

# Fabrication and Evaluation of Lercanidipine Hydrochloride Solid Dispersion Tablets

Ayesha NAZ<sup>\*\*</sup>, Syeda KULSUM<sup>\*\*</sup>, Salma BEGUM<sup>\*\*\*</sup>, Donthula SRILATHA<sup>\*\*\*\*</sup>

**Fabrication and Evaluation of Lercanidipine Hydrochloride Solid Dispersion Tablets**

**Lerkanidipin Hidroklorür Katı Dispersiyon Tabletlerinin Üretimi ve Değerlendirilmesi**

## SUMMARY

The present study aimed to develop a solid dispersion formulation of Lercanidipine Hydrochloride (LH), a BCS class II drug with poor water solubility. LH was mixed with various carriers like hydroxypropyl methylcellulose (HPMC), ethyl cellulose (EC), and polyvinyl acetate (PVA) in the ratios of 1:1 and 1:2. The solid evaporation method was employed to formulate solid dispersion (SD). A solid dispersion blend of LH was mixed with microcrystalline cellulose (MCC), sodium starch glycolate (SSG), lactose, talc, and magnesium stearate to formulate the tablets. The pre-compression blend of LH was characterized by the angle of repose, tapped density, bulk density, Carr's index, and Hausner's ratio. The solid dispersion tablets prepared using a rotary tablet punching machine with a 9 mm punch were appraised for quality control parameters viz. thickness, hardness, friability, weight variation, disintegration, and dissolution studies. The results of the pre-compression blend indicated good flow properties. The hardness was found to be 3.5 Kg/cm<sup>2</sup>. The tablets passed all the tests. The F5 formulation, containing drug and PVA in a 1:1 ratio, showed a good result of 64.67 % in 30 minutes. As the concentration of the carrier increased, the release of LH decreased. The in vitro LH release of solid dispersion tablets is higher than that of pure drug. This manifested in an increase in solubility of the LH. Hence from the dissolution data, it was evident that the F5 formulation is the better formulation.

**Keywords:** Ethyl cellulose, hydroxypropyl methylcellulose, Lercanidipine Hydrochloride, polyvinyl acetate, solid dispersion.

## ÖZ

Bu çalışmanın amacı, suda çözünürlüğü düşük olan BCS sınıf II ilaçlardan biri olan Lerkanidipin Hidroklorürün (LH) katı dispersiyon formülasyonunu geliştirmektir. LH, hidroksipropil metilselüloz (HPMC), etil selüloz (EC) ve polivinil asetat (PVA) gibi çeşitli taşıyıcılarla 1:1 ve 1:2 oranlarında karıştırılmıştır. Katı dispersiyon (SD) formülasyonu için katı buharlaştırma yöntemi kullanılmıştır. Tabletlerin formülasyonu için LH'nin katı dispersiyon karışımı, mikrokristalin selüloz (MCC), sodyum nişasta glikolat (SSG), laktoz, talk ve magnezyum stearat ile karıştırılmıştır. LH'nin sıkıştırma öncesi karışımı, akma açısı, vurma yoğunluğu, yığın yoğunluğu, Carr indeksi ve Hausner oranı ile karakterize edilmiştir. 9 mm'lik zımba ile döner tablet zımbalama makinesi kullanılarak hazırlanan katı dispersiyon tabletleri, kalite kontrol parametreleri, yani kalınlık, sertlik, kırılabilirlik, ağırlık değişimi, parçalanma ve çözünme çalışmaları açısından değerlendirilmiştir. Sıkıştırma öncesi karışımın sonuçları, iyi akış özellikleri göstermiştir. Sertliği 3,5 kg/cm<sup>2</sup> olarak bulunmuştur. Tabletler tüm testlerden geçmiştir. İlaç ve PVA'yı 1:1 oranında içeren F5 formülasyonu, 30 dakikada %64,67 gibi iyi bir sonuç göstermiştir. Taşıyıcının konsantrasyonu arttıkça, LH salımı azalmıştır. Katı dispersiyon tabletlerinin in vitro LH salımı, saf ilacınkinden daha yüksektir. Bu, LH'nin çözünürlüğünde bir artışla kendini göstermiştir. Dolayısıyla çözünme verilerinden, F5 formülasyonunun daha iyi bir formülasyon olduğu açıktır.

**Anahtar Kelimeler:** Etıl selüloz, hidroksipropil metilselüloz, lerkanidipin hidroklorür, polivinil asetat, katı dispersiyon.

Received: 12.09.2025

Revised: 26.01.2026

Accepted: 22.04.2026

\* ORCID: 0000-0001-9908-4512, Department of Pharmaceutics, MRM College of Pharmacy, Ibrahimpatnam, Telangana-501510, India

\*\* ORCID: 0000-0002-7028-3830, Department of Pharmaceutical Analysis, MRM College of Pharmacy, Ibrahimpatnam, Telangana-501510, India

\*\*\* ORCID: 0009-0002-0367-2235, Department of Pharmaceutics, MRM College of Pharmacy, Ibrahimpatnam, Telangana-501510, India

\*\*\*\* ORCID: 0009-0001-4441-2467, Department of Pharmaceutics, Brilliant Grammar School Educational Society's Group of Institutions- integrated Campus, Abdullahpurmet, Hyderabad, Telangana, India- 501505.

° Corresponding Author; Ayesha Naz  
Email: ayesha.naz06@gmail.com

## INTRODUCTION

Drugs with definite water solubility exhibit pharmacological effects. Most potent drugs show insufficiency in water solubility. The low solubility brings about poor bioavailability. A generalized approach to enhance solubility and bioavailability is to fabricate a solid dispersion.

Lercanidipine Hydrochloride (LH) used for treating hypertension is a derivative of the dihydropyridine. The 3,5-pyridine dicarboxylic acid, 1, 4 - dihydro - 2, 6-dimethyl - 4 - (3 - nitrophenyl) - 2- [(3,3-diphenylpropyl) methyl amino] - 1,1 -dimethyl ethyl methyl ester hydrochloride is poorly water-soluble (0.000156 mg/ml). Lercanidipine, a yellow amorphous powder, is readily soluble in methanol, chloroform, and practically insoluble in water. It hinders the calcium's transmembrane influx into vascular and cardiac smooth muscle. Compared to cardiac smooth muscle, a higher effect is elicited on vascular smooth muscle. Due to the direct relaxant impact on vascular smooth muscle, total peripheral resistance is lowered which reduces blood pressure. The high membrane partition coefficient of LH prolonged the antihypertensive activity. Administering 10–20 mg LH orally (daily), substantially lowers diastolic blood pressure (Charde et al., 2008).

Being BCS class II, LH has poor solubility and low permeability. Due to first-pass metabolism and poor solubility, LH has a bioavailability of 10% (Thadanki et al., 2004). By dispersing the drug in a carrier matrix, SDs can improve wettability, reduce particle size, and inhibit drug crystallization, culminating in improved dissolution profiles and bioavailability. The objective of the present investigation is to develop an LH solid dispersion via. solvent evaporation method in order to enhance the solubility of the drug in the GIT, which enhances bioavailability. The solid evaporation method, a solvent-based approach, facilitates the intimate mixing of LH with the chosen carrier at the molecular or colloidal level, ensuring homogenous dispersion

and improved dissolution characteristics. Further LH tablets were formulated from solid dispersion and then evaluated. The study systematically investigates the influence of carrier type and ratio on the physico-chemical properties, tablet formulation parameters, and dissolution characteristics of LH. Due to its facile powder manufacture and high yield, the SDs were the most investigated formulation for enhancing LH solubility (Choi et al., 2019). The findings are expected to contribute to the rational design of solid dispersion-based oral delivery systems for poorly soluble antihypertensive agents, ultimately enhancing patient outcomes through improved drug bioavailability.

