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Effect of Surfactants on Lansoprazole Solid Dispersions: A Pathway to Improved Dissolution and Development of Fast Disintegrating Tablets

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ABSTRACT

Aim: The study aimed to enhance the solubility and dissolution rate of Lansoprazole, a poorly water-soluble drug, using binary and ternary solid dispersions (SDs) with polyethylene glycol (PEG) 6000 and surfactants such as Tween 80 and sodium dodecyl sulfate (SDS). Additionally, fast-disintegrating tablets (FDTs) were developed using optimized solid dispersions to improve drug release.

Methods: Binary and ternary solid dispersions of Lansoprazole were prepared using the solvent-melt method. Physical mixtures were also formulated for comparison. These formulations were characterized through aqueous solubility studies, Fourier-transform infrared (FTIR) spectroscopy, X-ray diffraction (XRD), and in vitro dissolution studies. The optimized solid dispersion was further incorporated into FDTs using different superdisintegrants. The FDTs were evaluated for pre-compression and post-compression parameters, including drug content, hardness, friability, disintegration time, and in vitro dissolution. Stability studies were conducted on the optimized formulation.

Results: The ternary solid dispersion (SSD3) containing PEG 6000 and SDS significantly improved the solubility of Lansoprazole (3.12 mg/mL) compared to the pure drug (0.022 mg/mL). XRD analysis indicated reduced crystallinity in the solid dispersions, contributing to enhanced dissolution rates. The in vitro dissolution study revealed that SSD3 achieved 88.70% drug release in 60 minutes. Among the FDT formulations, F10, containing croscarmellose sodium (CCS), demonstrated the highest drug release (100%) within 40 minutes. Stability studies confirmed that F10 remained stable over six months with no significant deviation in drug content or dissolution profile.

Conclusion: The study successfully demonstrated that ternary solid dispersions incorporating surfactants significantly enhance the solubility and dissolution rate of Lansoprazole. Furthermore, the optimized fast-disintegrating tablet (F10) formulation exhibited rapid drug release, making it a promising approach for improving the bioavailability of poorly water-soluble drugs.

Keywords: *Lansoprazole, solid dispersion, ternary solid dispersion, polyethylene glycol (PEG) 6000, sodium dodecyl sulfate (SDS), Tween 80, solubility enhancement, dissolution rate, fast-disintegrating tablets (FDTs), and bioavailability.*

1. INTRODUCTION

A rising number of drug candidates being developed through drug discovery pipelines are poorly soluble in water [Rodriguez-Aller et al., 2015; Benet L.Z, 2013]. Although amorphous forms of these drugs provide greater transient solubility than their crystalline versions; however, this improvement in solubility is often inadequate for the effective delivery of drugs at high doses [Hancock B.C, 2000; Saboo S, 2020]. The solubility of an active pharmaceutical ingredient (API) is crucial during the formulation stage. A significant number of APIs available on the market are poorly water-soluble, resulting in a slow

