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Formulation and Evaluation of Transdermal Patches of Atenolol

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Abstract: *Atenolol, a β_1-selective adrenergic receptor blocker, is widely used in the management of hypertension, angina pectoris, and other cardiovascular disorders. However, its oral administration is often associated with poor bioavailability (approximately 50%) due to first- pass hepatic metabolism and variable gastrointestinal absorption. To overcome these limitations, this study explores the formulation and evaluation of transdermal patches of atenolol as an alternative drug delivery system. Transdermal patches were prepared using various polymers, including hydroxypropyl methylcellulose (HPMC), ethyl cellulose (EC), and Polyvinyl pyrrolidone K30, using solvent casting techniques. The patches' physicochemical characteristics, stability, in vitro drug release, homogeneity of drug content, and skin penetration tests were all evaluated.*

Keywords: Atenolol transdermal patch, Transdermal atenolol delivery, Atenolol patch, Transdermal drug delivery system, Beta-blocker transdermal patch, Controlled drug release, Topical beta- blocker

I. INTRODUCTION

There are a few medications whose side effects are dose-dependent, but there are many more whose undesirable effects are related with a certain method of administration. A transdermal delivery system has been developed very recently. For ages, people have also turned to topical applications, most often for the relief of localised skin conditions. Assuming there is little or no systemic accumulation, local treatment is merely allowing the medicine to penetrate the outer skin layer in order to cure the diseased condition. While it's true that every drug dosage type has its own special properties, the transdermal administration technique has a few advantages over the old ways. There is expected to be somewhat considerable molecular diffusion along the transfollicular channel, the quickest route, when the medicine passes through and across cells. Intracellular route avoids the cell contents.

The transfollicular route is a method by which a medication molecule diffuses or passes at hair shaft's pores. In comparison to other routes, this one has much lower diffusional resistance, making it suitable for the vast majority of medications. But there aren't many hair follicles per square inch of human skin, and the journey length is very long. Passive diffusion is primary mechanism by which most neutral substances undergo transdermal penetration. As an alternate method of administering drugs systemically, transdermal drug delivery devices were developed. Several benefits can be gained via systemic medication delivery through the skin, including a consistent blood drug level. It is optimal for half of the medicine to be hydrophilic and half to be lipophilic. Lipid-soluble substances can readily pass through the celmembrane's intercellular lipid bi-layer.The sole entrance points are the perspiration ducts and the hair follicles, which are deemed to be relatively minor

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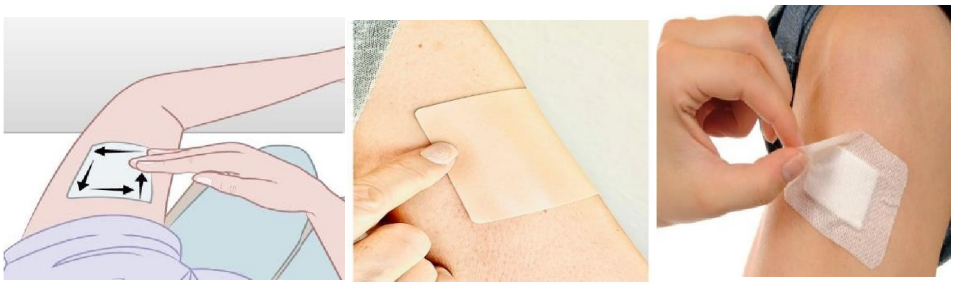

ADVANTAGES:

- Bypass the first-pass metabolism, enhancing drug efficacy.
- Enable sustained drug release, allowing for long-term delivery over extended periods.
- Improve bioavailability and optimize the blood concentration-time profile, minimizing side effects.
- Reduce dosing frequency and maintain more consistent plasma drug levels.
- Lower likelihood of drug-food interactions.
- Minimize inter- and intra-patient variability in drug response.
- Support self-administration and offer a non-invasive, painless, and user-friendly application method.
- Enhance patient compliance and overall comfort.
- Provide flexibility to discontinue treatment promptly if adverse reactions occur.

DRUG PROFILE:

ATENOLOL

Synonyms: Atenol, Atehexal, Normalol, Uniloc, Normiten, Vericordin, Tenormin.