## MATERIALS AND METHODS

### Materials

LH was procured from Torrent Pharmaceuticals, Mumbai. Hydroxypropyl methylcellulose (HPMC), ethyl cellulose (EC), polyvinyl acetate (PVA), acetone, hydrochloric acid, and methanol were purchased from Asian Scientific, Hyderabad.

### Methods

#### Fourier Transform Infrared Spectroscopy (FTIR)

Infrared spectroscopy was conducted using an FTIR (BRUKER) spectrophotometer (Reddy et al. 2021a). The LH, and LH-solid dispersions were dispersed in KBR (200–400 mg), suitably compressed as discs using a five - ton pressure for 5 min. The spectrum was obtained from 4000 – 400  $\text{cm}^{-1}$  by positioning the pellet in the path of light.

#### Differential Scanning Calorimetry (DSC)

DSC measurements were accomplished on a DSC-50, Shimadzu (Japan), equipped with a TA instrument<sup>4</sup>. Samples of 8–10 mg were placed in pans (aluminium) and thereafter sealed. The probes were heated from 25 to 400 °C at a rate of 10 K/min under nitrogen atmosphere.

Solubility studies

An excess of LH and LH-solid dispersions was placed in 25 ml conical flasks holding distilled water. Using rotary shaker, the samples were rotated for 24 h at 25° C (Mubarak et al., 2021). The filtered samples after suitable dilutions were analyzed at 242 nm using UV-Visible Spectrophotometer (Labindia UV3000).

Calibration curve

A series of dilutions 5, 10, 15, 20, 25, 30, and 35 µg/ml in 0.1N HCl (pH 1.2) were analyzed at 242 nm using a UV-Visible Spectrophotometer (Ganesan et al., 2015).

Preparation of LH solid dispersion

The solvent evaporation method was used to fabricate a solid dispersion of LH. Acetone was used as the solvent. LH (20 mg) was dissolved in 30 mL of acetone and mixed with carriers: HPMC (for F1–F2), EC (for F3–F4), and PVA (for F5–F6), each at 1:1 and 1:2 ratios. The mixtures adequately evaporated at room (ambient) temperature around 24 h were stored in desiccators (Mankar & Rachh 2021). Table 1 elicits the fabrication of LH solid dispersions.

Evaluation of LH solid dispersion

Percentage yield

%Yield = (Actual weight of the SDs / Total weight of drug and excipients) × 100

Drug content

The LH SDs (equivalent to 10 mg of Lercanidipine) were dissolved in 10 mL of methanol. Aliquots of 2.5 ml were diluted to 25 ml with distilled water. After being filtered via. cellulose nitrate membrane (0.45

%Drug content = (Practical amount of solid dispersion / Theoretical amount of solid dispersion) × 100

Flow properties

The flow constraints evaluated for LH solid dispersions were angle of repose, bulk density, tapped

Table 1. Fabrication of LH solid dispersion

| Formulation | Ingredients | Ratio |
|-------------|-------------|-------|
| F1          | LH: HPMC    | 1:1   |
| F2          | LH: HPMC    | 1:2   |
| F3          | LH:EC       | 1:1   |
| F4          | LH:EC       | 1:2   |
| F5          | LH: PVA     | 1:1   |
| F6          | LH: PVA     | 1:2   |

Formulation of LH solid dispersion tablets

The tablets of all six LH solid dispersion blends were formulated according to Table 2 and compressed into LH tablets using a 9 mm multi-punch rotary tablet machine (Saimach lab-model 8 station tablet press).

Table 2. Formulation of LH solid dispersion tablets

| Formulation ingredients                       | Quantity per tablet (mg) |
|-----------------------------------------------|--------------------------|
| Lercanidipine hydrochloride SD                | 20                       |
| Microcrystalline cellulose (binder)           | 20                       |
| Sodium starch glycollate (super disintegrant) | 9                        |
| Lactose (diluent)                             | 147                      |
| Magnesium stearate (lubricant)                | 2                        |
| Talc (glidant)                                | 2                        |
| Weight of tablet                              | 200                      |

The % yield includes the ratio of weight of dried LH Solid dispersion to the total weight of ingredients used in fabricating SDs (Pandey et al., 2012).

µm) samples were suitably diluted, and Lercanidipine was assayed by UV-Visible spectrophotometer at 242 nm. The Lercanidipine drug content was calculated (Subrahmanyam & Thimmasetty 2014).

density, Carr’s Index, and Hausner’s ratio (Husain et al., 2024). The angle of repose was typically measured by allowing a fixed quantity of powder to flow through a funnel onto a flat surface, forming a conical

pile. Bulk density was measured by pouring a known mass of powder into a graduated cylinder and recording the initial volume. Tapped density was obtained by mechanically tapping the cylinder, typically using a tapped density apparatus, until no further volume decrease was observed. Carr's Index was calculated as the percentage difference between tapped and bulk density. Hausner's ratio is the quotient of tapped density to bulk density, serving as another measure of flowability and cohesiveness.

#### Evaluation of LH SD tablets

##### Thickness

Using Vernier Calipers, LH tablets were measured for thickness thrice (Reddy et al., 2021b). Tablet thickness should be controlled within a  $\pm 5\%$  variation of the standard value.

##### Weight variation

A batch of 20 LH tablets was weighed individually using an electronic balance (Schimadzu). Then the mean was calculated. The deviation was determined.

Where, I = Individual weight of tablet; A = Average weight of tablet

$$\text{weight variation} = \left[ \frac{I - A}{A} \right] \times 100$$

##### Disintegration test

It is accomplished using the USP disintegration apparatus (Labindia). Uncoated tablets (according to USP) have a disintegration time as little as 5 minutes, and as long as 30 min.

##### Hardness

The force to break the LH tablets in the hardness tester (Pfizer) was recorded thrice.

##### Friability

In Roche Friabilator (Labindia), ten LH tablets previously weighed ( $W_1$ ) were allowed to fall from a height of 6 inches at 25 rpm for 4 min. Later, LH tablets were weighed again ( $W_2$ ). The % friability was assessed.

$$\% \text{Friability} = \left( \frac{W_1 - W_2}{W_1} \right) \times 100$$

##### Drug content

The ten LH tablets were powdered. An equivalent of 20 mg LH was dissolved in methanol. The samples, after being filtered through a  $0.45 \mu\text{m}$  filter, were diluted suitably. The absorbance was measured at 242 nm using a UV-Visible spectrophotometer.