dissolution rate in the gastrointestinal tract and consequently poor oral bioavailability. These issues present major challenges in the development of oral delivery systems. [Ibrahim AH, 2020; Ali W, 2010; Horter and Dressman, 2001] Solid dispersion is an early but still widely favored method for addressing this challenge. Due to its straightforward manufacturing process and ease of scaling up, solid dispersion has emerged as a highly active and promising research area that is of significant interest to pharmaceutical companies. (Vo et al., 2013; Vojinovic et al, 2018) The creation of solid dispersions often results in the transformation of a crystalline drug into a higher energy state, such as the amorphous form. From a thermodynamic perspective, this high-energy state is metastable, meaning it can eventually revert back to its stable crystalline form over time. (Yoshioka et al., 1995; Fukuoka et al., 1986; Izutsu et al; 1994) Various excipients are employed to stabilize amorphous active pharmaceutical ingredients (APIs) in solid dispersions; however, API recrystallization continues to be a significant challenge in their formulation. (Janssens and Van den Mooter, 2009). Over the past two decades, there has been growing interest in incorporating surfactants into solid dispersions. [Serajuddin AT. 1999; Mura P 2005]. The inclusion of surfactants in solid dispersions can increase the solubility of the drug within the carrier and boost the wettability of the entire system. [Sjkovist E 1991].Ternary SDs incorporating surfactants show altered performance relative to their binary counterparts. Improved wettability [Lakshman, 2008; Lang, B 2016; Lu, Y2019] crystallization inhibition, dissolution enhancement [Chen, J 2015], and enhanced formation as well as stabilization of amorphous drugrich solid dispersions [Que, C.2019;22 Feng, D 2018] are some of the advantages that have been observed with ternary SDs containing surfactants.The study aimed to enhance the solubility and dissolution rate of Lansoprazole, a poorly water-soluble drug, using binary and ternary solid dispersions (SDs) with polyethylene glycol (PEG) 6000 and surfactants such as Tween 80 and sodium dodecyl sulfate (SDS). Additionally, fast-disintegrating tablets (FDTs) were developed using optimized solid dispersions to improve drug release.

2. MATERIALS AND METHODS

2.1 Materials

In the present research work, Lansoprazole was obtained as a gift sample from Krebs Biochemicals & Industries Limited. Poly ethylene glycol (PEG) 6000, Tween80, sodium dodecyl sulfate (SDS), Croscarmellose sodium (CCS), Crospovidone (CP), Sodium Starch Glycolate (SSG), Mannitol, Microcrystalline Cellulose (MCC), Magnesium stearate, Talc were purchased from supplier S.D.Fine Chemicals Ltd, Mumbai, India and all chemicals used in the research work were of analytical grade.

2.2 Methods

2.1.1. Preparation of Binary and Ternary Solid Dispersion:

Solvent-Melt Method:

Lansoprazole was dissolved in an appropriate amount of isopropyl alcohol and combined with the molten carrier (PEG 8000) and co-carrier (Tween 80/SDS) in specified proportions (Table 1). The solvent was evaporated at a temperature of 25 ± 2 ℃. The resulted mass was pulverized, sieved through a no. 60 sieve, and stored for future use.

Physical Mixtures:

Binary and ternary physical mixtures of the drug, carrier (PEG 6000) and co-carrier (Tween80/SDS) (as indicated in Table 1) were combined in a poly bag and thoroughly mixed for 15 minutes to create a uniform powder blend. This blend was then sieved through a no. 60 sieve and subsequently stored in a desiccator.

Table 1. Formulation of Lansoprazole Binary & Ternary Solid Dispersions and Physical Mixtures

Carrier	Co-carrier	Drug:Carrier:Co-carrier	Formulation code	
			Solid dispersions	Physical Mixtures
PEG 6000	---	1:6	6SMSD3	6PM3
	Tween 80	1:6:0.5	TSD1	TPM1
		1:6:1	TSD2	TPM2
		1:6:2	TSD3	TPM3
	SDS	1:6:0.5	SSD1	SPM1
		1:6:1	SSD2	SPM2
		1:6:2	SSD3	SPM3

2.3 Aqueous solubility study

Dissolve a surplus amount of pure Lansoprazole, physical mixtures, and solid dispersions individually in 10 ml of distilled water. Shake continuously for 24 hours to ensure equilibrium is reached. Afterward, filter the equilibrated solutions using a membrane filter, and dilute them if necessary. Finally, measure the absorbance of the solutions at a wavelength of 285 nm.

2.4 FTIR Spectroscopy Study

FT-IR spectra were collected using the KBr pellet method. The sample was mixed with dry potassium bromide, and the resulting disk was placed in the FT-IR sample holder. IR spectra were recorded in transmittance mode over the range of 400 to 4000 cm−1.

