ancient lead-based products were applied for both appearance and, based upon religious beliefs, for protection against eye diseases [3]. However, these effects may have been real as recent studies involving incubation of low lead ion concentrations with skin cells produced NO, which is known to provide defence against infection. On the negative side, it could be asked if these lead products also caused toxicity, noting that high blood levels of lead have been reported in modern kohl users. A transdermal patch is used to deliver a specific dose of medication through the skin and into bloodstream. Transdermal patches products were first approved in 1981 by FDA [4]. Transdermal delivery systems are currently available containing scopolamine (hyoscine) for motion sickness, clonidine and nitroglycerin for cardiovascular disease, fentanyl for chronic pain, nicotine to aid smoking cessation. Transdermal delivery provides controlled, constant administration of the drug, and allows continuous input of drugs with short biological half-lives and eliminates pulsed entry into systemic circulation [5]. TDDS offers many advantages over conventional injection and oral methods. It reduces the load that the oral route commonly places on the digestive tract and liver. It enhances patient compliance and minimizes harmful side effects of a drug caused from temporary overdose. It is convenient, especially notable in patches which require only once weekly application. Such a simple dosing regimen aids in patient adherence to drug therapy [6]. Polymer matrix– backbone of TDDS, which control the release of the drug. Polymer should be chemically non-reactive, should not decompose on storage, should be nontoxic, cost should not be high. E.g.- cellulose derivatives, zein, gelatin, shellac, waxes, gums, Polybutadiene, hydrin rubber, polyisobutylene, silicon rubber, nitrile, acrylonitrile, neoprene, Polyvinyl alcohol, polyvinylchloride, polyethylene, polypropylene, polyacrylate, polyamide, polyurea, polyvinylpyrrolidone, polymethylmethacrylate [7]. Transdermal patch technology is a valuable drug delivery method with many advantages over other delivery routes. Patches can bypass the digestive system and first-pass metabolism to provide continuous dosing of drugs over an extended period of time.

They are commonly used to deliver drugs for various indications such as chronic pain, motion sickness, and hormone replacement therapy. In recent years, there have been many advances in transdermal patch technology, including the development of smart, dissolving/biodegradable, high-loading/release and 3D-printed patches. Transdermal patches have the potential to provide a convenient and effective means of drug delivery for a variety of ailments, but some challenges lie ahead, such as the possibility of self-inflicted toxicity due to improper dosing, poor adhesion, low drug penetration, potential trigger for skin irritation, or patch failure. All of this warrants further research and development to optimize the safety and efficacy of this delivery system [8]. Fluphenazine is a phenothiazine used to treat patients requiring long-term neuroleptic therapy. Fluphenazine is a trifluoro-methyl phenothiazine derivative intended for the management of schizophrenia and other psychotic disorders. Fluphenazine has not been shown effective in the management of behaviorial complications in patients with mental retardation. Fluphenazine blocks postsynaptic mesolimbic dopaminergic D1 and D2 receptors in the brain; depresses the release of hypothalamic and hypophyseal hormones and is believed to depress the reticular activating system thus affecting basal metabolism, body temperature, wakefulness, vasomotor tone, and emesis.

MATERIAL AND METHODS

Identification of maximum absorption wavelength (λmax): The identification of absorption maxima was determined by UV scanning of drug solution under ultraviolet spectrophotometer between 200 to 400 nm wavelengths offer drug sample i.e. Fluphenazine. Accurately weighed required quantity 50 mg of drug sample i.e. fluphenazine mixed in volumetric flask containing 50 ml of phosphate buffer pH 7.4 solvent. The solution was sonicated in bath sonicator for 20 min. The resulting solution was known as Stock-I, having concentration of 1000 µg/ml solution. Take 1 ml of Stock - I solution and diluted with phosphate buffer pH 7.4 solvent up to 100 ml in other volumetric flask separately and again sonicated for 20 min. The resulting solution was known as Stock-II, having concentration of 10 µg / ml solution. The resulting solution Stock II was run within the range of 200 – 400 nm range in double beam UV spectrophotometer (Shimadzu, UV-1800, Shimadzu Corporation, Japan) [9].