##### In vitro dissolution studies

The dissolution study of LH tablets in USP type-II (Labindia DS8000) was accomplished using 900 ml of HCl, pH 1.2, at  $37 \pm 0.5^\circ\text{C}$  and 50 rpm. Aliquots of 5 ml were withdrawn at 5, 10, 15, 20, 25, and 30 min and replaced with fresh medium. Filtered samples after appropriate dilution were analyzed using a UV-Visible spectrophotometer at 242 nm.

##### Stability studies

After 6 months of storage, the final optimized LH formulation was assessed after being kept in a stability chamber, at  $40 \pm 2^\circ\text{C}$  temperature and  $75 \pm 5\%$  RH.

## RESULTS

### FTIR

The characteristic FTIR peaks as shown in Figure 1 of LH include  $2959.20 \text{ cm}^{-1}$ ,  $2349.68 \text{ cm}^{-1}$ ,  $1843.34 \text{ cm}^{-1}$ ,  $1643 \text{ cm}^{-1}$ , and  $757.32 \text{ cm}^{-1}$ . A significant shift, addition, or deletion of the peaks was not observed in the remaining formulations which indicate no physical interaction of LH with carriers as shown in Figures 2, 3, and 4.

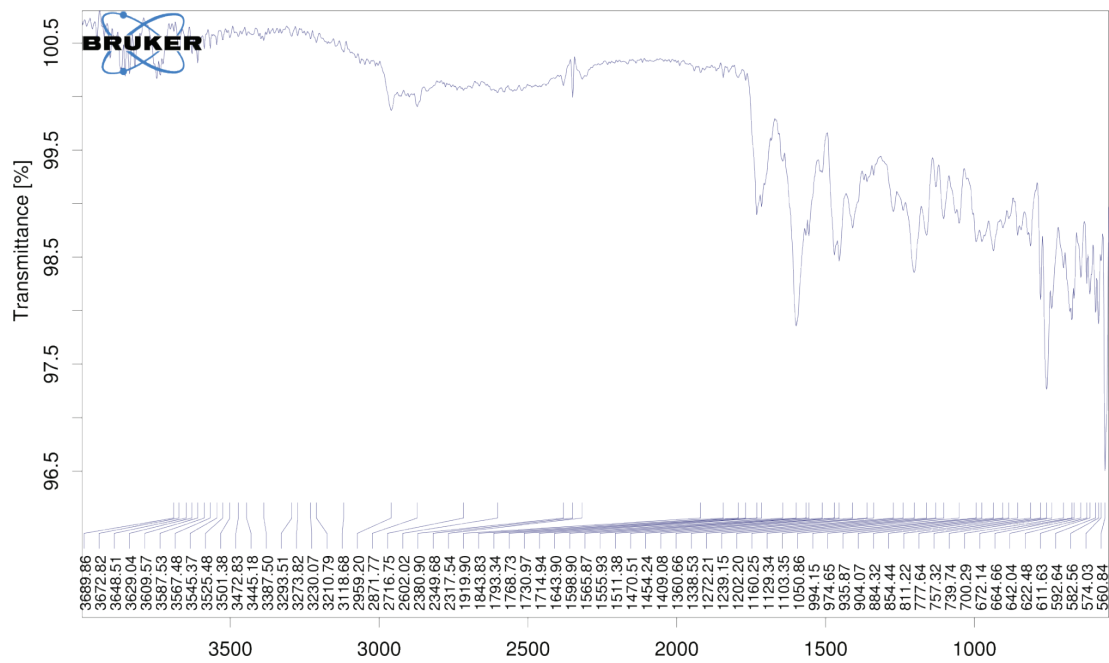


Figure 1. FTIR scan of Lercanidipine HCl

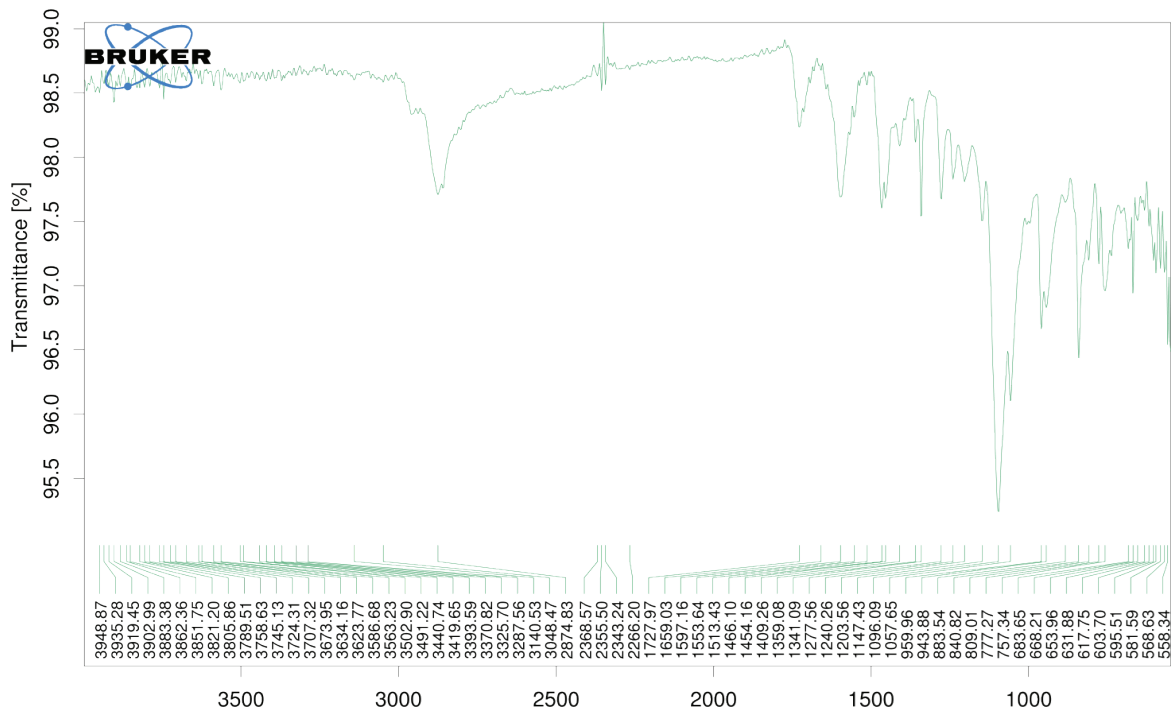


Figure 2. FTIR scan of Lercanidipine HCl with HPMC

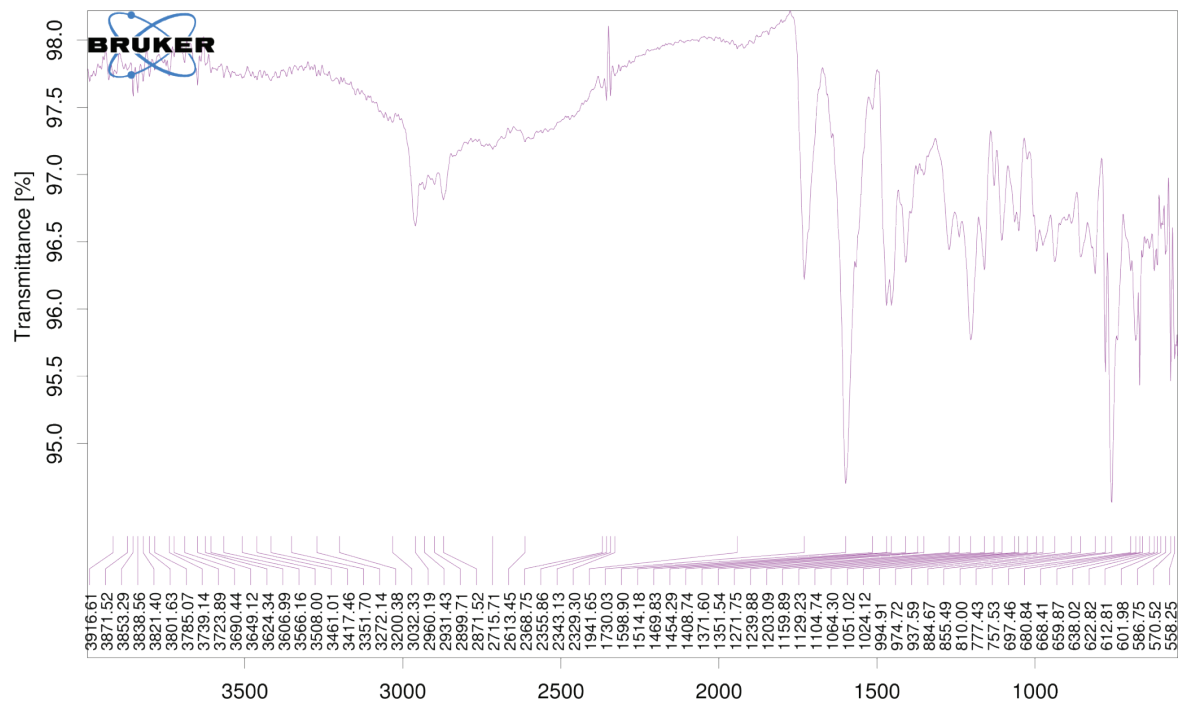


Figure 3. FTIR scan of Lercanidipine HCl with EC

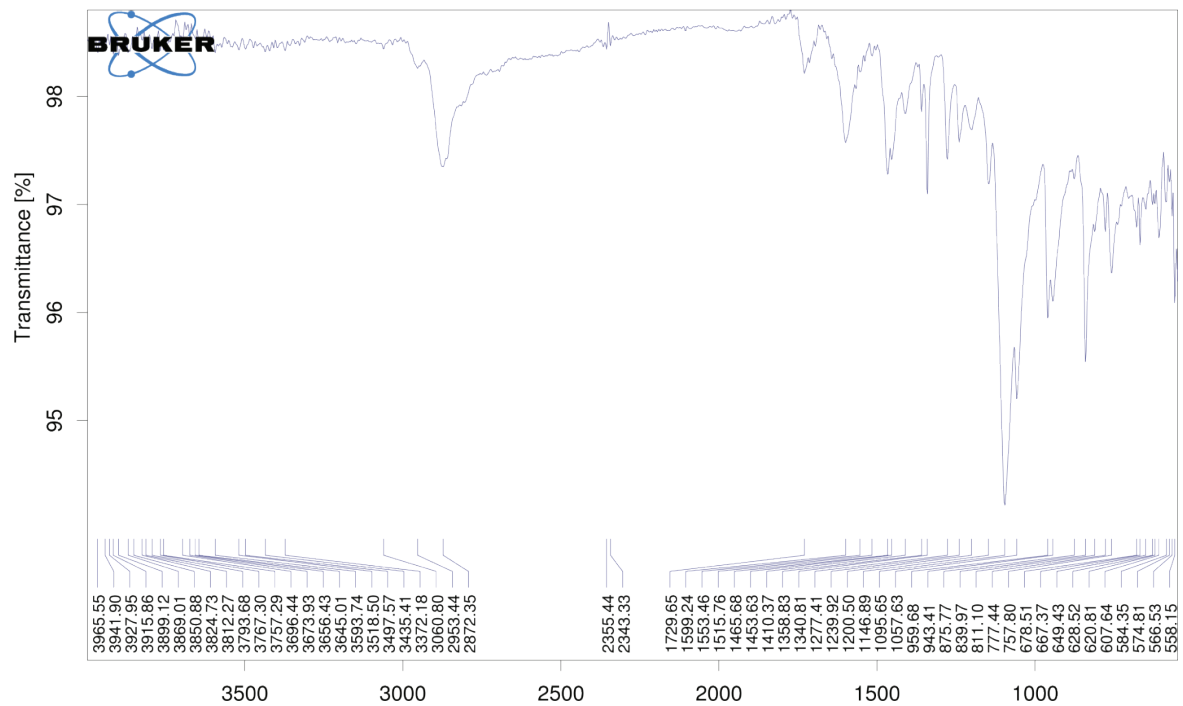


Figure 4. FTIR scan of Lercanidipine HCl with PVA

## DSC

The DSC thermogram for LH (Figure 5.) showed an endothermic peak at 255.10 °C with a fusion enthalpy of 1.34 mJ/mg. In contrast, no peaks were detected in the solid dispersions containing HPMC (Figure 6.) and PVA (Figure 7.). This implies the crys-

tallinity of LH had disappeared in these dispersions, confirming that LH in SD is more amorphous than crystalline. However, in the SD with EC (Figure 8.), a peak remained with a slight shift in temperature, suggesting a crystalline form of the drug, possibly due to the hydrophobic nature of EC.