2.5 X-ray Diffraction Study

Perform an X-ray diffraction (XRD) analysis on Pure Lansoprazole and solid dispersion samples using a Shimadzu XRD-7000 Maxima instrument, which has a sensitivity of 0.001. The samples will be analyzed with CuKα radiation at 40 kV and 50 mA. The XRD measurements will cover a 2θ range of 5° to 90°, with increments of 0.12°/s every 0.02° (Hou et al. 2013).

2.6 In vitro dissolution study for Solid Dispersions

For the in vitro dissolution study, introduce solid dispersion and physical mixture samples corresponding to 30 mg of Lansoprazole, as well as 30 mg of pure Lansoprazole, into 900 mL of pH 6.8 phosphate buffer in USP apparatus–II (paddle type) vessels (Lab India DS 8000). Set the paddle rotation to 70 rpm and maintain the temperature at 37±0.5°C. At designated intervals (10, 20, 30, 40, 50, and 60 minutes), withdraw 5 mL from each vessel, simultaneously adding an equal volume of fresh dissolution medium. Filter the samples through a 0.45-µm membrane filter. Analyze the absorbance of each sample using a UV spectrophotometer at 285 nm, and determine the drug dissolution rate from the slope of the regression line.

2.7 Formulation and Evaluation of Fast Disintegrating Tablets (FDTs):

Fast disintegrating tablets were developed using solid dispersion (SSD3) equivalent to 30 mg of Lansoprazole. The formulation included Sodium Starch Glycolate (SSG), Crospovidone (CP), and Croscarmellose Sodium (CCS) as super disintegrants, Magnesium Stearate as a lubricant, Talc as a glidant, and Aspartame as a sweetening agent, as outlined in Table 2. All components were thoroughly mixed in a poly bag to achieve a uniform blend. Following this, Bulk Density, Tapped Density, Angle of Repose, Carr's Index, and Hausner's Ratio were assessed. The blend was then compressed via direct compression, and the resulting tablets were tested for hardness, friability, weight variation, disintegration time, percentage drug content, and drug release in pH 6.8 phosphate buffer.

2.8 Weight Variation Test:

To verify consistency in tablet weight within a batch, randomly choose 20 tablets from the batch. Use an analytical balance to weigh each tablet separately. Calculate the mean weight of the 20 tablets. Find the percentage deviation of each tablet's weight from the mean.

Table 2. Fast disintegrating Tablet Formulations (SSD3)

Ingradients (mg).	**Formulation Code**									
	F1	**F2**	**F3**	**F4**	**F5**	**F6**	**F7**	**F8**	**F9**	**F10**
Solid dispersion (eq. to 30mg of LAN)	180	180	180	180	180	180	180	180	180	180
Sodium Starch Glycolate (SSG)	-	15	20	25	-	-	-	-	-	-
Crospovidone (CP)	-	-	-	-	15	20	25	-	-	-
Croscarmellose (CCS)	-	-	-	-	-	-	-	15	20	25
Mannitol	90	75	70	65	75	70	65	75	70	65
Micro Crystalline Cellulose (MCC)	20	20	20	20	20	20	20	20	20	20
Aspartame	5	5	5	5	5	5	5	5	5	5
Talc	3	3	3	3	3	3	3	3	3	3
Magnesium stearate	2	2	2	2	2	2	2	2	2	2

***Each Tablet wt. 300mg

2.9 Friability Test:

To assess the likelihood of tablets crumbling or breaking under stress, select a sample of 10 tablets or an equivalent weight. Weigh the tablets precisely and record the measurement. Place them in the friabilator drum and rotate it for 100 revolutions at a speed of 25 rpm. Afterward, remove the tablets, eliminate any dust, and weigh them again.

2.10 Hardness Test:

To assess the mechanical strength of the tablets, randomly select a minimum of 10 tablets. Position each tablet between the anvils of a hardness tester. Apply pressure until the tablet fractures, and record the amount of force needed to break each tablet.

