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Development and Evaluation of a Vericiguat Drug-in-Adhesive Transdermal Patch Using a Hybrid Polyacrylate Silicone Matrix for Controlled Drug Release

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Abstract: This study developed and evaluated a vericiguat drug-in-adhesive transdermal patch using a hybrid polyacrylate–silicone pressure-sensitive adhesive matrix for controlled release. Six formulations, VTP1–VTP6, were prepared by solvent casting with different polyacrylate-to-silicone ratios while maintaining constant drug and enhancer levels. The patches were assessed for appearance, thickness, weight variation, folding endurance, surface pH, moisture content, moisture uptake, adhesion, drug content, content uniformity, membrane diffusion, in vitro release, release kinetics and accelerated stability. VTP3, containing a 70:30 polyacrylate–silicone ratio, showed the best overall performance, with optimum adhesion, 98.64 ± 1.92% drug content, 94.84 ± 4.27% release and 89.12 ± 4.45% membrane diffusion at 12 hours. Release followed the Korsmeyer–Peppas model with non-Fickian transport. The optimized patch remained stable for two months under accelerated conditions.

Keywords: Vericiguat, drug-in-adhesive patch, transdermal delivery, polyacrylate, silicone adhesive, controlled release, membrane diffusion.

INTRODUCTION

Chronic heart failure requires long-term pharmacotherapy and careful maintenance of treatment. Advanced drug-delivery systems are sometimes investigated to reduce administration burden and provide controlled drug input, but the suitability of any cardiovascular drug for transdermal delivery depends on dose, molecular properties, adhesive compatibility, and skin permeability [1–4].

Vericiguat is a soluble guanylate cyclase stimulator used in selected patients with symptomatic chronic heart failure and reduced ejection fraction. It is currently administered orally. A transdermal formulation is therefore exploratory and must be interpreted as a formulation study rather than an established therapeutic alternative [5–8].

Transdermal patches are designed to release drug from a dosage form placed on intact skin. In drug-in-adhesive systems, the active ingredient is incorporated directly into the pressure-sensitive adhesive, allowing the adhesive layer to serve simultaneously as the drug reservoir and skin-contact layer. Product performance depends on uniform drug distribution, adhesion, flexibility, moisture response, release, and permeation [9–12].

Polyacrylate pressure-sensitive adhesives generally provide strong tack and broad drug compatibility, whereas silicone adhesives can improve flexibility and hydrophobicity. Hybrid matrices may therefore be used to adjust tack, cohesive strength, moisture uptake, and drug transport. Penetration enhancers such as Transcutol P and isopropyl myristate can further influence drug partitioning and membrane transport [13–16].

Previous drug-in-adhesive and hybrid-adhesive studies demonstrate that adhesive ratio can substantially affect release and adhesion [17–20]. The present study developed six vericiguat patches using different polyacrylate-to-silicone ratios and evaluated their physical properties, drug uniformity, synthetic-membrane diffusion, in vitro release, and short-term accelerated stability.

MATERIALS AND METHODS

Chemicals

Vericiguat (VRC) was obtained from Gift sample obtained from Metrochem API Private Ltd., Hyderabad. Polyacrylate pressure-sensitive adhesive was obtained from Henkel AG & Co. KGaA, Germany. Silicone pressure-sensitive adhesive was obtained from DuPont, USA. Transcutol® P was obtained from Gattefossé, France. Isopropyl myristate was obtained from Merck Life Science Pvt. Ltd., India. Ethyl acetate was obtained from Merck Life Science Pvt. Ltd., India. Acetone was obtained from Merck Life Science Pvt. Ltd., India.

Preformulation and analytical studies

Vericiguat was assessed by routine preformulation testing, UV spectrophotometry, and FTIR compatibility with the selected pressure-sensitive adhesives.

Formulation design

Six formulations, VTP1–VTP6, were prepared with constant vericiguat, Transcutol P, and isopropyl myristate while the polyacrylate-to-silicone pressure-sensitive adhesive ratio was varied.

