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FORMULATION AND IN VITRO CHARACTERIZATION OF AMLODIPINE-LOADED CHITOSAN NANOPARTICLES EMBEDDED IN CARBOPOL GEL FOR TRANSDERMAL DELIVERY

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ABSTRACT

The present work showed that transdermal delivery system for Amlodipine based on chitosan nanoparticles dispersed into gel was successfully prepared and characterized. There is no Incompatability between drug and polymers by performing FTIR and DSC. To characterize the rate controlling membrane of transdermal patchs. The thickness ranged between TNPGF1 to F9 0.11 ± 0.05 mm to 0.19 ± 0.07 mm, which indicates that they are uniform in thickness. The different batches of formulations weights variations were relatively good uniformity of weight variations among the various batches was observed, with all formulations and ranged from 1.40 ± 1.2% to 1.78 ± 2.0%. The flatness study showed that all the formulations had the same strip length before and after their cuts, indicating 99% flatness. The Tensile strength of the TNPGF1 to TNPGF9 shows the 10.14 ± 1.19 to 12.78 ± 2.45 shows the excellent viscosity. The total amount of drug is present in the transdermal patchs of TNPGF1 to TNPGF9 was found to be 90.5 ± 0.3 % to 98.5 ± 0.1 %. *In-vitro* Franz's diffusion drug Release Studies among all formulations the best formulation was TNPGF6. The drug release through the transdermal patches of Amlodipine follows First order kinetics with diffusion controlled mechanism. Effect of penetration enhancer like dimethyl sulfoxide has been checked on *in-vitro* permeation of drug and was found to be effective. Gels may create a drug reservoir to provide the system with Amlodipine over long period of time to control the blood pressure.

Keywords: *Amlodipine, Chitosan , Nanoparticles, Carbopol Gel, Transdermal Delivery.*

INTRODUCTION

Transdermal drug delivery system

The oral route is currently the most popular method of drug delivery. Although this has the noteworthy benefit of being simple to administer, it also has serious disadvantages, such as poor bioavailability because of hepatic metabolism (first pass) and a propensity to cause fast blood level spikes (both high and low), necessitating high and/or frequent dosing, which can be both expensive and inconvenient [1].

In order to address these challenges, new drug delivery systems must be developed. These systems will increase the therapeutic efficacy and safety of medications by placing them more precisely (i.e., site-specific), spatially, and temporally within the body, which will reduce the size and quantity of doses. In order to deliver innovative, genetically modified pharmaceuticals (such as proteins and peptides) to their site of action without causing severe

immunogenecity or biological inactivation, new drug delivery mechanisms are also crucial [2]. In addition to these benefits, pharmaceutical companies are aware of the potential for repurposing effective medications by utilizing the principles and methods of controlled drug delivery systems in conjunction with the higher costs associated with introducing novel pharmacological moieties to the market. Transdermal delivery, or the movement of medicinal chemicals via the skin for systemic action, has been one of the most widely used techniques. Percutaneous delivery, which involves conveyance into target tissues in an effort to prevent systemic effects, is closely linked [3]. A therapeutically effective dosage of medication is applied to a patient's skin via a transdermal drug delivery device (TDDS). The complete morphological, biophysical, and physicochemical characteristics of the human skin must be taken into account when delivering medicinal substances for systemic effects. With little proteolytic activity, skin offers a massive surface area (about 2 m2) for absorption. It is made up of three layers: dermis, epidermis, and subcutaneous tissue. It is thin enough to provide stimulation and flexible enough to withstand long-term deformation from movement [4]. The primary obstacle to transdermal administration is the stratum corneum (SC), a dead layer that diffuses slowly.

MATERIAL AND METHODS

Amlodipine was the gift sample of Hetero drug Limited, Hyderabad. Chitosan, Poloxamer, HPMC, Carbopol, acetic acid, dimethyl sulfoxide, Pentasodium tripolyphosphate was procure from Pharmaceutical Pvt Ltd, Navi Mumbai.

METHODOLOGY

Drug-Polymer Compatability studies:

FT-IR Spectra: Infrared spectra of the physical mixture of amlodipine, polymers separately, and the drug-polymer mixture were obtained before the dosage forms were developed. Using a Shimadzu 8400S FTIR spectrometer and 2% w/w of the sample in relation to a mixture of potassium bromide and drug KBr, the drug-polymer interaction was examined. Using a mortar, the mixture was ground into a fine powder before being compacted into KBr discs at a pressure of 10,000 PSI in a hydraulic press [5]. Ten scans at a resolution of 2 cm were performed on each KBr disc. The distinctive summits were noted.