2.11 Thickness Test:

To assess tablet thickness, which can affect both packaging and dissolution, randomly select a minimum of 10 tablets. Measure the thickness of each tablet using calibrated vernier calipers, and record each thickness in millimeters (mm).

2.12 Disintegration Test:

The disintegration test is essential for rapidly dissolving dosage forms, as it measures the time required for tablets to break down, ensuring the active pharmaceutical ingredient (API) is available for absorption. Place one tablet in each tube of the basket-rack assembly within a 1-liter beaker containing pH 6.8 buffer solution at a temperature of 37 ± 0.5ºC. Observe the disintegration of the tablets.

2.13 Tablet drug content:

Each of the 10 tablets was weighed individually, and then crushed, and a portion of the powder equivalent to 30 mg of Lansoprazole was transferred into a 10 ml volumetric flask. The powder was dissolved in methanol, adjusted to the final volume with methanol, and the absorbance was measured at 285 nm using UV-visible spectroscopy.

2.14 In-vitro dissolution study of Fast Disintegrating Tablets (FDTs):

For the dissolution study, 900 mL of pH 6.8 buffer was placed in the vessels of a USP apparatus–II (paddle type) (Lab India DS 8000). Tablets and pure drug samples were added to the vessels. The paddle was rotated at a speed of 70 rpm while maintaining the temperature at 37 ± 0.5°C. At time intervals of 10, 20, 30, 40, 50, and 60 minutes, 5 mL samples were withdrawn, and an equivalent volume of the medium was replaced. The absorbance of the samples was measured using a UV spectrophotometer at 285 nm, with a blank for reference.

3. RESULTS & DISCUSSIONS

3.1 Drug Content:

The drug content in all solid dispersions was found to range from 96.40% to 99.23%, as shown in Table 3. This range indicates a consistent and uniform dispersion of the drug throughout the solid dispersions.

3.2 Aqueous solubility studies:

Table 3: Aq.Solubility and % Drug content of Solid Dispersions & Physical Mixtures.

Formulation Code	Solubility in (mg/ml)	% Drug Content
6PM3	0.15±0.014	98.87 ± 1.07
TPM1	0.26±0.012	96.8±0.35
TPM2	0.35±0.010	98.2±0.57
TPM3	0.46±0.015	99.5±0.83
SPM1	0.38±0.012	95.7±0.62
SPM2	0.57±0.014	97.6±0.27
SPM3	0.69±0.016	94.8±0.31
6SMSD3	1.91±0.018	99.45 ± 1.12
TSD1	1.95±0.012	96.4±0.84

TSD2	1.98±0.013	97.3±0.72
TSD3	2.13±0.011	99.3±0.59
SSD1	2.29±0.010	99.03 ± 0.75
SSD2	2.63±0.017	99.11 ± 0.68
SSD3	3.12±0.016	99.23 ± 0.54
Pure Drug	0.022±0.012	--

The investigation into aqueous solubility was conducted according to the established experimental protocol. Formulation SSD3 exhibited the highest solubility, measured at 3.12±0.016mg/ml. In contrast, the solubility of the pure drug was found to be 0.022 ± 0.012 mg/ml, suggesting that the solid dispersions demonstrated enhanced solubility in aqueous environments. The solubility of the physical mixtures was higher compared to pure Lansoprazole. SDs of Lansoprazole in hydrophilic carrier considerably enhanced solubility compared to the physical mixtures (Table 3).

