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RESEARCH ARTICLE

Formulation and *In-vitro* Evaluation of Lisuride Patches for Transdermal Drug Delivery System

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ABSTRACT

In present study transdermal drug delivery of Lisuride was developed to overcome the first pass metabolism and to reduce frequency of dosing compared to oral route. Oral drug delivery system has various drawbacks like poor bioavailability due to hepatic metabolism (first pass) and the tendency to produce rapid blood level spikes (both high and low), leading to a need for high and/or frequent dosing, which can be both cost prohibitive and inconvenient. Matrix type of transdermal patches was developed by using polymers Eudragit polymers Transdermal patches were prepared by employing solvent casting method. Drug excipient compatibility studies were carried out by using FTIR, and it was observed that there were no interactions. Formulations were prepared with the varying concentrations polymers ranging from F1-F9, and all the formulations were evaluated for various physical parameters Physical appearance, Flatness, Weight variation, Thickness, Folding endurance, Drug content, Moisture uptake, Moisture content and Swelling study and all the results were found to be were found to be within the pharmacopeial limits, in-vitro drug release studies by using dialysis membrane. Among all the 12 formulations F9 formulation which contains Eudragit S-100 and Eudragit L-100 25mg each had shown 99.6% cumulative drug release within 8 hours.

Keywords: Lisuride, Transdermal patches, Eudragit S-100, Eudragit L-100

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CONTENTS

1. Introduction

Transdermal therapeutic systems are defined as self-contained discrete dosage forms which, when applied to the intact skin, deliver the drug(s), through the skin, at controlled rate to the systemic circulation. Skin is the largest and easily accessible organ of the body and therefore can be extensively used as a prominent route of delivery for local and systemic effects. Though it presents a multifunctional barrier between body and surrounding particles, there are chances to deliver therapeutic carriers, particularly in diseased skin. For dermal and transdermal drug delivery, the horny layer, i.e, the uppermost layer of the skin serve as the most resistant layer to be crossed. To circumvent this barrier, different perforation techniques are used that relatively widen the skin opening and allow the passage of drug (≤ 10 mg) and micromolecules, but this amateur disruption of the skin can be avoided in order to preserve this barrier against cutaneous microbiota by using deformable carriers . Transdermal drug delivery system (TDDS) in this context provides a means to sustain drug release as well as reduce the intensity of action and thus minimize the side effects associated with its oral therapy. Transdermal systems are self contained, discrete dosage form. It delivers a drug through intact skin at a controlled rate into the systemic circulation. Delivery rate is controlled by the skin or membrane in the delivery system.

2. Materials and methods

Materials: Lisuride, Eudragit-L100, Eudragit-S100, Dimethyl formamide, Ethanol, Propylene glycol (Drops), all the chemicals used were lab grade.

Formulation:

Development of Transdermal patches:

Transdermal drug delivery patches were prepared by solvent casting method.

Solvent casting method: Transdermal patches were prepared according to the formula shown in Table 01. Eudragit L100, Eudragit S100 were weighed in requisite ratios and they were then dissolved in dimethyl formamide and ethanol as solvent using magnetic stirrer. Lisuride (10mg) with a magnetic stirrer**.** Propylene glycol and PEG 400 was added to the above dispersion under continuous stirring. The uniform dispersion was poured in the petri plate. The rate of evaporation of solvent was controlled by inverting cut funnel over the patches. After 24h, the dried films were taken out and stored in desiccator.

Evaluation: Physical appearance, Thickness, Weight variation, Flatness, Folding endurance, Moisture uptake, Moisture content, Drug content determination, In vitro permeation studies using dialysis membrane are the various evaluation tests performed to the prepared patches.

3. Results and discussion

Calibration curve method:

Evaluation of Lisuride Transdermal patches:

Physical appearance: All the Transdermal patches were visually inspected for colour, clarity, flexibility.

Flatness: All the Transdermal patches were found to be flat without any foams.

The prepared Lisuride Transdermal patches were evaluated for their physical parameters such as Physical appearance, Flatness, Weight variation, Thickness, Folding endurance, Drug content, Moisture uptake, Moisture content and all the results were found to be were found to be within the pharmacoepial limits.