Preparation of standard calibration curve of fluphenazine in phosphate buffer pH 7.4 solution: Accurately weighed required quantity 50 mg of drug sample i.e. fluphenazine mixed in volumetric flask containing 50 ml of phosphate buffer pH 7.4 solvent. The solution was sonicated in bath sonicator for 20 min. The resulting solution was known as Stock-I, having concentration of 1000 µg/ml solution. Take 1 ml of Stock - I solution and diluted with phosphate buffer pH 7.4 solvent up to 100 ml in other volumetric flask separately and again sonicated for 20 min. The resulting solution was known as Stock-II, having concentration of 10 µg / ml solution. Now, for the preparation of calibration curve aliquots of 1 ml, 2.0 ml, 3.0 ml upto 5.0 ml were withdrawn from above Stock-II and diluted up to 10 ml with phosphate buffer pH 7.4 solvent in volumetric flasks. The concentration of resulting solutions were 10 µg / ml, 20 µg / ml, 30 µg / ml, upto 50 µg / ml respectively. The absorbance of all resulting solution was calculated individually at 260 nm with phosphate buffer pH 7.4 as a blank. The absorbance was measured and standard curve was plotted between absorbance vs. concentration [10].

Validation of analytical method development

Specificity test: The specificity test for the analytical method is defined as the capability to notice the analyte of attention in the occurrence of interfering material. Specificity is exposed by spiking recognized stage of impurities or corrupting agents in to a test with a known quantity of the analyte of concentration.

Precision test: As per the ICH guidelines precision test was classified in to two parameters i.e.; repeatability test and intermediate precision test.

Repeatability test Accurately weighed required quantity 50 mg of drug sample i.e. Fluphenazine mixed in volumetric flask containing 50 ml of phosphate buffer pH 7.4 solvent. The solution was sonicated in bath sonicator for 20 min. The resulting solution was known as Stock-I, having concentration of 1000 µg/ml solution. Take 1 ml of Stock - I solution and diluted with phosphate buffer pH 7.4 solvent up to 100 ml in another volumetric flask separately and again sonicated for 20 min. The resulting solution was known as Stock-II, having concentration of 10 µg / ml solution. So, for identification of absorbance of each drug solution was measured with phosphate buffer pH 7.4 as blank solution at different time

intervals with replicates of ten times. The absorbance was determined at 260 nm for fluphenazine using UV spectrophotometer. As per the guideline the percent RSD should not be more than 1 %.

Intermediate precision test: As per guidelines Intermediate precision test was also classified in to two parameters i.e.; Intra-day precision test and Inter-day precision precision test. Intra-day precision was determined at predetermined time interval within a day by assessment of the absorbance of 10 µg / ml drug Fluphenazine in phosphate buffer pH 7.4 solution. Inter-day precision test was determined on three different days by by assessment of the absorbance of 10 µg / ml drug Fluphenazine in phosphate buffer pH 7.4 solution. The absorbance was determined at 260 nm for fluphenazine using UV spectrophotometer. As per the guideline the percent RSD should not be more than 1 %. The results of intra-day and inter-day precision test.

Accuracy test: The test of accuracy study of analytical method was specified as the difference between the measured quantity and the used quantity [11].

Preformulation Studies: The class of studies which need to be successfully completed before actually the formulation development and optimization starts are termed as preformulation studies. These studies are important as the processes for optimizing the delivery of candidate drug through determination of physicochemical properties of drug that could influence drug performance and development of an efficacious, safe and stable dosage form, These studies must resolve problems with drug analysis, stability, and pharmaceutical technology. Complete preformulation studies can decrease problems with instability of drug formulations during the shelf-life period caused by the selection of unsuitable excipients. The major parameters studied in this category are: characterization of the Active pharmaceutical ingredient (API), development of analytical methods, stability and compatibility studies of the drug with the excipients etc, It is through the proper completion of these preformulation studies that an optimal dosage form for desired therapeutic efficacy and utility could be designed. Preformulation studies of Fluphenazine were carried out, which included physicochemical characterization of drug (melting point, solubility, infra-red spectroscopy, particle size analysis, nuclear magnetic resonance spectroscopy [12].