3.3 Fourier Transform Infrared Spectroscopy (FTIR):

The FTIR spectra obtained are presented in Figure 1. The pure Lansoprazole drug exhibits NH stretching bands at 3394.08 cm^{-1} and 3523.25 cm^{-1}, with C=C stretching at 1645.78 cm^{-1}, Ar-C=C peaks at 1577.63 cm^{-1}, fluorine stretching peaks at 1265.65 cm^{-1}, and S=O bending vibration at 1162.80 cm^{-1} (Figure 1a). In the FTIR spectrum of the solid dispersion formulation, Lansoprazole shows NH stretching at 3396.70 cm^{-1} and 3524.34 cm^{-1}, C=C stretching at 1642.04 cm^{-1}, Ar-C=C peaks at 1572.96 cm^{-1}, fluorine stretching peaks at 1266.51 cm^{-1}, and S=O bending vibration at 1163.45 cm^{-1} (Figure 1b). The FTIR analysis reveals that all characteristic absorption bands of the Lansoprazole molecule remain unchanged in the solid dispersions, indicating no alteration in the absorption pattern. This suggests that there are no interactions between Lansoprazole and the carrier (PEG 6000). The absence of significant changes in the characteristic peaks of Lansoprazole confirms that no chemical interaction or degradation occurs between the drug and the carriers. The results indicate compatibility between Lansoprazole, PEG 6000, and SDS, with the excipients aiding in dispersion and possibly enhancing solubility without altering the molecular structure of the drug.

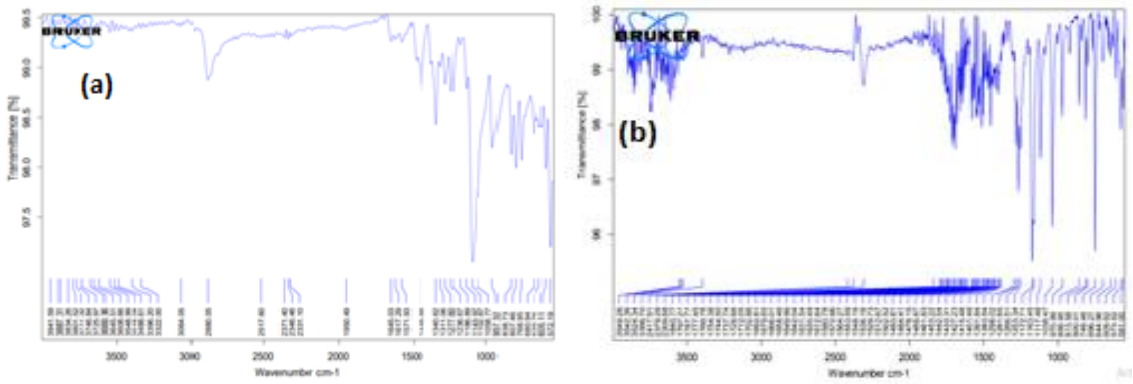

Figure 1. FTIR Spectrum of pure LAN (a) and Solid dispersion (b).

3.4 X-ray diffraction studies:

The XRD (X-ray diffraction) spectra of Lansoprazole solid dispersions containing PEG 6000 and SDS (sodium dodecyl sulfate) demonstrate the crystalline or amorphous nature of the formulation. In the diffractogram of pure Lansoprazole, distinct sharp peaks are observed, indicating its crystalline structure crystalline peaks of Lansoprazole are typically noted (Figure 2). This change suggests the transformation of Lansoprazole from a crystalline to an amorphous or partially amorphous state within the dispersion. The presence of PEG 6000 and SDS, which act as carriers and surfactants, likely contributes to this structural alteration, enhancing the drug's solubility and dissolution rate. The XRD results confirm that the solid dispersion technique effectively modifies the crystalline properties of Lansoprazole, improving its performance as a formulation component.