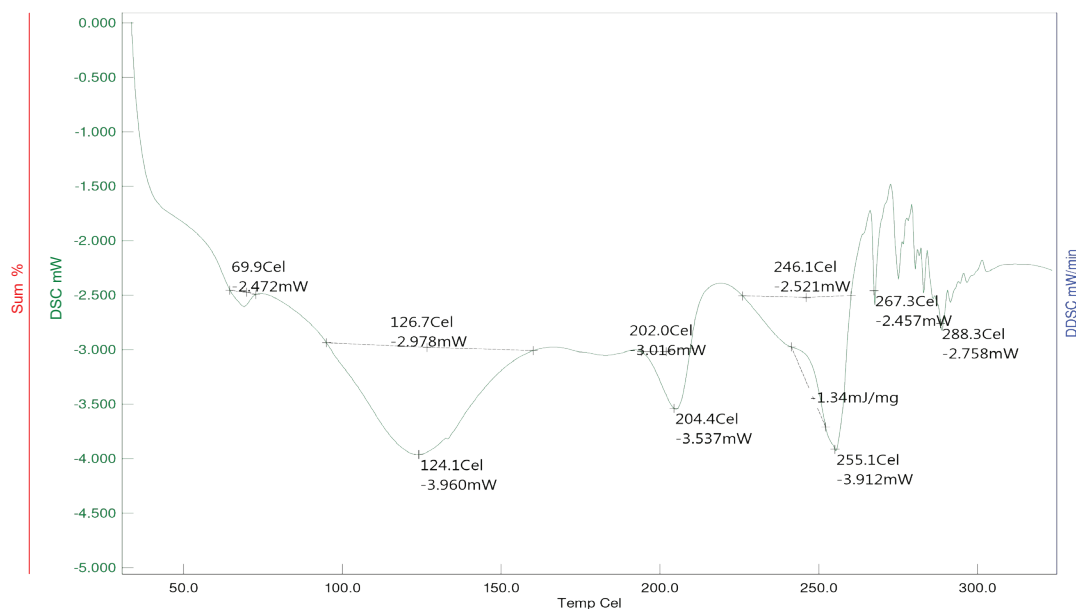


Figure 5. DSC scan of Lercanidipine HCl

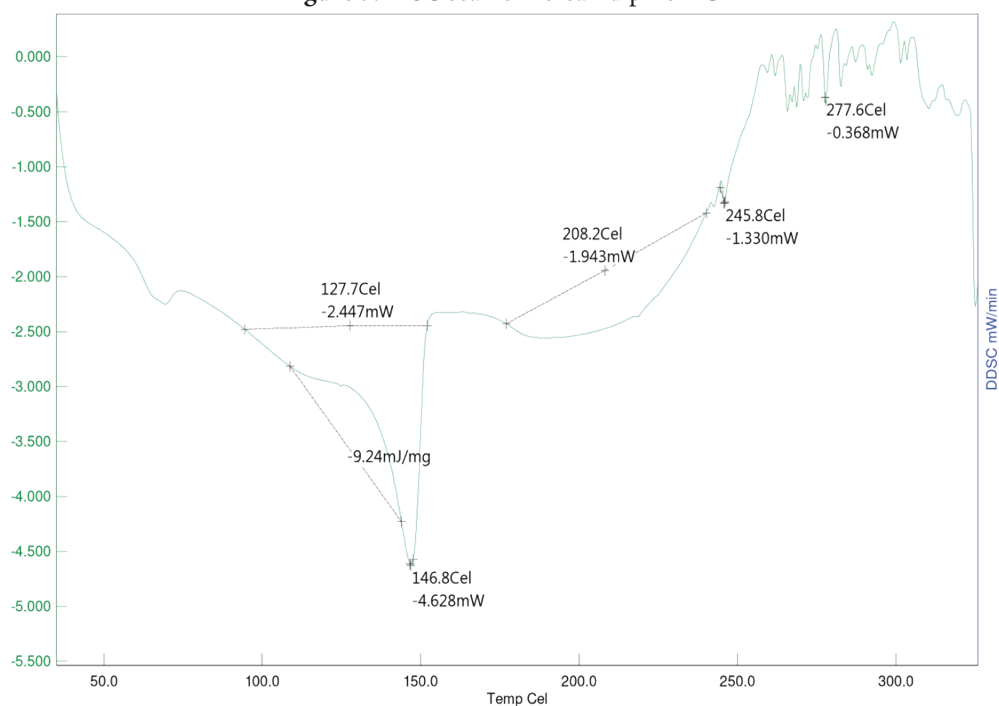


Figure 6. DSC scan of Lercanidipine HCl with HPMC

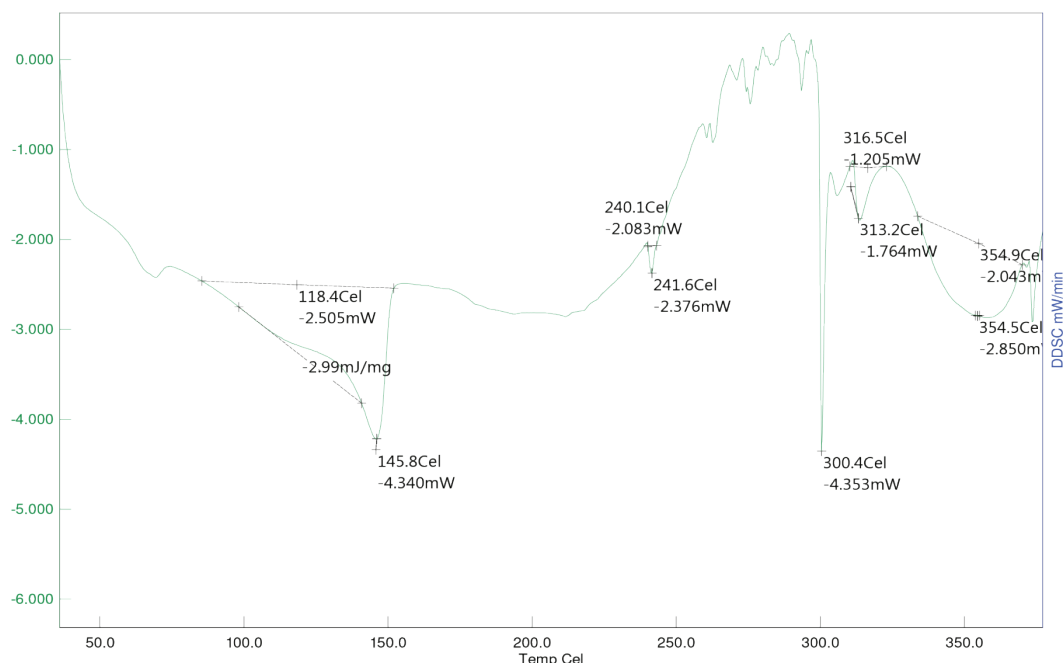


Figure 7. DSC scan of Lercanidipine HCl with PVA

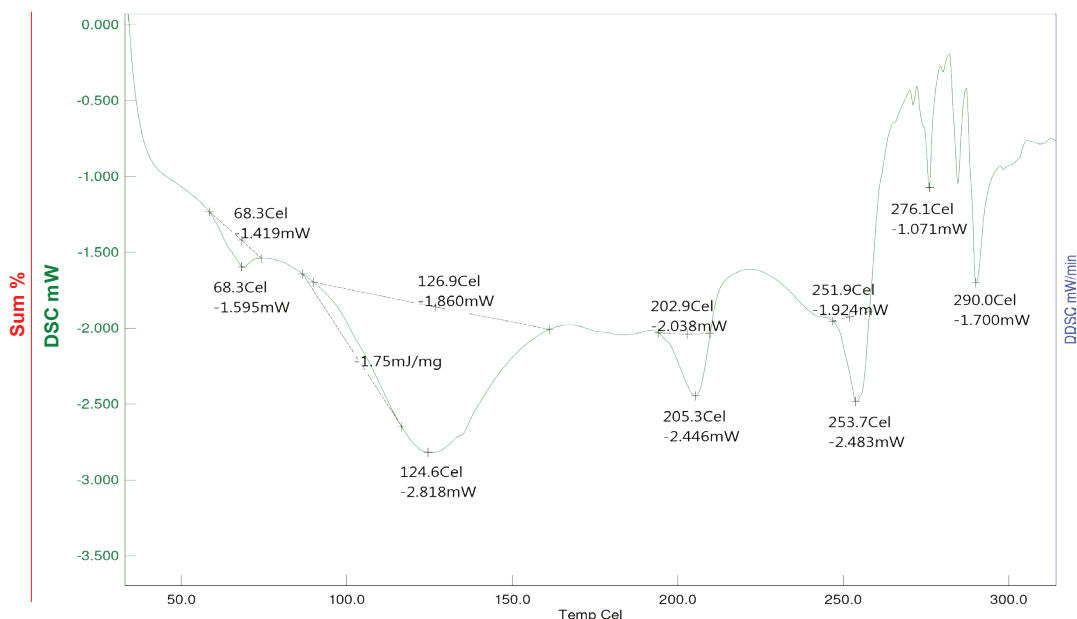


Figure 8. DSC scan of Lercanidipine HCl with EC

### Solubility studies

Solubility data of LH carried out in water, HCl pH 1.2, phosphate buffer pH 6.8, and phosphate buffer pH 7.2 are shown in Figure 9.