Preparation of the fluphenazine transdermal patch: The objective of present study was to prepare transdermal film containing Fluphenazine able to release drug within short time interval. The sodium alginate/ carboxy methyl cellulose solutions or guargum were prepared separately by dissolving the required quantities in distilled water, whereas chitosan solution was prepared by dissolving the polymer in 1 % v/v acetic acid solution with stirring at 40 °C. The API Fluphenazine quantity 20 mg were dissolved in casing solvent before addition of polymeric solution separately as given in **Table 1**. The drug polymer mixture was continuously stirred on thermostatic magnetic stirrer at 37±2°C. The plasticizers Glycerin/ PVP/ PEG400 were added with stirring. All the solutions were allowed to stand overnight to remove the air bubbles. After stirring completion, it was sonicated in ultrasonic water bath and poured in petri dishes containing mercury base having circular glass bangles with open at both sides. The bottom of the bangle was wrapped with aluminum foil to allow solvent evaporation at 35°C (Olven Instruments, India). The films were prepared by solvent casting method. The dried films were separated, cut into circular films of 2 cm^2 (4 mg drug), wrapped in aluminum foil and stored in air tight polyethylene bags in desiccators [13-14].

Characterization of transdermal patch:

Physical appearance: The parameters i.e. "optical checking, smoothness, color, transparency and flexibility" were observed**.**

Thickness: Measurement of thickness of patch was performed by utilizing a screw gauge (least count of 0.02 mm)

Weight variation: Prepared polymeric patch was weighed cautiously in triplicate manner and calculated the mean. The weight of individual patch should be within permitted limit the mean weight of patch.

Uniformity of content: The prepared patch were cut as strips. One patch cut from centre and two were cut from other sides. After cutting the strips of patch, measure the length by using scale. There should not be any constriction in patch [15].

Surface pH: Digital pH meter was used to determine the pH of surface of prepared patch. The prepared patch piece was cut and kept in 0.5 ml double distilled water and allowed to swell for 1 h.

Tensile strength: Tensile strength of 2 cm^2 film was measured by using fabricated tensile strength apparatus. The patch were fixed by tapes and placed in the film holder. A small hole was made in the adhesive tape in which a hook was inserted. A thread was tied to this hook. This hook was passed over the pulley and a small pin attached to the other end to the hold the weights. A small pointer was attached to the thread, which travels over the graph paper affixed on the base plate. Now add the weights from initial low mass to the more until the patch was broken. The weight required to break the patch was noted as break force and tensile strength calculated by the following formulae

Tensile strength (N / mm^2) = Breaking force (N) / Cross sectional area of sample (mm^2)

Folding endurance: Folding endurance of prepared patch was ascertained by manual method as cutting a portion of patch. The cut piece or portion of patch was folded at the same place. The folding procedure was performed repeatedly till the patch broke. Folding endurance were calculated mean of the number of times the patch was folded at the same place without breaking [16]**.**

Moisture content: The patches were weighed, dried with current of air at 60°C and were kept in desiccators having calcium chloride at 40°C for 24 h. Then dried patch were kept at room temperature and temperature 75 ± 0.5% Relative humidity (75% humidity maintained by saturated solution of sodium chloride during storage till equilibrium, weighed patch, calculated the increase in weight percent.

Swelling Ratio: Patches were placed in petri dish having distilled water till patch achieved constant weight, which as ascertained by weighed the patch at a certain time interval. Degree of swelling (SR %) was calculated using the below equation**.**

$$\text{SR (\%)} = \frac{\text{Mass of patch at time of investigation} - \text{Initial mass of patch}}{\text{Initial mass of patch}} * 100$$

Moisture uptake percentage: Moisture uptake percentage was determined by weighted the piece of patch which was carefully cut by knife. It was placed in desiccators for 24 h at temperature 25-30°C; 75% Relative humidity, then weighed and calculated moisture uptake property using the below equation.

$$\text{Moisture uptake percentage of film} = \frac{\text{Final mass of patch - Initial mass of Film}}{\text{Initial mass of Film}} \times 100$$

Drug content: Square piece of prepared patch (2^2 cm) placed in of dissolution medium (100 ml), stirred constantly for 24 hours. The resulting mixture was ultrasonicated for 15 min, filtered. Filtrate was diluted with same dissolution medium and subjected to UV method for drug content determination [17].