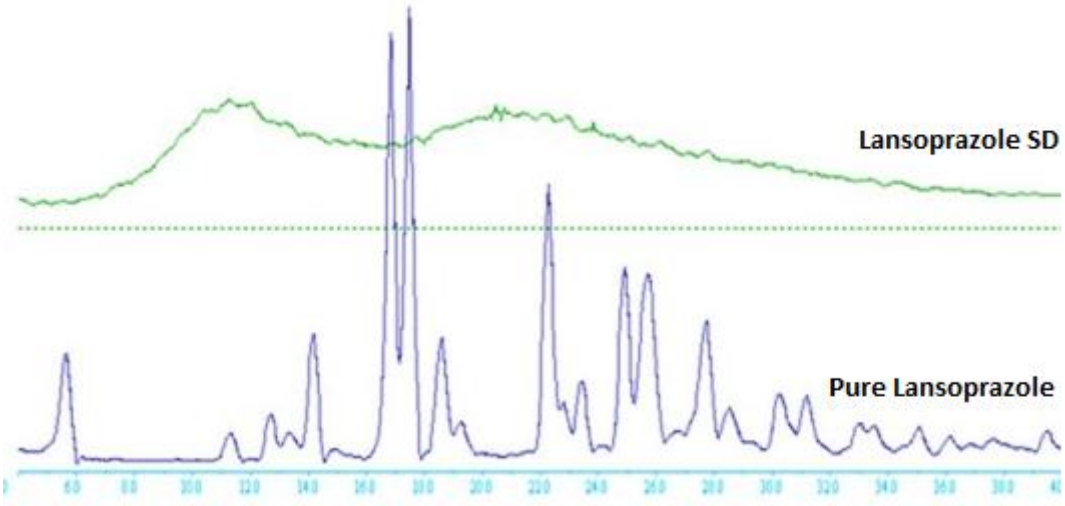

Figure 2. X-ray diffraction spectra of pure Lansoprazole and Solid dispersions

3.5 In vitro dissolution study for Solid Dispersion:

With reference to our previous research work, solid dispersion 6SMSD3 was optimized [M.Vijaya laxmi et al., 2014]. In present study, ternary solid dispersions of 6SMSD3 was formulated by adding surfactants (Tween 80, SDS) as co-carriers in different proportions and its solubility and dissolution behavior is studied. In vitro dissolution of samples equivalent to 30 mg of pure drug was carried out in a USP apparatus II using pH 6.8 phosphate buffer as dissolution media. Figure 3 describes the dissolution behavior of binary (6SMSD3) and ternary Solid dispersions containing Lansoprazole with both PEG 6000 and Tween 80 or SDS provided higher release rate than the release rate of pure Lansoprazole. The release profile showed that release rate was increased by increasing in amount of Tween 80 or SDS. The drug release increased by increasing in amount of Tween 80 from Drug: Carrier: Co-carrier ratio 1:6:0.5 to 1:6:1 and 1:6:2 (TSD1, TSD2, and TSD3 respectively). At the same time, the drug release increased by increasing in amount of SDS from Drug: Carrier: Co-carrier ratio 1:6:0.5 to 1:6:1 and 1:6:2 (SSD1, SSD2, SSD3 respectively). TSD3 had shown 82.30 ± 0.25% drug release whereas SSD3 shown 88.70 ± 0.18% drug release at the end of 60 min.