Molecular Weight: 266.34 g/mol

Molecular Formula: $C_{14}H_{22}N_2O_3$

Structural Formula

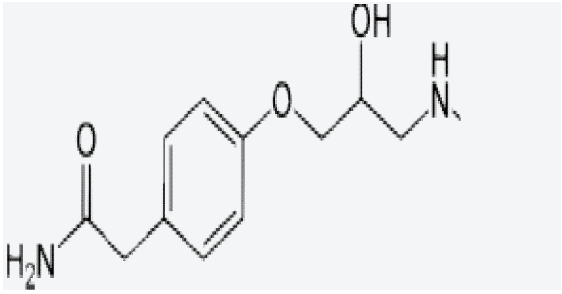

Fig. 1 Chemical structure of Atenolol

Use

As a long-term medication for hypertension, atenolol also helps with angina pectoris, acute myocardial infarction, and antiarrhythmic therapy

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II. MATERIALS AND METHODS

List of chemicals: Table1

Material
Atenolol
Polyvinyl pyrrolidoneK30
Ethyl Cellulose
HPMC
Propylene glycol
Ethanol
DMSO
Eugenol

List of Instruments used: **Table2**

Instrument
UV-Visible Spectrophotometer
Franz diffusion cell
Electronic balance
Magnetic stirrer
Sonicator
Hot air oven
FTIR spectrophotometer
Micrometer

Formulation of Transdermal Patches:

Solvent casting is used to produce transdermal patches of the drug-loaded matrix kind. The entire area of the petri plate is 50.24 cm². To create a transparent solution, polymers are precisely weigh, dissolved in a 1:1 solution of water & methanol, and then set aside. Dissolving and combining the medication produced a clear solution. Propylene glycol and permeation enhancers eugenol, ethanol, and dimethyl sulfoxide are synonymous. A glycerine-lubricated petri plate receives the uniform mixture of the above fluids. The dish has 24 hours to dry at room temperature. Placing an inverted funnel over a petridish reduces the rate of solvent evaporation. This was followed by pouring of solution onto 50.54 cm^2 Petri plate. Patches were then divided into 2x2 cm^2.

PROCEDURE:

1: Dissolve the polymer in a suitable solvent.
2: Add the plasticizer and stir until a homogeneous solution is obtained
3. Incorporate the API into the solution with continuous stirring.
4: Pour the mixture onto a leveled surface, such as a Petri dish lined with aluminium foil.
5: Allow the solvent to evaporate at room temperature under controlled conditions to form a thin film.
6: Once dried, peel off the film and cut it into desired sizes.
2-12 µg/ml was obtained by diluting 0.2, 0.4, 0.6, 0.8& 1.0 millilitres of the previously described standard solution with 10 millilitres of phosphate buffer (PH 7.4). In order to test absorbance of these solutions at 275 nm, a UV spectrophotometer was used, with phosphate buffer PH 7.4 serving as a blank.

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Table 3: Formulation table of Atenolol patches.

Name of ingredient	F1	F2	F3	F4	F5	F6
Drug (mg)	30	30	30	30	30	30
EC (mg)	400	-	-	400	400	400
HPMC (mg)	-	400	-	-	-	-
PVPK30 (mg)	-	-	400	-	-	-
Propylene glycol (%)	30	30	30	30	30	30
Ethanol (%)	-	-		5		
DMSO (%)	-	-	-	-	5	
Eugenol (%)	-	-	-	-	-	5