Differential scanning calorimetry: Plotting heat flux (rate) against temperature at a certain temperature rate is the DSC's output. DSC shows a potential interaction between medication and polymers in formulations and gives information about the sample's physical characteristics, such as its crystalline or amorphous nature. Based on the thermograms [6].

Formulation of Amlodipine Loaded chitosan nanoparticles dispersed in carbopol gel

Preparation of Nanoparticles: Penta soidum tripolyphosphate and various ratios of chitosan, as indicated in the table, were combined to create nanoparticles using the ionic gelation process at room temperature. TPP was dissolved in Milli-Q water, and chitosan was dissolved in acetic acid solution that had been adjusted to a pH of 4.5. The system measures the electrical resistivity of the water to determine the ion concentration. An identical amount of chitosan solution was mixed with TPP solution drop wise while being magnetically stirred for 60 minutes at 650 rpm. The same procedure described above was used to create amlodipine-loaded chitosan nanoparticles [7], however, the proper quantity of amlodipine was dissolved in the chitosan solution prior to the dropwise addition of TPP solution.

Formulation of gels

The cold approach was used to create poloxamer gels. A certain volume of cold Milli Q water (5–10 °C) was gradually mixed with poloxamer while being continuously stirred for 60 minutes at 650 rpm. At 30 minutes, more Cold Milli-Q water was added to the mixture to bring the volume up to par. Carbopol 940 (1% and 2% w/v) gels were made by dispersing the proper amount of carbopol into a specific volume of Milli-Q water at room temperature with continuous stirring for 60 minutes at 650 rpm. Poloxamer solutions were kept in the refrigerator (4-5 °C) for the night and then at room temperature for an additional 24 hours [8]. At 30 minutes, Milli-Q water was added to the mixture to bring the volume up to the final quantity. For a full day, carbopol gels were stored at room temperature.

Combination gels of poloxamer and carbopol were made. using techniques similar to those mentioned above. For sixty minutes, both were agitated at 650 rpm. After mixing the two for 30 minutes, MilliQ Water was added to the mixture while stirring to get the volumes up to the total. For a full day, these gels were stored at room temperature. Each of the gels mentioned above that included amlodipine was made independently. Amlodipine was dissolved in a tiny volume of Milli-Q water prior to the final gels being built up to the volume, but otherwise, the same procedures were followed [Table 1]. Every gel's pH was brought to 5.5.

Formulation of nanoparticles / gels transdermal delivery Systems

The properties of the resulting transdermal delivery systems were assessed using the generated amlodipine-loaded chitosan nanoparticles distributed in carbopol gels integrated in transdermal molds [9] as shown in the table 01.

Table 01: Formulation design of Transdermal Patches of Amlodipine Loaded chitosan nanoparticles dispersed in carbopol gels TNPGF1 to TNPGF5

INGREDIENTS	TNPG F1	TNPG F2	TNPG F3	TNPG F4	TNPG F5	TNPG F6	TNPG F7	TNPG F8	TNPG F9
Amlodipine (gms)	1	1	1	1	1	1	1	1	1
Chitosan (gms)	2	2	2	2.5	2	3	1	1	1
Polaxamer (gms)	5	5	5	4	4	4	3	3	3
HPMC (gms)	2	1	0.5	1	1	1	1.5	1.5	1.5
Pentasodium tripolyphosphate(gms)	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
Dimethyl sulfoxide (ml)	1	1	1	1	1	1	1	1	1
Carbopol (gms)	2	2	2	2	2	2	2	2	2
Acetic acid (ml)	15	15	15	15	15	15	15	15	15

PHYSICOCHEMICAL EVALUATION OF FILMS

Thickness of the Patch

The thickness of patches was measured at three different places using a micrometer (Mitutoyo Co., Japan) and mean values were calculated [10].

Weight Variation

The patches were subjected to mass variation by individually weighing randomly selected patches. Such determination was carried out for each formulation [11].

Moisture Content:

The patches (n = 3) were weighed separately and stored for 24 hours at 37 °C in a desiccator filled with calcium chloride. When each patch's weight remained constant, the final weight was recorded. The difference between the initial and final weights in relation to the final weight was used to compute the percentage of moisture content [12].