Table 1: Formulation composition of vericiguat drug-in-adhesive transdermal patches

Formulation	Vericiguat (mg)	Polyacrylate PSA* (mg)	Silicone PSA* (mg)	Polyacrylate:Silicone Ratio	Transcutol P (mg)	Isopropyl Myristate (mg)	Solvent System q.s.
VTP1	50	850	--	100:0	50	50	Ethyl acetate:Acetone
VTP2	50	680	170	80:20	50	50	Ethyl acetate:Acetone
VTP3	50	595	255	70:30	50	50	Ethyl acetate:Acetone
VTP4	50	510	340	60:40	50	50	Ethyl acetate:Acetone
VTP5	50	425	425	50:50	50	50	Ethyl acetate:Acetone

VTP6	50	--	850	0:100	50	50	Ethyl acetate:Acetone

Preparation method

Vericiguat was dissolved or uniformly dispersed in an ethyl acetate:acetone solvent system containing Transcutol P and isopropyl myristate. Polyacrylate and silicone pressure-sensitive adhesives were combined at the required ratio, followed by incorporation of the drug phase. The deaerated casting solution was spread on a release liner or glass surface, dried to remove solvent, and cut into patches of the required area.

FTIR compatibility study

FTIR spectra of pure vericiguat, polyacrylate adhesive, silicone adhesive, and optimized formulation VTP3 were compared to assess preservation of characteristic spectral regions and possible interactions.

Evaluation

Patches were evaluated for appearance, weight, thickness, folding endurance, surface pH, adhesion, moisture content, moisture uptake, drug content, and content uniformity.

In vitro release and membrane diffusion

Drug release and synthetic-membrane diffusion were evaluated using the conditions reported in the thesis, including a Franz-cell membrane study in phosphate buffer pH 7.4. These tests assess formulation release and diffusion through the synthetic barrier.

Stability study

Optimized VTP3 was stored at 40 ± 2°C/75 ± 5% RH for two months. Physical appearance, crystallization, adhesion, drug content, and release were assessed.

RESULTS AND DISCUSSION

FTIR compatibility

The characteristic vericiguat and adhesive spectral regions remained identifiable in the optimized patch with only limited shifts and overlap. No new major band indicating an obvious chemical incompatibility was reported.