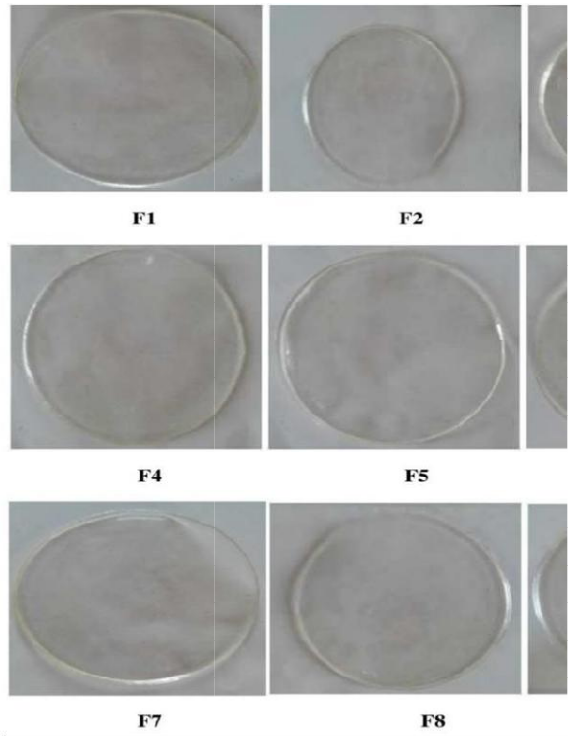

Fig 2: Formulation of transdermal patches of atenolol

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Evaluations of transdermal patches:

Thickness:

Digital verniercallipers with a minimum count of 0.001mm was used. We averaged the results from five separate locations and calculated the standard deviation to get a feel for the thickness homogeneity.

Weight variation:

A weight variation test was conducted by cutting and weighing three 2x2 cm^2 discs using an electronic balance.

Percentage Elongation:

Using the length immediately preceding the break point in the formula shown below, one can ascertain the percentage elongation break.

Folding endurance:

To find out, we folded a single patch in the same spot until it snapped.

Moisture content:

We maintained the films in a desiccator with $CaCl_2$ at 40°C in a drier for at least 24 hours or awaiting their weight remained constant.

$$\text{Percentage moisture content} = \frac{\text{Initial wt.} - \text{Final wt.}}{\text{Final wt.}} * 100$$

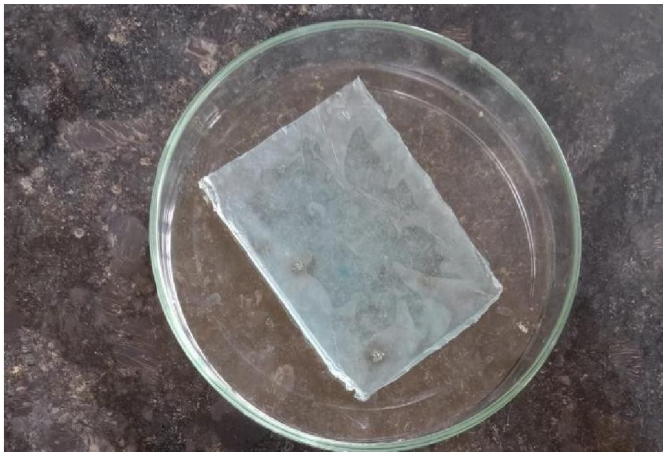

Fig 3: Excised and gathered transdermal atenolol patches.

Swelling index:

After being weighed, the 2x2 cm^2patches were positioned in a Petri dish with 10 ml of double distilled water and left to soak.

Drug content:

Film measuring two centimeters by two centimeters was cut and dissolved in a hundred milliliters of phosphate buffer (pH 7.4) in a volumetric flask

III. RESULT AND DISCUSSION

FTIR:

As shown in Figure 4, the FTIR spectrum of Atenolol exhibited characteristic peaks that belonged to measure functional groups. These peaks included principle peaks at 1631, 1510, 1234, 750, and 1443cm^{-1}, which were caused by aromatic substitution, -C-O stretching, -N-H stretching, and -C-H deformation, respectively.