Moisture Uptake

A weighed film that had been stored in desiccators at 40 °C for 24 hours was removed and exposed to two different relative humidity levels in two separate desiccators at room temperature: 75% RH (saturated solution of sodium chloride) and 93% RH (saturated solution of ammonium hydrogen phosphate). The weights were then periodically measured to determine constant weights [13].

Flatness

The prepared medicated film was sliced into longitudinal strips, and the lengths of each strip were measured [14]. The length variance brought on by the uneven flatness was then measured. Strip constriction was used to calculate flatness, with zero percent constriction being equivalent to 100% flatness. Constriction (%) = L1-L2 × 100

L2

Where,

L1- initial length of strip

L2 - final length of strip.

Determination of Tensile Strength

The polymeric patch was pulled using a pulley system to measure the elongation as a tensile strength. Weights were progressively added to the pan to increase the pulling effort until the patch broke [15]. Using a magnifying lens on the graph paper, the elongation that is, the distance the pointer moved before the patch broke was recorded, and the tensile strength was computed as kg cm2.

Folding Endurance

This was determined by repeatedly folding one film at the same place till it broke. The Timber of times the film could be folded at the same place without breaking gave the value of folding endurance [16].

Water Vapour Transmission (WVT) Rate

The amount of moisture transferred across a unit area of film in a unit of time is known as WVTR. Using adhesive tape, the film was affixed to the top of a glass vial that held 3 g of fused calcium chloride as a desiccant. The vial was weighed and stored in desiccators with a saturated potassium chloride solution to achieve an 84% relative humidity. For duration of 72 hours, the vial was removed and weighed every 24 hours. Plots of the amount of water vapor communicated vs time were used to compute the water vapor transmission rate [17].

Drug Content Determination

The 1 cm2 patches were cut and placed in a beaker with 100 ml of a pH 7.4 phosphate buffered solution. For five hours, a magnetic bead covered in Teflon was used to stir the mixture. After filtering the mixture, the drug content was measured using spectrophotometry at 219 nm with the appropriate dilution [18].

***In vitro* Franz's diffusion studies of Transdermal patches of Amlodipine though chitosan nanoparticles dispersed in carbopol gels**

A modified Franz diffusion cell can be used to conduct in vitro release investigations during a 12-hour period. Aliquots of samples containing the released medication are removed from the acceptor compartment at predetermined intervals and measured using an appropriate technique [19]. The manufactured film was applied to the rat skin and affixed to the diffusion cell so that the drug-releasing surface of the cell faced the receptor compartment, which was filled with a pH 7.4 phosphate buffer solution at 37±1 °C. Magnetic stirring was used to the elution medium. At prearranged intervals, the aliquots (5 ml) were removed and refilled with the same volume of pH 7.4 phosphate buffer. A UV spectrophotometer set at 219 nm was used to determine the drug content of the samples.

Release Order Kinetics

To analyse the mechanism for the release and release rate kinetics of the dosage form, the data obtained and it was fitted in to Zero order, First order, Higuchi matrix and Korsmeyer and Peppas model. Comparing the r-values are obtained, the best-fit model was selected [20-25].

RESULTS AND DISCUSSION

Drug-Polymer Compatability studies

Excipients were integral components of almost all pharmaceutical dosage forms.The Fourier transform infra red spectroscopythat the scanning range was 400-4000cm-1, resolution was 4cm-1. Spectra of theAmlodipine, and the drug with sodium alginate were obtained and compared for the compatibility. The FT-IR spectrum of the pure Amlodipine sample, Chitosan, Poloxamer,HPMC, TPP, Carbopol Mixture of Compounds was recorded by FT-IR spectrometer is shown in Figure 01. This was compared with standard functional group, of Observed & Characteristic frequencies as shown in Table 02.