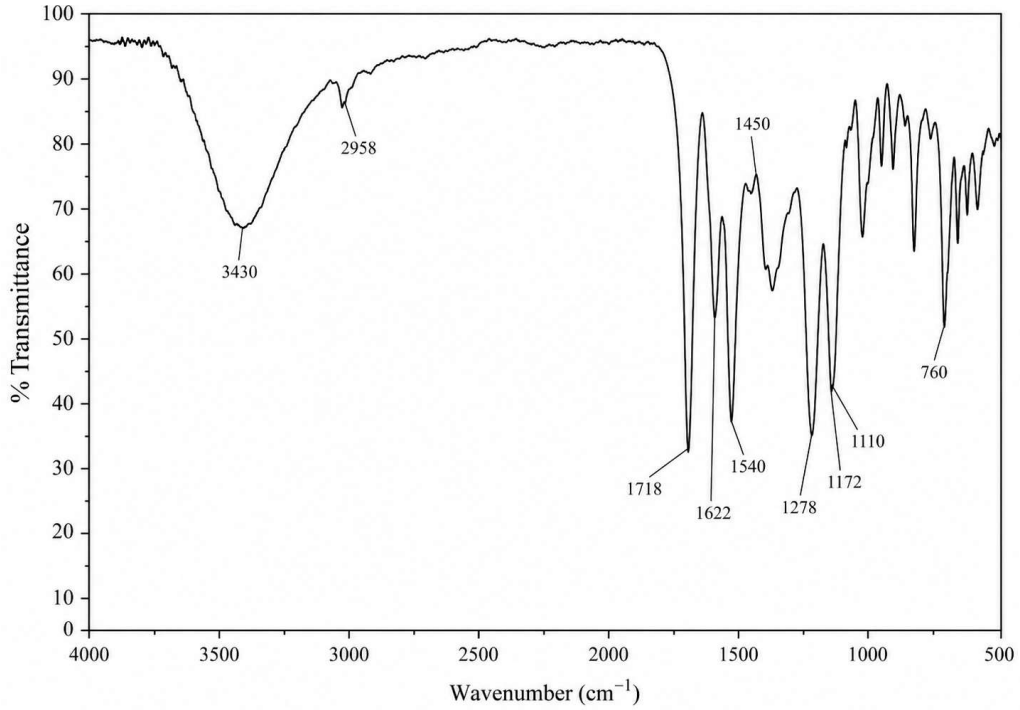

Fig 1: FTIR spectrum of pure vericiguat.

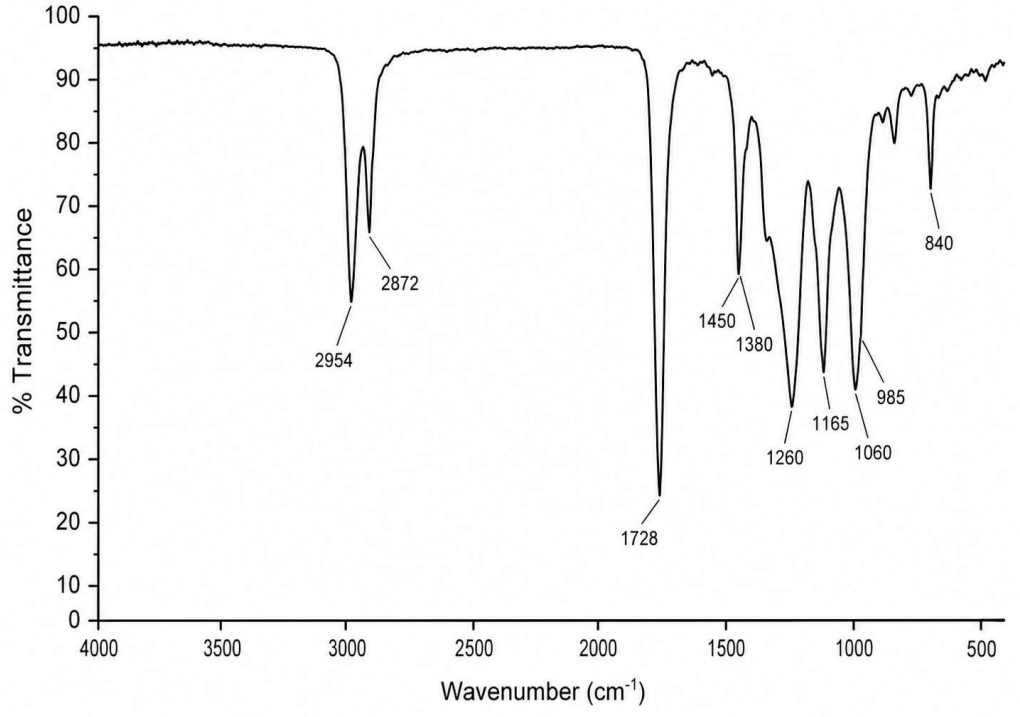

Fig 2: FTIR spectrum of polyacrylate pressure-sensitive adhesive.