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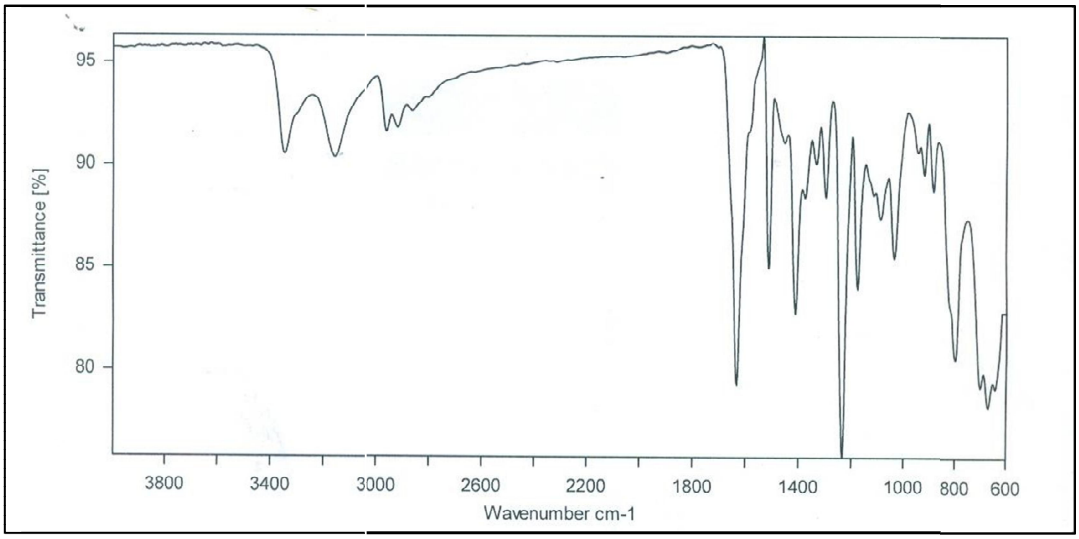

Fig. 4. FTIR Spectra of Pure Atenolol.

Appearance & colour of drug: White powder
Melting Point: 158°C
Solubility: Soluble in ethanol & methanol

IV. DISCUSSION

A pre-formulation trial is a crucial part of developing any dosage form. Because the medicine must penetrate the living tissue's aqueous environment and multi-layered lipid sheet, this is especially true for transdermal drug delivery devices. The aim of these initial investigations to identify
The essential physicochemical properties of drug
Its kinetic behavior and rate profile
Its compatibility by commonly used excipients or additives

Determination of λmax:
Atenolol at a concentration of 10µg/ml was scanned between 200 and 400nm. In a phosphate buffer (pH of 7.4) medication showed a maximum absorption wavelength of 275 nm and was reproducible. The spectrum obtained is shown in fig5. The stated peak and the one shown in the figure are very similar

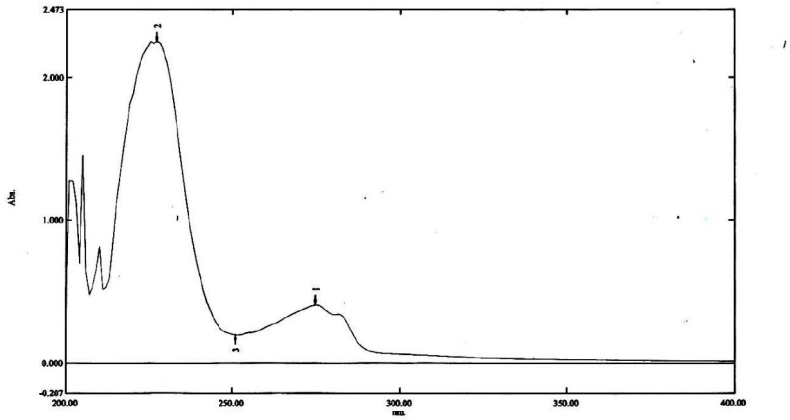

Fig 5:Determination of λmax:

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Calibration curve of Atenolol:

In a phosphate buffer (pH of 7.4) data for Atenolol calibration curve at 275 nm may be found in fig5 illustrates the standard calibration curve prepared in a phosphate buffer at ph 7.4 featuring a regression value of 0.999 and slope of 0.064, and intercept of 0.013. A straight line was shown in the graph at concentrations between 2 and 12µg/ml. The results obtained show that atenolol conforms with Beer-Lambert's law within the 2- 12 µg/ml range.

Table 4. Calibration curve of Atenolol.