Compatability Studies

Fourier Transform Infrared Spectroscopy

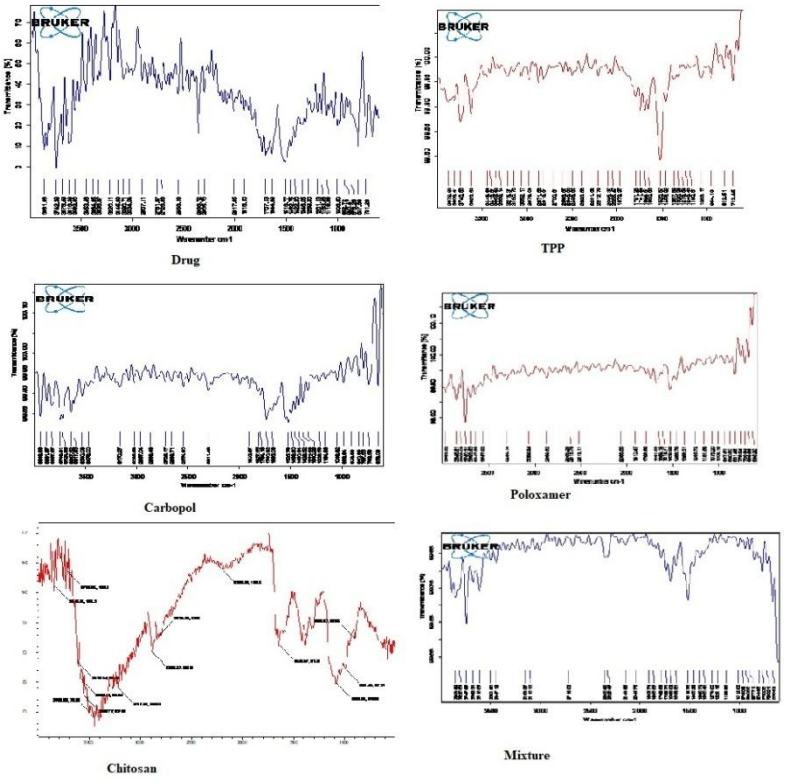

Figure 01: FTIR Spectra of Amlodipine (pure drug)

Table 02: FTIR spectrum of observed and characteristic peak of Amlodipine

IR absorption bands (cm-1)		Bond	Functional group
Observed peak	Characteristic peak		
Amlodipine			
3678.49	3000-3700	O-Hstrech	Alkenes,aromatic
1422.30	600-1500	C-Clstretch	Alkanes
1346.05	600-1500	C-Clstretch	Alkanes
1163.48	600-1500	C-Clstretch	Alkanes
1008.50	600-1500	C-Clstretch	Alkanes
952.72	600-1500	C-Clstretch	Alkanes
TPP			
3623.09	3000-3700	O-Hstrech	Alkenes,aromatic
3410.81	3000-3700	O-Hstrech	Alkenes,aromatic
1458.92	600-1500	C-Clstrech	Alkanes
1320.38	600-1500	C-Clstretch	Alkanes
954.18	600-1500	C-Clstrech	Alkanes
Carbopol			
3647.52	3000-3700	O-H strech	Alkenes,aromatic
3540.03	3000-3700	O-H stretch	Alkenes,aromatic
2869.43	2500-3000	C-Hstretch	Alkenes,aromatic ring
1493.80	600-1500	C-Clstretch	Alkanes
906.69	600-1500	C-Clstretch	Alkanes
Poloxamer			
3693.53	3000-3700	O-Hstrech	Alkenes,aromatic
2869.82	2500-3000	C-Hstrech	Alkenes, aromatic ring
1466.79	600-1500	C-Cl stretch	Alkanes
947.51	600-1500	C-Cl stretch	Alkanes
Chitosan			
3618.64	3000-3700	O-H strech	Alkenes,aromatic
3560.77	3000-3700	O-H strech	Alkenes,aromatic
2225.96	2100-2660	C=Cstrech	Alkynes
1639.57	1600-1900	C=Ostrech	Aldehyde,ketones,carboxylic acid
991.46	600-1500	C-Clstrech	Alkanes
HPMC			
3414.17	3010-3300	N-H strech	Aromatic ring
2538.45	2100-2660	C=C strech	Alkynes
1377.24	600-1500	C-Clstrech	Alkanes
794.71	600-1500	C-Clstrech	Alkanes
Mixture			
3682.31	3000-3700	O-Hstrech	Alkenes,aromatic
2718.03	2500-3000	C-Hstrech	Alkenes, aromatic ring
1460.22	600-1500	C-Cl stretch	Alkanes
940.55	600-1500	C-Cl stretch	Alkanes