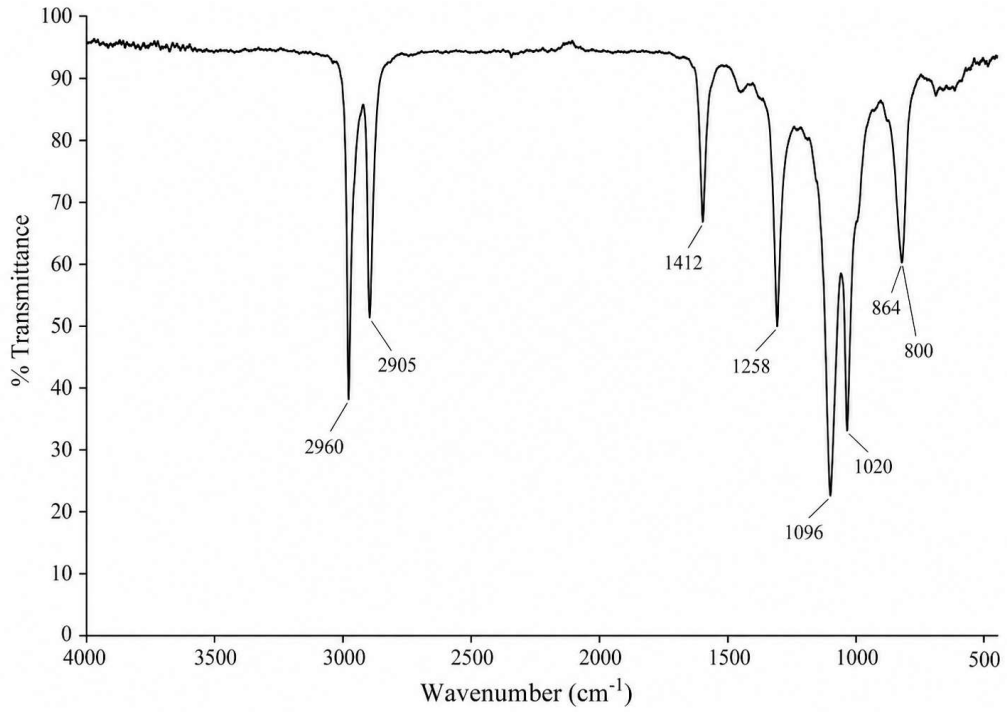

Fig 3: FTIR spectrum of silicone pressure-sensitive adhesive.

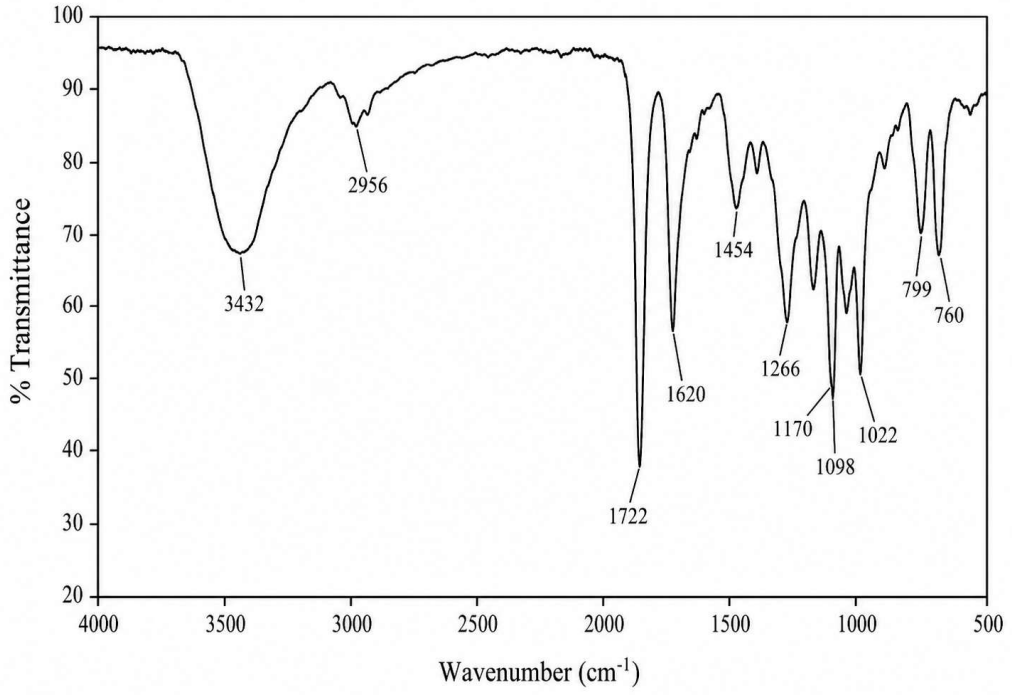

Fig 4: FTIR spectrum of optimized formulation VTP3.