All solid dispersions of LH showed enhanced aqueous solubility over pure LH. The aqueous solubility of

LH at 25 °C is 0.00871 mg/ml. Among all solid dispersions, F6 formulation (LH: PVA in 1:2) showed the highest solubility of 0.1879 mg/ml, which was nearly twenty-fold higher than that of pure LH. For formulating LH Solid dispersion tablets, F6 was selected as an optimized formulation. The solubility of the fabricated Solid dispersion is illustrated in Figure 10.

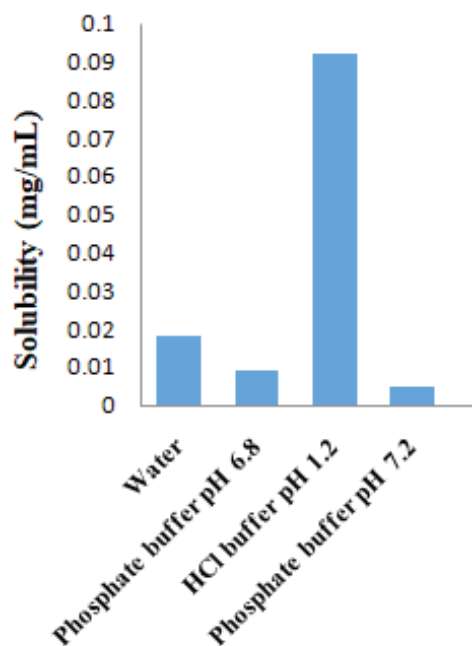


Figure 9. Solubility of LH in various solvents

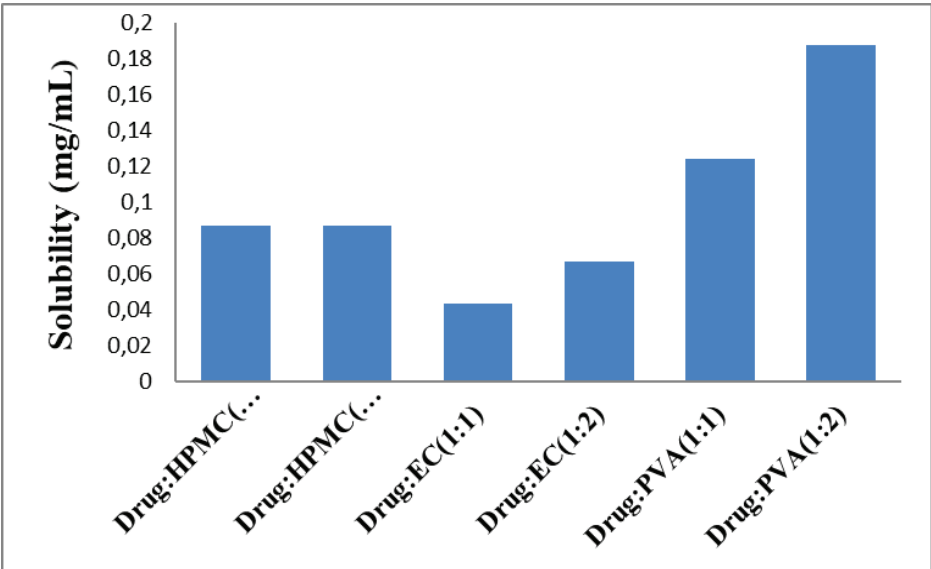


Figure 10. Solubility of solid dispersion

**Calibration curve**

The calibration curve (Figure 11.) of LH obtained

from concentration 5 to 35 µg/ml shows a regression value of 0.9982, slope of 0.0312, and intercept of 0.023 in HCl, pH 1.2.

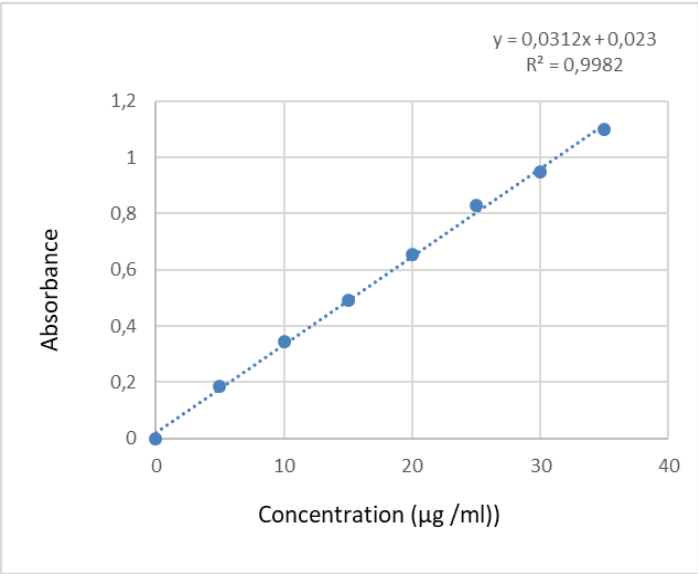


Figure 11. Calibration curve of LH

Evaluation of LH solid dispersion

containing PVA.

Percentage yield

Drug content

As illustrated in Figure 12, the percentage yield ranged from 78.36 to 85.45% for solid dispersion containing HPMC, 62.22 to 68.12% for solid dispersions containing EC, and 86.78 to 93.5% for solid dispersion

As illustrated in Figure 12, the drug content of the solid dispersions ranged from 97.83–98.96%. The maximum drug content was 98.96% in the F6 formulation.

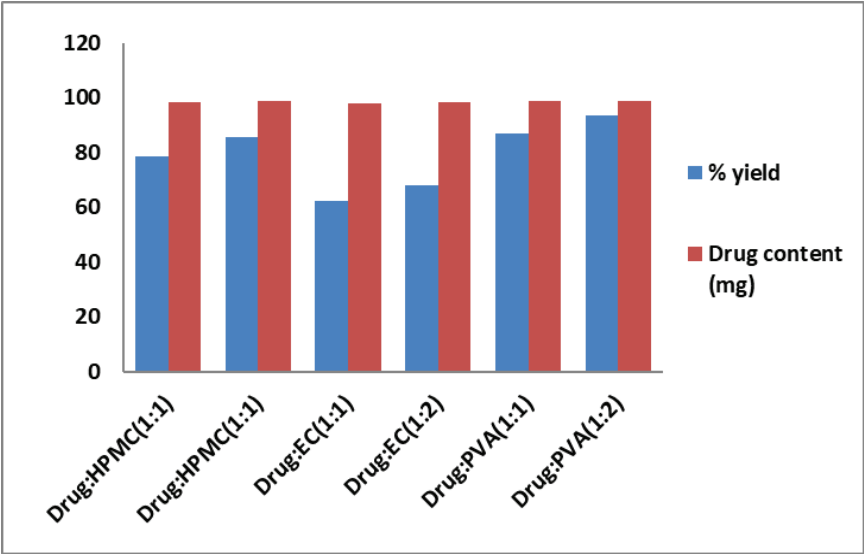


Figure 12. Comparison of % Yield, Drug content of solid dispersion

Flow properties

As recorded in Table 3, the angle of repose ranged

from  $23.92 \pm 0.23$  to  $27.40 \pm 0.23$ , Carr's index ranged from  $9.40 \pm 0.13$  to  $10.34 \pm 0.13$ , and Hausner's ratio ranged from  $1.09 \pm 0.02$  to  $1.17 \pm 0.03$ .