Diffirential Scanning Calorimetry Studies

The DSC spectra of the sample (pure drug) the exothermic peak cannot be found out & endothermic peak 2.851 J/g & 277.59°C. The DSC spectra of chitosan the exothermic peak was found to be 55.35°C & endothermic peak was found to be 223.91°C. The DSC spectra of HPMC the exothermic peak cannot found in spectum & endothermic peak was found to be 223.91°C. The DSC spectra of Carbopol the exothermic peak was found to be 20.22 °C/ 201.3 J/g & endothermic peak was found to be 52.96°C/157.5 J/g. The DSC spectra of TPP the exothermic peak was found to be 220.1 °C & endothermic peak was found to be 53.17°C/134.9 J/g. The DSC spectra of Mixtures the endothermic peak was found to be 229.24 °C / 201.3J/g & exothermic peak was found to be 50.34°C/157.78 J/g. The drug and excipients

there is no incompatibility in these formulations. The drug and excipients is suitable for the transdermal patches. The DSC spectra as shown in DSC spectra as shown in figure 2 & Table 03.

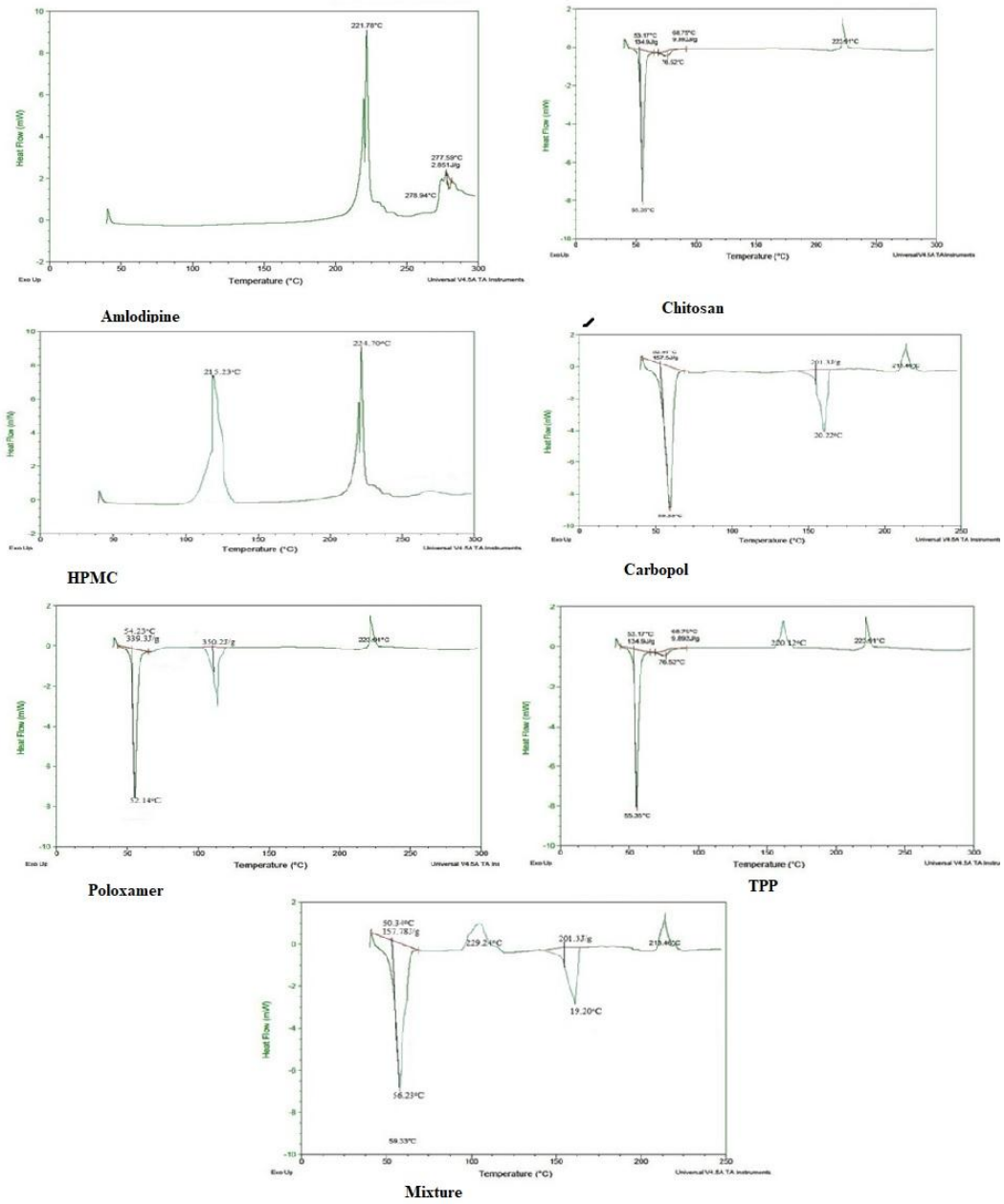

Figure 02: DSC Spectrum of Amlodipine and Mixtures

Table 03: DSC Spectrum of Amlodipine, Excipients & Mixtures

Sl.No	Ingredients	Endothermic peak	Exothermic peak
1	Amlodipine	2.8515 J/g & 277.59°C	--
2	Chitosan	223.91 °C	55.35 °C
3	Hydroxy propyl methyl cellulose	224.70 °C&215.23 °C	--
4	Carbopol	52.96 °C/157.5 J/g	20.22 °C/201.3 J/g
5	Poloxamer	54.23 °C/339.3 J/g	223.91 °C/350.2 J/g
6	TPP(Pentasodium tripolyphosphate)	53.17 °C/134.9 J/g	220.1 °C

7	Mixtures	229.24 °C/201.3 J/g	50.34 °C/157.78J/g

EVALUTION OF AMLODIPINE TRANSDERMAL PATCHS

Physicochemical Evaluation of Films

Thickness of the Patch The thickness ranged between **0.12 ± 0.04 mm to 0.20 ± 0.06 mm,** indicating that the patches are fairly uniform in thickness as shown in Table 03.

Weight Variation: The different batches of formulations weights variations were relatively good uniformity of weight variations among the various batches was observed, with all formulations and ranged from **1.42 ± 1.1% to 1.80 ± 1.9%.**The results indicate that the process employed to prepare patches in this study was capable of producing patches with uniform drug content and minimal patch variability. As shown in the Table 04.

Moisture Uptake: Moisture content and moisture uptake studies indicated that the increase in the concentration of hydrophilic polymer was directly proportional to the increase in moisture content and moisture uptake of the patches. The moisture content of the prepared formulations was low, which could help the formulations remain stable and reduce brittleness during long term storage. The moisture uptake of the formulations was also low, which could protect the formulations from microbial contamination and reduces bulkiness. As shown in Table 05.