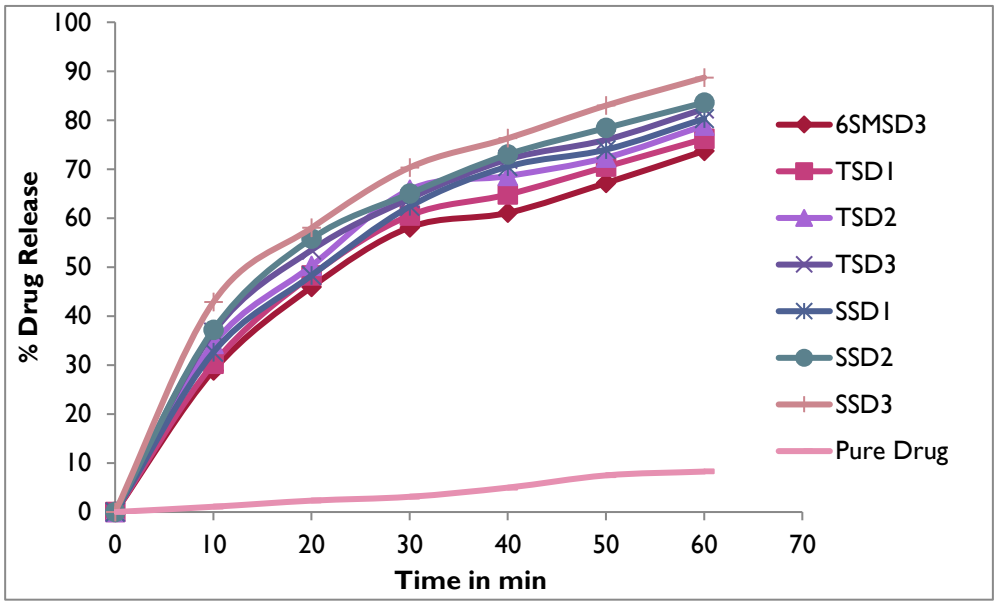

Figure 3. Dissolution profiles of Solid dispersions

In one study, solid dispersions of Meloxicam containing PEG 6000 and SDS showed a significant increase in dissolution rate with an increase in PEG 6000 and the surfactant sodium dodecyl sulfate [Dehghan MH et al., 2006]. Possible mechanisms of increased dissolution rates of solid dispersions have been proposed by Craig, and include: reduction of drug crystallite size, a solubilisation effect of the carrier, absence of aggregation of drug crystallites, improved wettability and dispersibility

of a drug from the dispersion, dissolution of the drug in the hydrophilic carrier, conversion of the drug to the amorphous state and finally the combination of the above mentioned methods. Mixing of Lansoprazole with PEG and Tween or SDS brings drug in close contact with the hydrophilic carrier and surfactant. The increased dissolution rate in this study can thus be contributed by several factors such as a solubilisation effect of the carrier, reduced crystallinity, and conversion of drug to amorphous state, improved wettability and dispersibility of the drug [Craig DQ, 2002]. This study showed that the ternary solid dispersions of Lansoprazole with PEG 6000 and SDS (SSD3) improved dissolution when compared with binary solid dispersions and pure drug.

3.6 Evaluation of Fast disintegrating tablets (FDTs):

3.6.1 Blend Evaluation: Prepared lubricated blend with Optimized Lansoprazole Solid dispersion (SSD3) and excipients and checked for pre-compression parameters. The obtained results (Table 4) proved that the excellent flow characteristic of blend powder for direct compression method.Table values are expressed as mean Standard Deviation ±n=3

Table 4. Pre-compression parameters of SSD3

Formulation code	Angle of repose (θ)	Bulk density (gm/ml)	Tapped density (gm/ml)	Carr's index (%)	Hausner's ratio
F1	27.77 ± 0.50	0.35 ± 0.004	0.39 ± 0.054	8.9 ± 0.055	1.10 ± 0.05
F2	25.54 ± 0.33	0.34 ± 0.021	0.38 ± 0.043	8.5 ± 0.065	1.09 ± 0.05
F3	29.89 ± 0.44	0.36 ± 0.034	0.39 ± 0.057	9.1 ± 0.056	1.12 ± 0.18
F4	26.13 ± 0.27	0.38 ± 0.044	0.41 ± 0.065	7.2 ± 0.077	1.05 ± 0.08
F5	25.94 ± 0.71	0.35 ± 0.032	0.39 ± 0.012	7.9 ± 0.098	1.14 ± 0.04
F6	29.44 ± 0.51	0.39 ± 0.045	0.42 ± 0.044	7.8 ± 0.087	1.04 ± 0.06
F7	27.65 ± 0.34	0.33 ± 0.007	0.37 ± 0.065	7.7 ± 0.055	1.13 ± 0.09
F8	25.55 ± 0.11	0.34 ± 0.003	0.38 ± 0.034	7.6 ± 0.054	1.05 ± 0.17
F9	24.76 ± 0.43	0.34 ± 0.043	0.36 ± 0.034	7.4 ± 0.033	1.04 ± 0.04
F10	24.98 ± 0.88	0.37 ± 0.005	0.40 ± 0.044	7.5 ± 0.047	1.08 ± 0.01

3.6.2 Tablet Evaluation:

Prepared tablets checked for Post-compression parameters, DT and verified results given in Table 5. Friability of all formulation tablets were found between 0.40 ± 0.32 to 0.71 ± 0.65% which is well below the standard NMT 1 %. From the disintegration test, the prepared tablets were disintegrated immediately between 26 - 42 seconds.