In vitro skin permeation study (Bhattacharya and Ghosal, 2000): In vitro drug release study was performed using distilled water in a glass Franz-diffusion cell composed in laboratory. The prepared formulations films 2 cm^2 were cut and were uniformly spread onto the cellophane membrane in between donor and receptor compartments of the diffusion cell and were held tightly by springs. The donor compartment was empty, whereas the receptor compartment was filled with 75 ml of phosphate buffered saline (pH 7.4). The magnetic stirrer was set at 100 rpm and the temperature was maintained at 37±5°C. The amount of drug released was determined by withdrawing 5 ml aliquots at different time intervals upto 12 h. The volume withdrawn was replaced with an equal volume of fresh, prewarmed (37±5°C) phosphate buffered saline (pH 7.4). The resulting aliquates was ultrasonicated for 15 min, filtered. Filtrate was diluted with same dissolution medium and subjected to UV method for drug content determination at 260 nm [18].

RESULTS AND DISCUSSION

The absorption maxima (λ-max) of fluphenazine (10 µg / ml) in pH 7.4 phosphate buffer solution were found to be at 260 nm respectively. The spectrum peak point graph of absorbance of drug vs. wavelength is shown in Figure 1. Fluphenazine was estimated in-vitro by reported UV spectrophotometric methods. The reported UV spectrophotometric methods were slightly modified and optimized according to the existing laboratory conditions. The drug was estimated in the dissolution medium (pH 7.4 phosphate buffer). The calibration curves in the various dissolution medium (pH 7.4 phosphate buffer) were prepared with drug solutions of known concentrations. The calibration curves show excellent linearity of data as evidenced by the values of correlation coefficients that were found to be greater than 0.99. The curves were found to be recti-linear in the concentration range 10 µg / ml to 50 µg / ml for the drug. The estimation procedures for drugs were found to be sensitive, precise and reproducible. The sensory

evaluation test of drug sample i.e. Color, odor and taste etc were observed and the result were shown in Table 6.7. The drug sample fluphenazine was white in color, odorless and slightly bitter in taste. The particle shape of fluphenazine were crystalline in nature. The particle size of unmilled Fluphenazine was to be 82 μm. The flow properties of drug powders were characterized shown in Table 6.8. The result was concluded that unmilled powders have good to passable type of flow in nature. The solubility of fluphenazine at Water, 0.1 N HCl, Phosphate buffer pH 4.5, Phosphate buffer pH 6.8 and Phosphate buffer pH 7.4 were 1.323 (mg / ml), 1.786 (mg / ml), 0.821 (mg / ml), 3.122 (mg / ml) and 1.061 (mg / ml) respectively. The results were shown in Table 6.10. The partition coefficient of fluphenazine was found to be 1.93 (Table 6.9). The melting point of drug sample fluphenazine was 123°C (Table 6.10). The interpretation of IR study spectrum is shown in Figure 6.6 – 6.7. The FTIR spectra of pure fluphenazine illustrated sharp distinctive peaks at The spectrum of FLZ (Figure 9A) shows different absorption peaks; for example, the band at 3,200 cm−1 is related to the O-H stretching vibrations, while the band at 3,053 cm−1 is related to the C-H stretching vibrations of rings 1 and 2 (Figure 11). The band at 1,602 cm−1 was related to the stretching vibrations of C-S-C and C-C at rings 1 and 2. The bands at 1,240 cm−1 are related to the stretching vibration of C-H at rings I and II and also the stretching vibration of CF−3−. All the above distinctive peaks appeared in the spectra of physical mixture at the same wave numbers representing no alteration or communication between the polymers and drug.

The prepared fluphenazine transdermal patch were characterized a number of optimized parameters i.e. “optical checking, smoothness color, transparency and flexibility, thickness, weight variation, uniformity of content, surface pH of patch, tensile strength, Folding endurance, percent elongation, Water uptake property, swelling index, Wetness of patch. The values obtained after the examination identified by in-vitro drug release study (58.34 – 95.37 %), that polymers chitosan have hydrophilic nature and able to enhanced spreadability and dispersibility of the water-soluble Fluphenazine. The hydrophilic polymer layer produces a water-permeable with more hydrated patch. Such hydration allows losing the polymer matrix and consequently enhanced drug release more than 95.5% within a 6 - 7 h as needed for immediate release. The polymeric transdermal patch (FTP3) were selected on the basis of its physical appearance, tensile strength, percentage elongation, folding endurance, swelling ratio, moisture content, moisture uptake nature, drug content and in-vitro drug release study parameters. The release kinetic study confirmed the prepared patch was followed supercase II transport mechanism of diffusion kinetics (with sustained release within specific time period. Regression analysis was performed and the r^2 values suggested that the curves were fairly linear and slope values were computed from the graph.