Flatness: The flatness study showed that all the formulations had the same strip length before and after their cuts, indicating 99% flatness. Thus, no amount of constriction was observed; all patches had a smooth, flat surface; and that smooth surface could be maintained when the patch was applied to the skin. As shown in the Table 05.

Determination of Tensile Strength: The tensile strength of formulations TNPGF1 to TNPGF9 ranged from **10.20 ± 1.15 to 12.85 ± 2.40 psi,** indicating good mechanical strength of the prepared patches. The results suggest that the formulations possess adequate flexibility and strength to withstand handling and application without breaking. As shown in Table 07.

Folding Endurance: Folding endurance test results indicated that the patches would not break and would maintain their integrity with general skin folding when applied.As shown in the Table 04.

Water Vapour Transmission (WVT) Rate: The WVTR was found to be TNPGF1 to TNPGF94.79 ± 0.43 to 1.28 ± 0.19. As shown in the table 09.

Drug Content Determination: The total amount of drug is present in the transdermal patchs of TNPGF1 to TNPGF9 was found to be 90.8 ± 0.2 % to 98.2 ± 0.2 %. As shown in the Table 04.

Table 04: Thickness of the Transdermal patch of Amlodipine loaded chitosan nanoparticles dispersed in carobopol gels

Formulation Code	Thickness (mm)	Weight variation (%)	Moisture uptake	Flatness %	Tensile Strength (psi)	Folding Endurance (F)	Water Vapour Transmission	Drug content (%)
TNPGF1	0.12±0.04	1.66±1.4	3.115±0.14	96	11.15±1.10	132.2± 2.20	3.59± 0.20	95.3±0.3
TNPGF2	0.13±0.04	1.80 ± 1.9	2.135±0.23	95	10.20±1.15	122.3± 3.10	2.74± 0.14	93.5±0.3
TNPGF3	0.14±0.03	1.63±1.1	3.145±0.33	97	11.18±2.05	166.1± 2.10	4.59± 0.22	90.8±0.2
TNPGF4	0.16±0.05	1.67±1.4	2.155±0.24	96	11.14± 1.95	242.3± 3.00	1.28± 0.19	91.7±0.3
TNPGF5	0.15±0.02	1.28±2.3	3.165±0.42	98	12.18± 1.95	152.4± 2.00	2.18± 0.40	92.0±0.3
TNPGF6	0.19±0.02	1.42±1.1	4.20±0.25	99	11.20± 1.98	200.2± 1.10	3.08± 0.20	98.2± 0.2
TNPGF7	0.11±0.04	1.57±0.6	2.145±0.14	98	12.85± 2.40	212.3± 2.00	2.05± 0.14	93.3±0.3
TNPGF8	0.14±0.03	1.66±1.4	3.155±0.34	97	12.60± 2.55	312.5± 3.10	3.72± 0.21	94.0±0.2
TNPGF9	0.20±0.06	1.68±1.3	1.135±0.60	96	11.80±2.05	262.4± 3.00	4. 79± 0.43	88.5±0.3