Table 3. Physical properties of solid dispersion blend

| Formulation Code | Angle of repose (°) | Bulk density (gm/cm <sup>3</sup> ) | Tapped density (gm/cm <sup>3</sup> ) | Carr's Index (%) | Hausner's ratio |
|------------------|---------------------|------------------------------------|--------------------------------------|------------------|-----------------|
| F1               | 24.20±0.05          | 0.53±0.01                          | 0.59±0.01                            | 9.43±0.12        | 1.09±0.02       |
| F2               | 24.33±0.21          | 0.54±0.03                          | 0.60±0.02                            | 9.40±0.13        | 1.10±0.01       |
| F3               | 25.81±0.12          | 0.54±0.02                          | 0.58±0.03                            | 10.01±0.19       | 1.13±0.06       |
| F4               | 27.40±0.23          | 0.51±0.01                          | 0.61±0.06                            | 10.11±0.02       | 1.16±0.01       |
| F5               | 23.92±0.23          | 0.58±0.03                          | 0.63±0.03                            | 10.34±0.13       | 1.17±0.03       |
| F6               | 24.31±0.01          | 0.59±0.03                          | 0.58±0.03                            | 10.12±0.34       | 1.11±0.06       |

\*All the values represent mean ± standard deviation (SD), n=3; %: percentage; °: degree; gm: gram; cm: centimeter

Evaluation of LH SD tablets

Physical evaluation

As recorded in Table 4, the average weight ranged from 196.32 ± 2.3 to 208 ± 1.2. The hardness of LH

tablets ranged from 3.2 to 3.8 kg/cm<sup>2</sup>. The thickness of LH tablets ranged from 3.71 to 3.81 cm. The friability for LH tablets was less than 0.862%. The drug content was 98-100%. The disintegration time was less than 5 min.

Table 4. Physical evaluation of LH tablets

| Formulation code | Average Weight (mg) | Thickness (cm) | Hardness (kg/cm <sup>2</sup> ) | Friability (%) | Content uniformity (%) | Disintegration (min) |
|------------------|---------------------|----------------|--------------------------------|----------------|------------------------|----------------------|
| F1               | 208±1.2             | 3.76±0.01      | 3.5±0.7                        | 0.820          | 99±0.12                | 2±0.45               |
| F2               | 196.32±2.3          | 3.74±0.04      | 3.2±0.5                        | 0.641          | 98±0.3                 | 1±1.32               |
| F3               | 201.41±1.2          | 3.71±0.01      | 3.6±0.6                        | 0.563          | 100±0.1                | 3±0.77               |
| F4               | 200.3±2.01          | 3.80±0.06      | 3.8±0.5                        | 0.561          | 100±0.3                | 2±0.95               |
| F5               | 199.9±3.2           | 3.81±0.04      | 3.8±0.4                        | 0.782          | 99±0.6                 | 1±0.84               |
| F6               | 200.12±1.1          | 3.74±0.05      | 3.4±0.6                        | 0.862          | 99±0.4                 | 2±0.89               |

\*All the values represent mean ± standard deviation (SD), n=6; mg: milligram, cm: centimeter; Kg: kilogram, %: percentage, min: minute

In vitro dissolution studies

As evident from Figure 13, the LH release was higher than 50% in 30 min for all the formulations. The formulations, F1 and F2, containing HPMC showed a release of 50.66% and 46.86% after 30 minutes. The

formulations, F3 and F4, containing EC showed a release of 56.15% and 52.72% after 30 minutes. The formulations, F5 and F6, containing PVA showed a release of 64.67% and 60.39% after 30 minutes. The pure drug LH showed the release of 34.87% in 30 minutes.

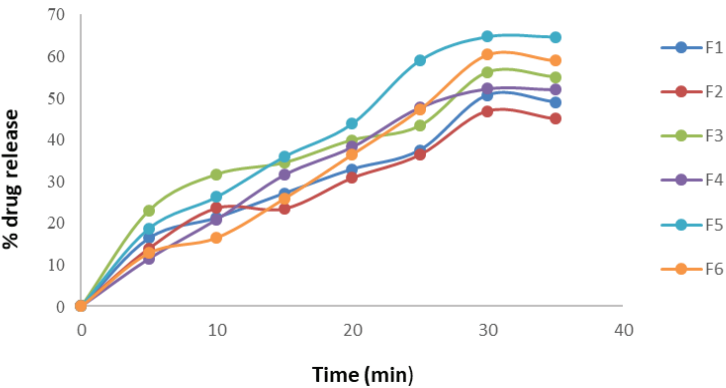


Figure 13. Comparison of in vitro drug release profile of LH tablets

### Stability studies

The F5 formulation tested for stability at 40 °C/75% RH for a period of 6 months had no modifications in the drug content and the *in vitro* release of LH from the tablets.

### DISCUSSION

The FT-IR spectra confirmed compatibility of LH with the carriers. DSC scans confirmed the conversion of crystalline form to amorphous, which increased its solubility. The calibration curve ascertained linearity within 5-35 µg/ml. The product yield of LH increased in the solid dispersions with an increase in the polymer ratio. All SD tablets complied with pharmacopeial specifications for drug content (95–105%), indicating efficient mixing and uniform distribution of LH in the tablet matrix. The high drug content confirmed the application of the solvent evaporation method for fabricating a solid dispersion. The angle of repose was lower than 28°, Carr's index less than 11, for all LH solid dispersion blends, indicating good to fair flowability and compressibility. Hausner's ratio less than 1.25 indicated good flow properties. These results suggest that the SD powders, irrespective of carrier type and ratio, are amenable to direct compression tablet manufacturing. The uniformity in flow properties is crucial for ensuring consistent tablet weight and content uniformity.

All the LH tablets passed the weight variation limits  $\pm 7.5\%$  of the target weight, indicating uniform distribution of SD blend and excipients during compression. All LH tablets displayed acceptable thickness and hardness meeting the pharmacopeial requirements for uncoated tablets. The friability lower than 1% indicated that the solid dispersion tablets of LH were compact and hard. The LH tablets had good uniformity in drug content. The tablets exhibited rapid disintegration, with time less than 5 minutes, depending on the carrier type and concentration. Notably, tablets containing PVA (F5 formulation) demonstrated the shortest disintegration time, attributed to the hydrophilic nature of PVA and its interaction with

SSG. All the physical attributes of the LH solid dispersion tablets were within the control limits.

The *in vitro* studies of F1 to F6 demonstrated higher release of LH compared to pure drug (LH). Incorporation of polymers rendered the LH amorphous, which increased the dissolution rate. As the carrier-to-LH ratio increased, the LH release decreased in the formulation. This significant decrease was due to the increase in viscosity of the polymer due to its gelling nature, and an increase in polymer matrix density further increased the diffusion path length. At increased concentration, the gel-forming ability of the polymer retards the release of the LH. At higher carrier concentration, the larger particle size confined the total surface area, leading to slower release. An appropriate ratio of LH and polymer was required for the release of the LH from the solid dispersions. The pure LH tablet released only 27.4% of the drug at 30 minutes, highlighting the efficacy of the SD approach.