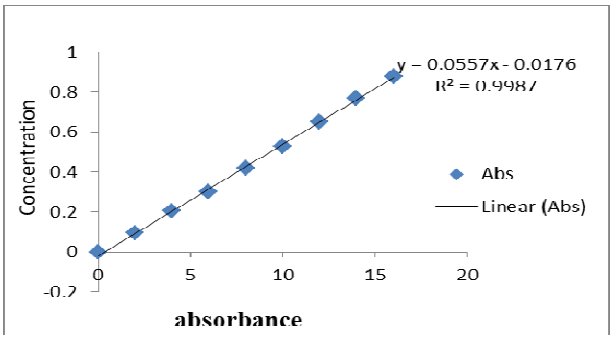

Fig 1: Standard curve of Lisuride

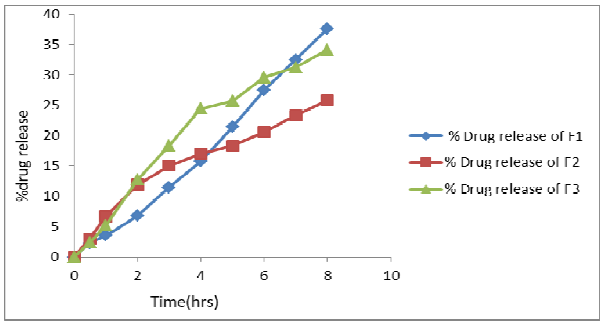

Fig 2: % drug release of F1, F2, F3

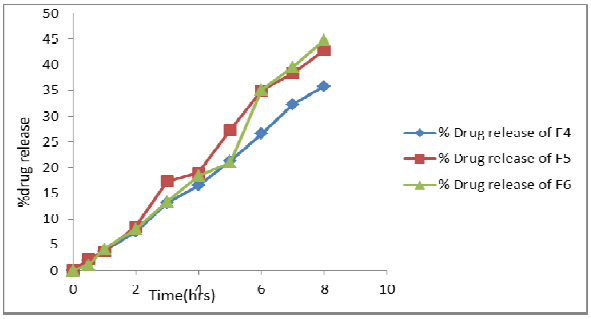

Fig 3: % drug release of F4, F5, F6

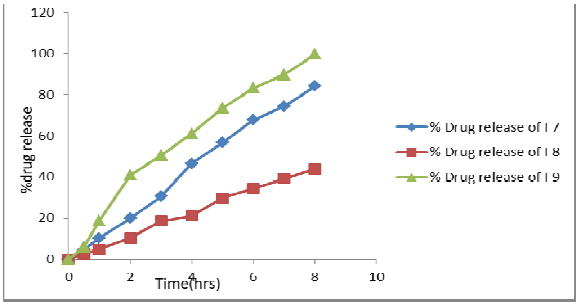

Fig 4: % drug release of F7, F8, F9

The prepared Lisuride Transdermal patches were evaluated for In-vitro permeation studies using dialysis membrane, among all the 9 formulations F9 formulation was shown 99.6% cumulative drug release within 8 hours.

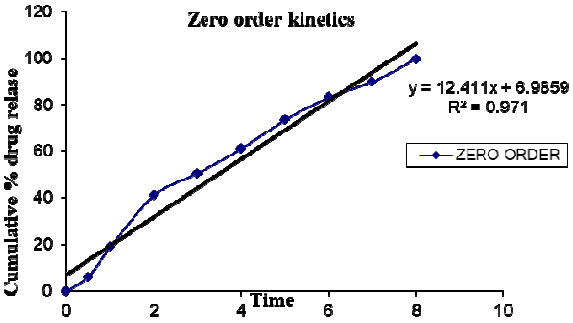

Fig 5: Zero order kinetics

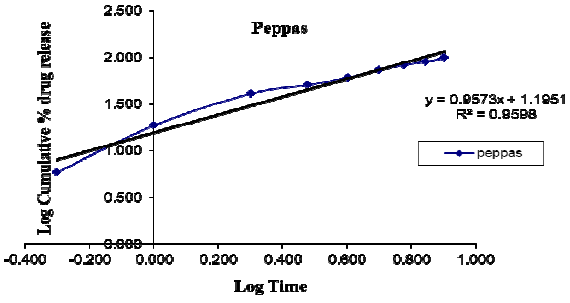

Fig 7: Peppas plot

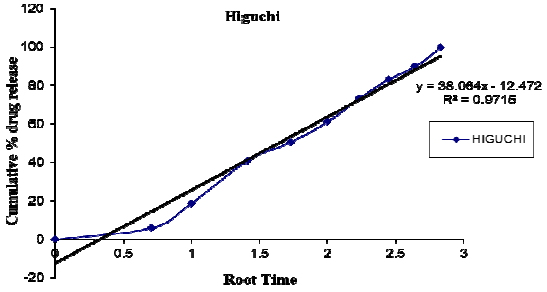

Fig 6: Higuchi plot

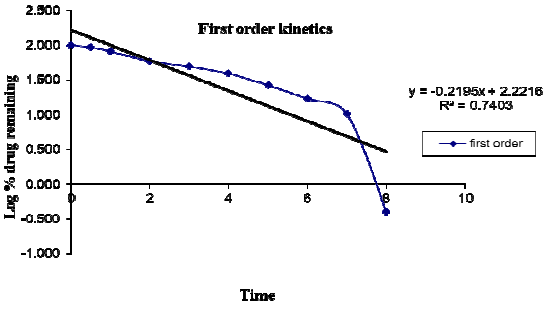

Fig 8: First order kinetics

Table 1: Formulations of Lisuride Transdermal Patch

S.No	Ingredients	F1	F2	F3	F4	F5	F6	F7	F8	F9
1	Drug(mg)	10	10	10	10	10	10	10	10	10
2	Eudragit-L100(mg)	25	50	75	100					25
3	Eudragit-S100(mg)					25	50	75	100	25
4	Dimethyl formamide (ml)	15	15	15	15	15	15	15	15	15
5	Ethanol(ml)	10	10	10	10	10	10	10	10	10
6	Propylene glycol(Drops)	5	5	5	5	5	5	5	5	5