***In vitro* release drug diffusion studies were performed using modified Franz diffusion cell**

In vitro release studies can be performed in a modified Franz diffusion cell over a period of time 5 hours. At specific time intervals, aliquots of samples containing the released drug are taken from the acceptor compartment and are quantified using a suitable method of determination Such as UV VISIB spectroscopy Amlodipine = λmax 219. The sink condition is

usually maintained by replacing the volume of aliquots taken by similar volumes of the buffer to resemble constant clearance of drugs from their physiological site of action.

***In vitro* drug release kinetics**

For understanding the mechanism of drug release rate kinetics of the drug from dosage forms, the *invitro* drug diffusion data obtained was fitted to various mathematical models such as zero order, First order, Higuchi matrix, and Krosmeyer Peppas model. The % drug release with data to various kinetic models for different Transdermal Patchs formulations is presented in table No. 51 to 60 & Figure 61.

Table 05: In Vitro Franzs diffusion studies of Transdermal patch of Amlodipine loaded chitosan nanoparticles dispersed in carobopol gels TNPGF6

S.No	Time	Absorbance	Amount of Drug Release	Concentration	Cumulative Amount Of Drug Release	% Of Drug Release	Cumulative % Of Drug Release
1	15 Mints	0.029	0.09	0.04	80	9	8000
2	30 Mints	0.110	0.29	0.12	280	30	28500
3	45 Mints	0.190	0.55	0.25	530	43	49500
4	60 Mints	0.240	0.60	0.30	620	68	62000
5	75 Mints	0.275	0.75	0.33	760	83	78500
6	90 Mints	0.380	0.96	0.40	780	95	80500

Table 06: *In Vitro* Franz's diffusion studies of Transdermal patch of Amlodipine loaded chitosan nanoparticles dispersed in carobopol gels TNPGF1 to TNPGF9

S.No	Time	Absorbance	Amount of drug release	Concentration	Cumulative amount of drug release	% of drug release	Cumulative % of drug release
1	15 Mints	0.029	0.09	0.04	80	9	8000
2	30 Mints	0.110	0.29	0.12	280	30	28500
3	45 Mints	0.190	0.55	0.25	530	43	49500
4	60 Mints	0.240	0.60	0.30	620	68	62000
5	75 Mints	0.275	0.75	0.33	760	83	78500
6	90 Mints	0.380	0.96	0.40	780	95	80500