Table 2: Comparative FTIR peak

Functional group	Pure Vericiguat (cm^{-1})	Polyacrylate PSA (cm^{-1})	Silicone PSA (cm^{-1})	Optimized formulation (cm^{-1})
O–H stretching region	3430	–	–	3432
Aliphatic C–H	2958	2954, 2872	2960, 2905	2956

stretching				
Carbonyl stretching region	1718	1728	–	1722
Aromatic region	1622, 1540	–	–	1620
CH bending region	1450	1450, 1380	1412	1454
C–O fingerprint region	1278, 1172, 1110	1260, 1165, 1060	1258, 1096, 1020	1266, 1170, 1098, 1022
Silicon-associated fingerprint region	–	–	1096, 1020, 864, 800	1098, 1022, 799
Aromatic out-of-plane region	760	840	800	760

Patch properties and drug uniformity

All formulations were smooth and flexible without visible crystallization or phase separation. Increasing silicone content improved flexibility and reduced moisture uptake, but excessive silicone reduced tack. Drug content ranged from 96.42 ± 2.18% to 98.64 ± 1.92%, with low variability across equal patch areas.

Table 3: Physical appearance and organoleptic characteristics of vericiguat patches

F code	Colour and transparency	Surface characteristics	Flexibility	Tackiness
VTP1	Clear to slightly translucent	Smooth and uniform	Moderately flexible	High
VTP2	Clear and translucent	Smooth and homogeneous	Good	Good
VTP3	Clear to slightly opalescent	Smooth, non-greasy and uniform	Very good	Optimum
VTP4	Slightly opalescent	Smooth and uniform	Very good	Moderate
VTP5	Translucent	Slightly soft surface	High	Moderate to low
VTP6	Translucent to slightly cloudy	Soft and mildly oily	Very high	Low

Table 4:. Physical and mechanical properties of vericiguat patches

Formulation	Weight (mg/10 cm²)	Thickness (mm)	Folding endurance	Surface pH	Adhesion	Moisture content (%)
VTP1	101.6 ± 3.8	0.213 ± 0.012	184 ± 11	6.31 ± 0.10	High tack	3.84 ± 0.26
VTP2	102.4 ± 4.1	0.219 ± 0.014	196 ± 13	6.34 ± 0.09	Good	3.56 ± 0.24
VTP3	103.1 ± 3.7	0.224 ± 0.013	218 ± 15	6.38 ± 0.11	Optimum	3.28 ± 0.22
VTP4	102.8 ± 4.0	0.231 ± 0.015	236 ± 17	6.41 ± 0.12	Satisfactory	3.02 ± 0.21
VTP5	104.2 ± 4.3	0.238 ± 0.016	254 ± 18	6.45 ± 0.10	Moderate	2.76 ± 0.19
VTP6	103.7 ± 4.5	0.245 ± 0.017	272 ± 20	6.48 ± 0.13	Low tack	2.42 ± 0.18

Table 5: Moisture uptake and drug content

Formulation	Moisture uptake (%)	Drug content (%)
VTP1	5.62 ± 0.41	96.42 ± 2.18

VTP2	5.14 ± 0.38	97.36 ± 2.06
VTP3	4.72 ± 0.35	98.64 ± 1.92
VTP4	4.26 ± 0.32	98.12 ± 2.14
VTP5	3.84 ± 0.29	97.48 ± 2.25
VTP6	3.31 ± 0.27	96.86 ± 2.31

Table 6: Content uniformity of vericiguat patches

Formulation	Vericiguat content (mg/10 cm²)	Content uniformity (%)
VTP1	4.82 ± 0.11	96.42 ± 2.18
VTP2	4.87 ± 0.10	97.36 ± 2.06
VTP3	4.93 ± 0.10	98.64 ± 1.92
VTP4	4.91 ± 0.11	98.12 ± 2.14
VTP5	4.87 ± 0.11	97.48 ± 2.25
VTP6	4.84 ± 0.12	96.86 ± 2.31

Membrane diffusion and in vitro release

VTP3, containing a 70:30 polyacrylate–silicone ratio, showed the highest and most balanced transport performance. It achieved 89.12 ± 4.45% synthetic-membrane diffusion and 94.84 ± 4.27% drug release at 12 h. These values demonstrate release from the adhesive matrix and transport through the test membrane.