Summary And Conclusion: Complex drug regimens can further confuse patients, leading to poor medication compliance. The foundation of currently recommended treatment plans is the use of antipsychotics; however, since the pathophysiology of the disease is not completely known, the available drugs are designed to target for treatment. The purpose of the present research work was to design, assess, and estimate the developed transdermal matrix-type formulation comprising fluphenazine with the objective of enhancing the bioavailability and compliance of the patient. Transdermal patch of fluphenazine were developed using a solvent casting method.

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Table 1: Preparation of fluphenazine containing transdermal patch

F. Code	Polymers (gm)				Plasticizers		Stabilizer
	Sodium alginate	Chitosan	Guar gum	Carboxy methyl cellulose	Glycerine (ml)	PVP (gm)	Tween 80 (ml)
FTP1	2	-	-	-	5	-	1
FTP2	-	2	-	-	5	-	1
FTP3	-	-	2	-	5	-	1
FTP4				2	5	-	1
FTP5	2	-	-	-	-	1	1
FTP6	-	2	-	-	-	1	1
FTP7	-	-	2	-	-	1	1
FTP8				2		1	1

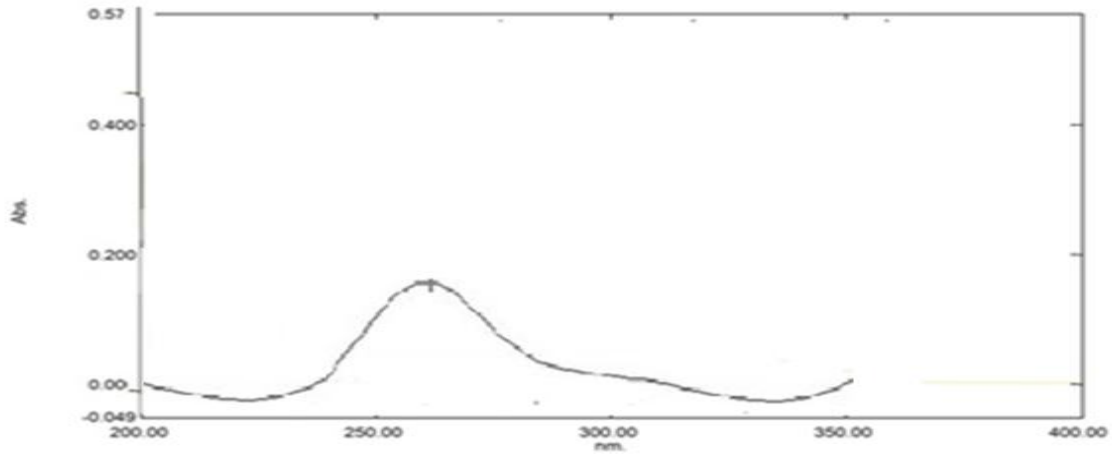

Figure 1: Absorption maxima (λ-max) of fluphenazine in phosphate buffer pH 7.4 solution (10 µg/ml)