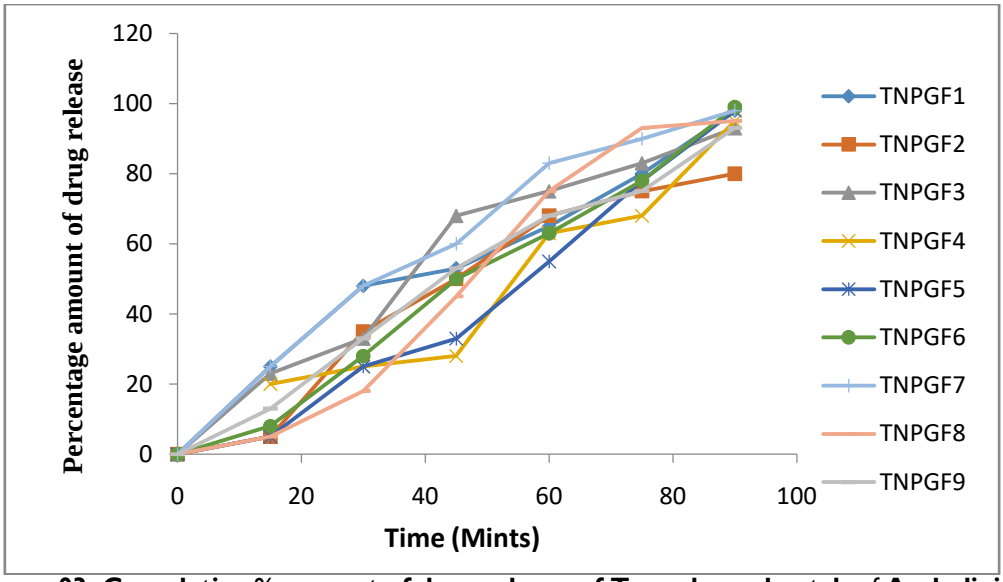

Figure 03: Cumulative % amount of drug release of Transdermal patch of Amlodipine loaded chitosan nanoparticles dispersed in carobopol gels TNPGF1 to TNPGF9

Table 07: Release kinetics of optimized formulation of Transdermal patch of Amlodipineloaded chitosan nanoparticles dispersed in carobopol gels TNPGF1 to F4

Model	TNPGF1		TNPGF2		TNPGF3		TNPGF4	
	R^2	m	R^2	m	R^2	M	R^2	M
Zero order	0.971	10.12	0.954	9.823	0.947	10.35	0.941	9.880
First order	0.602	0.025	0.688	0.021	0.648	0.024	0.702	0.026
Higuchi's Matrix	0.955	98.85	0.905	94.12	0.938	102.8	0.818	92.45
Korsmeyer-	0.948	1.520	0.980	1.550	0.962	1.532	0.960	1.485

Formulation Code	Zero order		First order		Higuchi Matrix		Korsmeyer Peppar		Best fit Model
	R2	m	R2	m	R2	m	R2	m	

Model	TNPGF5		TNPGF6		TNPGF 7		TNPGF 8		TNPGF 9	
	R^2	m	R^2	m	R^2	m	R^2	m	R^2	m
Zero order	0.970	11.05	0.790	11.58	0.948	28.85	0.952	12.18	0.985	10.28
First order	0.768	0.028	0.782	0.030	0.705	0.031	0.788	0.030	0.752	0.027
Higuchi's Matrix	0.815	100.4	0.862	107.5	0.918	282.6	0.825	112.4	0.922	99.85
Korsmeyer -Peppar	0.15	0.006	0.992	1.54	0.976	1.775	0.990	1.572	0.090	1.525

Table 08: Release kinetics of optimized formulation of Transdermal patch of Amlodipine loaded chitosan nanoparticles dispersed in carobopol gels TNPGF5 to F7

Table 09: Release kinetics of optimized formulation of Transdermal patch of Amlodipineloaded chitosan nanoparticles dispersed in carobopol gels TNPGF6

TNPG F6	0.790	11.58	0.782	0.030	107.3	0.992	0.995	1.54	Fist order

CONCLUSION

The present work showed that transdermal delivery system for Amlodipine based on chitosan nanoparticles dispersed into gel was successfully prepared and characterized. There is no Incompatability between drug and polymers by performing FTIR and DSC. To characterize the rate controlling membrane of transdermal patchs. The thickness ranged between TNPGF1 to F9 0.11 ± 0.05 mm to 0.19 ± 0.07 mm, which indicates that they are uniform in thickness. The different batches of formulations weights variations were relatively good uniformity of weight variations among the various batches was observed, with all formulations and ranged from 1.40 ± 1.2% to 1.78 ± 2.0%. The flatness study showed that all the formulations had the same strip length before and after their cuts, indicating 99% flatness. The Tensile strength of the TNPGF1 to TNPGF9 shows the 10.14 ± 1.19 to 12.78 ± 2.45 shows the excellent viscosity. The total amount of drug is present in the transdermal patchs of TNPGF1 to TNPGF9 was found to be 90.5 ± 0.3 % to 98.5 ± 0.1 %. *In-vitro* Franz's diffusion drug Release Studies among all formulations the best formulation was TNPGF6. The drug release through the transdermal patches of Amlodipine follows First order kinetics with diffusion controlled mechanism. Effect of penetration enhancer like dimethyl sulfoxide has been checked on *in-vitro* permeation of drug and was found to be effective. Gels may create a drug reservoir to provide the system with Amlodipine over long period of time to control the blood pressure.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

INFORMED CONSENT

Not Applicable.

ETHICAL STATEMENT

No human or animal studies were performed.

AUTHOR CONTRIBUTION

Both Authors contributed equally.

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