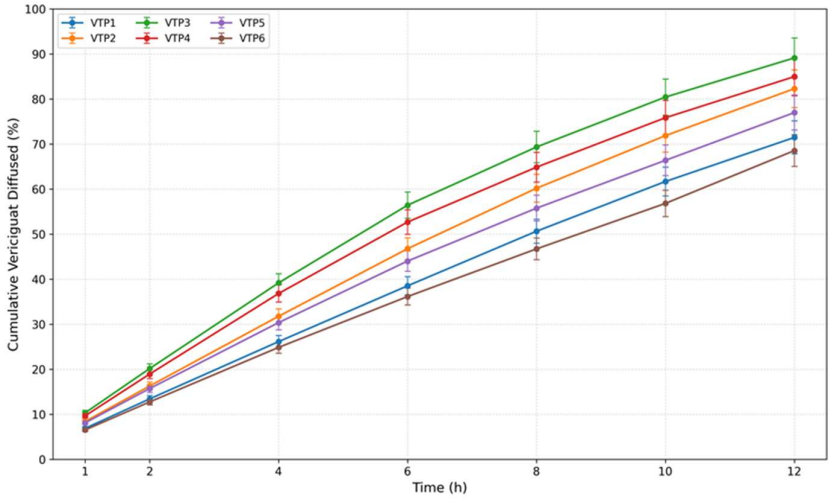

Fig 5: In vitro synthetic-membrane diffusion profiles of vericiguat patches.

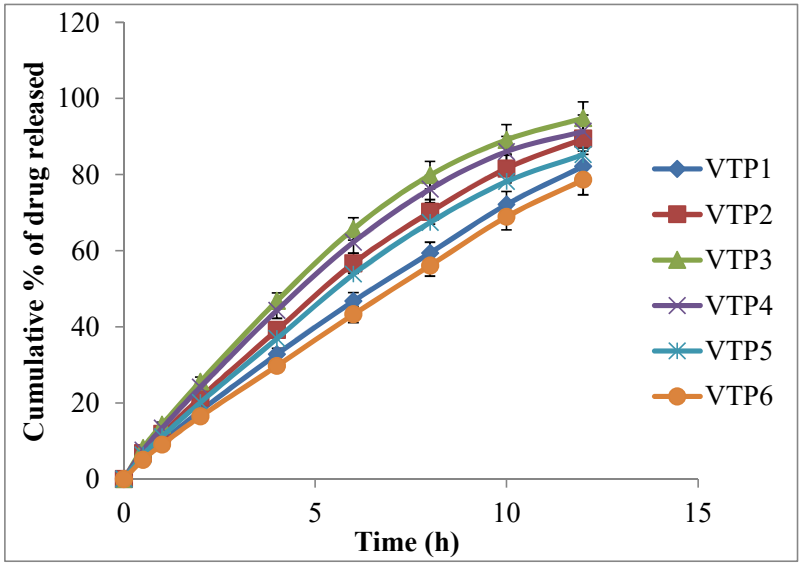

Fig 6: In vitro drug-release profiles of vericiguat patches.

Optimized formulation and stability

VTP3 was selected because it provided the best overall balance of adhesion, flexibility, drug uniformity, membrane diffusion, and controlled release. It remained physically stable during two months of accelerated storage with no visible crystallization or major loss of adhesion and only minor changes in drug content and release.

CONCLUSION

A vericiguat drug-in-adhesive patch was successfully prepared using a hybrid polyacrylate–silicone pressure-sensitive adhesive matrix. The adhesive ratio influenced flexibility, tack, moisture behaviour, drug distribution, membrane diffusion, and release. VTP3, containing a 70:30 polyacrylate–silicone ratio, showed the best overall performance, with 98.64 ± 1.92% drug content, 94.84 ± 4.27% release, and 89.12 ± 4.45% synthetic-membrane diffusion at 12 h. The optimized patch remained acceptable during two months of accelerated storage.

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