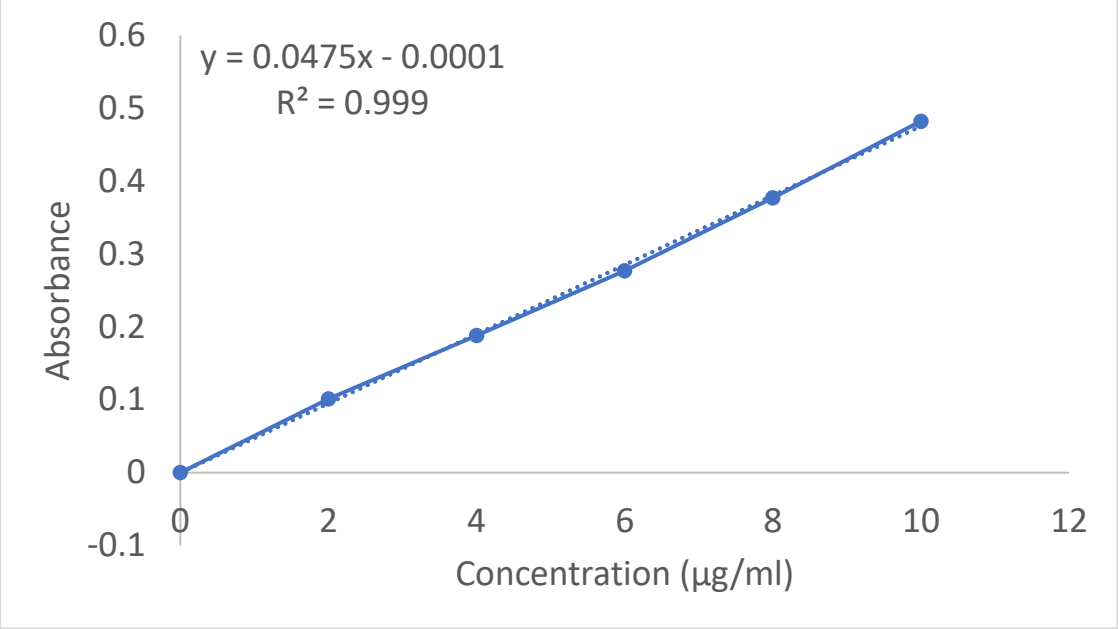

Figure 2: Standard curve of fluphenazine in phosphate buffer pH 7.4 solution (260 nm)

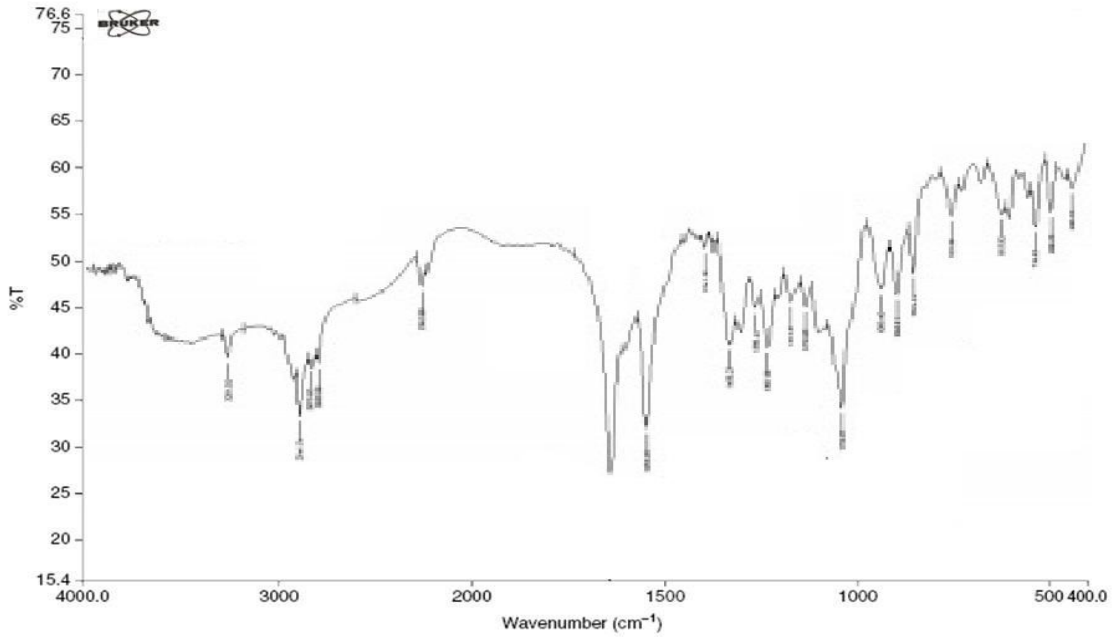

Figure 3: The I. R. Spectrum of Fluphenazine drug and all excipient (S2)

Table 2: Physical appearance of patch of Fluphenazine containing transdermal patch

Formulation code	Flexibility	Smoothness	Transparency	Stickness	Thickness (mm)	Average weight (mg)
FTP1	Flexible	Smooth	Transparent	Non sticky	0.31±0.03	113.32.±1.154
FTP2	Flexible	Smooth	Transparent	Non sticky	0.28±0.02	112.33±1.156
FTP3	Flexible	Smooth	Transparent	Non sticky	0.27±0.03	114.60±0.144
FTP4	Flexible	Smooth	Transparent	Son sticky	0.26±0.02	121.23±1.154
FTP5	Flexible	Smooth	Opaque	Non sticky	0.25±0.01	120.33±1.155