The formulations F1 and F2 containing HPMC had shown low improvement in dissolution, with 50.66% and 46.86% at 30 min for 1:1 and 1:2 ratios, respectively. This is due to the low wetting ability of the low-grade HPMC. In spite of the presence of hydrophobic polymer EC, the dissolution of formulations, F3 and F4, was higher than that of pure drug LH, with release of 56.15% and 52.72% at 30 min. EC-based formulations (F3, F4) demonstrated slower and more sustained release profiles, consistent with the hydrophobic nature of EC. The higher dissolution rate of F5 and F6 was due to the presence of hydrophilic polymer PVA, which reduced the interfacial tension between the LH and PVA. This led to an increase in wetting properties, which increased the dissolution rate. Amidst the formulations, F5 (LH: PVA 1:1) manifested the highest LH release, i.e., 64.67% within 30 min. Beyond that, there was no increase in dissolution. As a result, F5 was optimized.

### CONCLUSION

This research paper systematically demonstrates the fabrication and evaluation of Lercanidipine Hy-

drochloride solid dispersion tablets using HPMC, EC, and PVA as carriers. The substantial enhancement in LH dissolution observed with SD tablets can be attributed to several mechanisms: reduction in drug crystallinity, increased wettability, and the formation of a high-energy amorphous state. The solid evaporation method ensured molecular-level mixing of LH with the carriers, promoting rapid dissolution upon tablet disintegration.

The choice of carrier played a pivotal role in modulating the dissolution behavior. Among the formulations tested, the PVA-based SD at a 1:1 drug-to-carrier ratio (F5) exhibited superior dissolution, releasing 64.67% of LH within 30 minutes and passing all quality control tests. PVA, due to its moderate hydrophilicity and film-forming properties, facilitated the dispersion of LH at a molecular level while preventing agglomeration. The 1:1 ratio was optimal; higher carrier content 1:2 led to a denser matrix, which paradoxically retarded drug release. This phenomenon underscores the importance of rational carrier selection and optimization in SD formulations. HPMC, known for its swelling and gel-forming capacities, improved LH dissolution but to a lesser extent than PVA. The higher viscosity of HPMC at increased concentrations could hinder water penetration and drug diffusion, accounting for the observed reduction in dissolution rate at the 1:2 ratio. EC, being water-insoluble, acted as a release retardant. Its inclusion in SDs sustained LH release over a prolonged period, which may be advantageous for certain therapeutic indications requiring controlled release. However, for immediate-release antihypertensive therapy, hydrophilic carriers such as PVA and HPMC are preferable.

The study underscores the critical role of carrier selection and optimization in SD formulation, with direct implications for the oral delivery of BCS Class II antihypertensive agents. The investigation results indicate solvent evaporation method could be propitiously employed to fabricate LH solid dispersions. LH tablets formulated have enhanced the solubility,

dissolution rate, and bioavailability. By overcoming the solubility limitations of LH, the SD approach may enable dose reduction, minimize inter-patient variability, and improve patient compliance through more effective blood pressure control.

#### ACKNOWLEDGEMENT

The authors thank Principal, and Management of MRM College of Pharmacy for supporting this research.

#### AUTHOR CONTRIBUTION STATEMENT

Design, Investigation, writing manuscript (AN), literature research, performed experiments, preparing figures (SB, DS), review & editing, framed discussion of the manuscript (SK).

#### CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

#### REFERENCES

- Charde, S., Mudgal, M., Kumar, L., & Saha, R. (2008). Development and evaluation of Bucco adhesive controlled release tablets of lercanidipine. *AAPS Pharm SciTech*, 9(1), 182-90. doi: 10.1208/s12249-007-9031-7.
- Choi, J. S., Ahn, J. B., & Park, J. S. (2019). Amorphous multi-system of celecoxib improves its anti-inflammatory activity in vitro and oral absorption in rats. *International Journal Pharmaceutics*, 555, 135-145. doi: 10.1016/j.ijpharm.2018.11.050.
- Ganesan, P., Soundararajan, R., Shanmugam, U., & Ramu, V. (2015). Development, characterization and solubility enhancement of comparative dissolution study of second generation of solid dispersions and microspheres for poorly water-soluble drug. *Asian Journal of Pharmaceutical Sciences*, 10(5), 433-441. doi.org/10.1016/j.ajps.2015.05.001.

- Husain, A., Koshta, A., Joshi, A., Malviya, S., & Kharia, A. (2024). Formulation and evaluation of solid dispersion tablet containing tinidazole. *International Journal of Pharmaceutical Sciences and Research*, 15(4), 1223-1237. doi:10.13040/IJPSR.0975-8232.
- Mankar, S. D., & Rachh, P. R. (2021). Formulation, Development, Evaluation and Solubility Enhancement of Lercanidipine Hydrochloride by Solid Dispersion Techniques. *Journal of Pharmaceutical Research International*, 33(53B), 195-213. doi: 10.9734/jpri/2021 /v33i53B33697.
- Mubarak, E. H. E., Osman, Z. A. R., & Rahman, M. A. (2021). Formulation and evaluation of solid dispersion tablets of Furosemide using polyvinylpyrrolidone K-30. *International Journal of Current Pharmaceutical Research*, 13(2), 43-50.
- Pandey, S., Chandekar, E. K. K., Wattamwar, A., Pandit, S., Joshee, H., & Patil A. (2012). Enhancement of wettability and in vitro dissolution properties of lercanidipine hydrochloride by solid dispersion technique. *Thai Journal of Pharmaceutical Sciences*, 36, 108-116. Retrieved from <https://thaiscience.info/Journals/Article/TJPS/10898815.pdf>
- Reddy, N., Dugasani, S., & Nayakanti, D. (2021a). Fabrication and assessment of lercanidipine hydrochloride solid dispersions for solubility preferment using polymer combination. *Asian Journal of Pharmaceutical and Clinical Research*, 14(7), 77-81. doi:10.22159/ajpcr.2021 .v14i7.41972.
- Reddy, N., Dugasani, S., & Nayakanti, D. (2021b). Fabrication and Characterization of Lercanidipine Hydrochloride Solid Dispersions by Fusion Technique. *International Journal of Life Sciences and Pharmaceutical Research*, 11(1), 78-86. <https://doi.org/10.22376/ijpbs /lpr.2021 .11.1.P78-86>.
- Subrahmanyam, C. V. S., & Thimmasetty, J. (2014). *Laboratory manual of Physical Pharmaceutics*. Delhi: Vallabh Publications.
- Thadanki, M. L., Ramaiah, M., & Devu, S. S. (2024). Fabrication and evaluation of Lercanidipine hydrochloride solid dispersions to improve its solubility and stability. *International Journal of Chemical and Biochemical Sciences*, 25(15), 310-320. Retrieved from <https://www.iscientific.org/wp-content/uploads/2024/03/36-IJCBS-24-25-15-36.pdf>