Concentration (µg/ml)	Absorbance at 275 nm
0	0
2	0.155
4	0.275
6	0.405
8	0.535
10	0.655
12	0.789

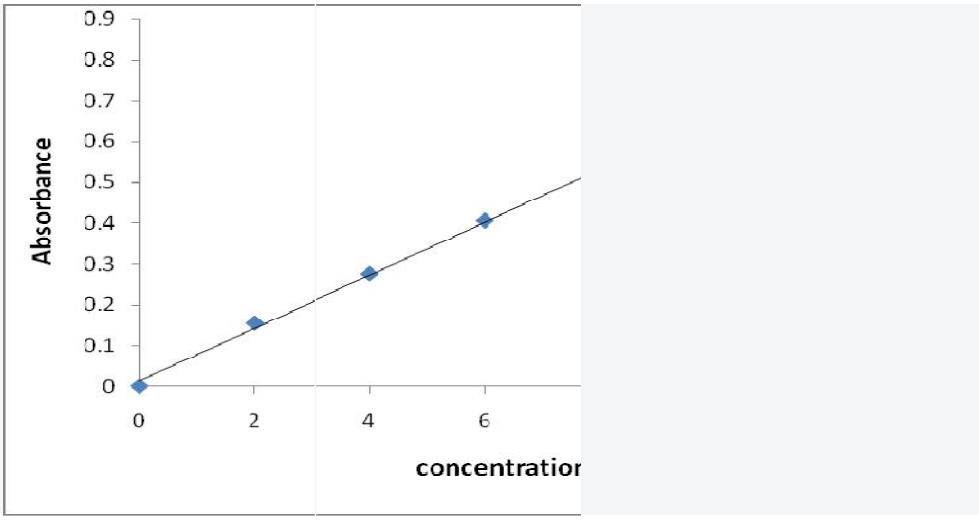

Fig. 6. Standard graph of Atenolol

Solubility:

It is in a particular vehicle dictates the optimal concentration for topical administration to the skin. Therefore, for a medicine to be delivered through delivery systems, it must have adequate solubility in the chosen vehicle. Atenolol dissolves in water very little, almost completely in ether, and rather weakly in dichloromethane and ethanol.

Partition Coefficient:

It is difficult for the medicine to pass the lipid bilayer if it does not have enough lipophilicity. A drug reservoir may build inside these layers, though, if the lipophilicity becomes excessive. As a result, drug architectures should ideally exhibit a compromise between hydrophilicity and lipophilicity; the partition coefficient of an octanol-phosphate buffer (PH7.4) suggests this. A partition coefficient of 0.051 was reported for atenolol.

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Melting Point:
A lower melting point results in higher penetration, as indicated by the linear association among log flux and reciprocal of melting points. It was discovered that Atenolol has a melting point of 158°C.

Compatibility studies:
The spectra of the individual polymers and the pure medication were used to compare the combinations. Combinations produced a principal peak that was quite close to the drug's. no changes were detected in FTIR spectra of the drug PVPK30, EC, HPMC, of the combinations of the drug with EC and HPMC. Since the medicine and formulation did not exhibit any significant changes to their respective absorption bands, the likelihood of an interaction was dismissed.

Stability Studies:
For a drug product to be considered high-quality, effective, and safe, stability is paramount. A change in physicochemical properties of the medicinal product can occur if its stability is inadequate. While there were minor adjustments to the physicochemical evaluation parameters, there were no noticeable modifications to the material's look, colour, or pliability . Degradation rates of 1-2 percent relative to medication content were noted. Thus, according to the formulations exhibited stability.

Calculation for Dose:
If normal dose of drug is 60mg daily orally then total oral dose 60mg we develop for one day total drug incorporated into patch 60mg. Oral bioavaliblity50% it bypass hepatic metabolism and Enters directly into the circulation so, one half of oral for drug would be 60/2 =
30.Calculationof drug for circular patch Cast patch having internal diameter 8cm surface area of ring 50.54cm2. Diameter of patch 2cm, Area of patch πr222/7*1sq is equalto3.14cm2.No of patch prepared one circular cast film are 50.54/3.14=16.Atenolol dose60mg in a daily = 60mg, but 60/2 i. e 30*16 =480mg.

V. CONCLUSION

Results of the study revealed that the prepared transdermal patches formulation from atenolol drug to treat the medical condition like high blood pressure. Also the physical analysis and stability studies of the prepared patches proved potency and efficacy. Thus, this formulation is used to treat high blood pressure (Hypertension).

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Author Contributions
- Viraj Hatekar: Conceptualization and formulation
- Sohel Momin: Experimental execution
- Onkar Jagtap: Quality evaluation
- Deepak Kare: Supervision and review

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