FTP6	Flexible	Smooth	Opaque	Non sticky	0.24±0.01	116.66±1.165
FTP7	Flexible	Smooth	Opaque	Non sticky	0.25±0.03	118.37±1.154
FTP8	Flexible	Smooth	Opaque	Non sticky	0.28±0.03	115.78±0.111

Table 3: Physical appearance of patch of Fluphenazine containing transdermal patch

Formulation code	Percentage Elongation Mean ± SD; n = 3	Tensile Strength N/mm^2	Swelling ratio (%)	Surface pH	Drug content
FTP1	95.74±0.15	4.66±1.18	23.97± 0.43	5.5 ± 0.14	93.99±0.8
FTP2	96.81± 0.02	8.69±0.23	22.32 ± 0.39	5.6 ± 0.14	94.95±0.9
FTP3	103.42± 0.09	6.93±0.13	22.18 ± 0.58	5.7 ± 0.12	95.79±0.10
FTP4	117.52± 0.02	8.79±0.23	21.43 ± 0.49	5.8± 0.12	99.59±0.11
FTP5	119.12± 0.03	6.86±1.18	19.42 ± 0.57	5.5 ± 0.13	98.07±0.12
FTP6	121.11±0.02	7.13±0.13	16.63 ± 0.54	5.5 ± 0.14	99.85±0.13
FTP7	97.91±0.15	6.76±1.18	20.13 ± 0.55	5.6 ± 0.14	97.55±0.14
FTP8	108.72±0.15	6.59±0.23	22.87 ± 0.46	5.7 ± 0.14	99.74±0.15

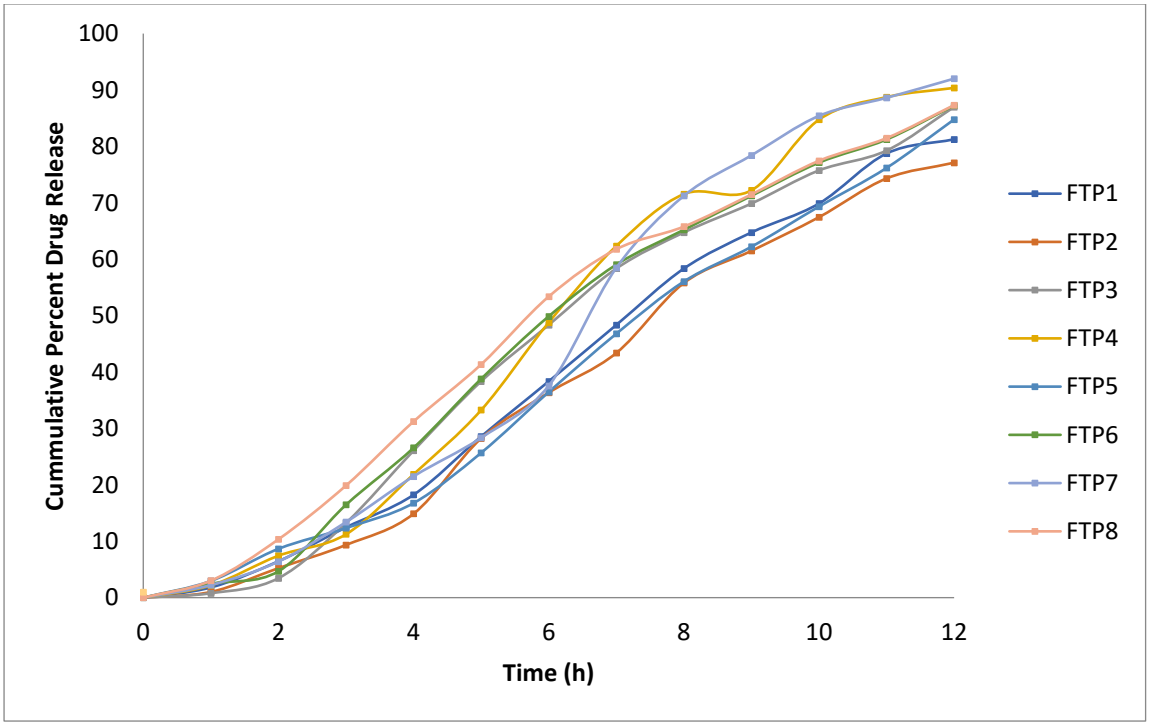

Figure 3: In vitro drug release profile (Zero-order) of Fluphenazine containing transdermal patch (FTP1-FTP8)