Table 2: Standard graph of Lisuride

Concentration(µg/ml)	Absorbance
0	0
2	0.295
4	0.203
6	0.301
8	0.417
10	0.528
12	0.653
14	0.771
16	0.881

Table 3: Evaluation of Lisuride Transdermal patch by physical methods

Formulation	Weight variation (mg)	Thickness (mm)	Folding endurance	Drug content (%)	Moisture uptake (%)	Moisture content (%)
F1	590.2	0.569	20	65	7.98	3.77
F2	598.3	0.520	25	65	25.05	9.2
F3	599.5	0.570	27	57.5	13.09	5.16
F4	598.3	0.596	24	60	15.63	5.66
F5	599.6	0.560	30	67.5	11.73	4.87
F6	593.1	0.517	32	92.5	19.65	12.67
F7	589.5	0.578	40	99.7	9.42	3.43
F8	591.1	0.537	37	85	10.87	4.72
F9	600	0.503	44	100	6.44	3.62

Table 4: Evaluation of Lisuride Transdermal patch by In-vitro permeation studies using dialysis membrane

Time (Hrs)	% Drug release								
	F1	F2	F3	F4	F5	F6	F7	F8	F9
0	0	0	0	0	0	0	0	0	0
0.5	2.31	2.98	2.36	2.06	2.10	1.11	4.43	2.59	5.86
1	3.53	6.71	5.2	3.8	3.68	4.21	10.3	4.84	18.7
2	6.78	11.9	12.7	7.48	8.50	8.01	19.8	10.3	40.9
3	11.5	18	18.3	13.1	17.3	13.3	30.5	18.6	50.5
4	15.7	2	24.4	16.5	19.0	18.4	46.4	21.1	61.0
5	21.4	18.3	25.7	21.3	27.3	21.0	56.6	29.7	73.4
6	27.5	20.6	29.6	26.6	35.0	35.1	67.6	34.3	83.1
7	32.5	23.3	31.2	32.3	38.4	39.6	74.3	39.2	89.8
8	37.6	25.8	34.1	35.8	42.8	44.8	84.1	43.9	99.6

Table 5: Kinetics of *In-vitro* permeation studies of optimized formulation

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 remain	Q01/3	Qt1/3	Q01/3-Qt1/3
0	0	0			2.000				100	4.642	4.642	0.000
5.86	0.5	0.707	0.768	-0.301	1.974	11.720	0.1706	-1.232	94.14	4.642	4.549	0.092
18.7	1	1.000	1.272	0.000	1.910	18.700	0.0535	-0.728	81.3	4.642	4.332	0.310
40.9	2	1.414	1.612	0.301	1.772	20.450	0.0244	-0.388	59.2	4.642	3.895	0.746
50.5	3	1.732	1.703	0.477	1.695	16.833	0.0198	-0.297	49.5	4.642	3.672	0.970
61.0	4	2.000	1.785	0.602	1.591	15.250	0.0164	-0.215	39	4.642	3.391	1.250
73.4	5	2.236	1.866	0.699	1.425	14.680	0.0136	-0.134	26.6	4.642	2.985	1.656
83.1	6	2.449	1.920	0.778	1.228	13.850	0.0120	-0.080	16.9	4.462	2.566	2.075
89.8	7	2.646	1.953	0.845	1.009	12.829	0.0111	-0.047	10.2	4.642	2.169	2.473
99.6	8	2.828	1.998	0.903	-0.398	12.450	0.0100	-0.002	0.4	4.642	0.737	3.905

4. Conclusion

In present study transdermal drug delivery of Lisuride was developed to overcome the first pass metabolism and to reduce frequency of dosing compared to oral route. Oral drug delivery system has various drawbacks like poor bioavailability due to hepatic metabolism (first pass) and the tendency to produce rapid blood level spikes (both high and low), leading to a need for high and/or frequent dosing, which can be both cost prohibitive and inconvenient. Matrix type of transdermal patches was developed by using polymers Eudragit polymers Transdermal patches were prepared by employing solvent casting method. Drug excipient compatibility studies were carried out by using FTIR, and it was observed that there were no interactions. Formulations were prepared with the varying concentrations polymers ranging from F1-F9, and all the formulations were evaluated for various physical parameters Physical appearance, Flatness, Weight variation, Thickness, Folding endurance, Drug content, Moisture uptake, Moisture content and Swelling study and all the results were found to be were found to be within the pharmacopeial limits, in-vitro drug release studies by using dialysis membrane. Among all the 12 formulations F9 formulation which contain Eudragit S-100 and Eudragit L-100 25mg had shown 99.6% cumulative drug release within 8 hours.

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