Table 5. Post-compression parameters of FDTs

Formulation	Thickness (mm)	Hardness (kg/cm^2)	Weight variation (mg)	Friability (%)	Disintegration time (Sec)	Drug content (%)
F1	3.2 ± 0.24	2.5 ± 0.11	300.08 ± 0.56	0.71 ± 0.32	42± 0.82	99.70 ± 0.67
F2	3.1 ± 0.39	2.7 ± 0.43	301.24 ± 0.77	0.56 ± 0.54	38 ± 1.21	98.43 ± 0.99
F3	3.0 ± 0.22	2.6 ± 0.65	299.48 ± 0.45	0.49 ± 0.87	35 ± 0.97	97.77 ± 0.32
F4	3.2 ± 0.61	2.5 ± 0.65	299.98 ± 0.43	0.44 ± 0.98	33 ± 0.73	99.43 ± 0.66
F5	3.3 ± 0.68	2.6 ± 0.99	298.34 ± 0.99	0.48 ± 0.76	32 ± 0.98	98.11 ± 0.21
F6	3.2 ± 0.62	2.5 ± 0.65	299.98 ± 0.89	0.41 ± 0.33	30 ± 0.53	97.33 ± 0.99
F7	3.1 ± 0.66	2.5 ± 0.55	299.87 ± 0.43	0.47 ± 0.88	28 ± 0.88	98.99 ± 0.23

F8	3.1 ± 0.45	2.6 ± 0.78	300.70 ± 0.99	0.40 ± 0.77	31 ± 1.02	98.66 ± 0.99
F9	3.0 ± 0.32	2.7 ± 0.44	300.69 ± 0.98	0.43 ± 0.55	29 ± 1.09	99.67 ± 0.43
F10	3.2 0.33	2.5 ± 0.99	301.6 ± 0.99	0.45 ± 0.65	26 ± 1.33	98.76 ± 0.11

*Table values are expressed as mean Standard Deviation ±n=3

3.6.3 Tablet drug content*:*

Tablet powder weighed and dissolved in Methanol and measured the absorbance at 285 nm by UV visible-spectroscopy. The obtained results showed in Table 5.

3.6.4 Tablet Dissolution Test:

Drug release studies were conducted for ten formulations (F1-F10) and results are indicated in figure 11. Formulations of FDTs (F1-F10) were prepared by direct compression method using Sodium starch glycolate (SSG), crosspovidone (CP), croscarmellose sodium (CCS) as super disintegrants in various propor-tions and studies were conducted. F1 shows 88.49% drug release in 60min in which no super disintegrants were added. The formulations F2, F3 and F4 shown (90.76%, 92.13%, 95.87%) percentage drug release in 60min respectively, among F2, F3, and F4, the formulation F4 shown higher percentage drug release (i.e.,95.87%) due to increased proportion of sodium starch glycolate (SSG) as super disintegrant. The formulations F5, F6, and F7 shown (91.41%, 94.41%, 99.24%) percentage drug release in 60min respectively, among F5, F6, and F7, the formulation F7 has shown higher percentage drug release (i.e, 99.24%) due to increased proportion of cross povidone as super disintegrant. The formulations F8 shown 95.56% drug release in 60 min, F9 shown 100% drug release in 50 min whereas F10 shown 100% drug release witin 40min only. Among F8, F9, and F10, the formulation F10 has shown higher percentage drug release (i.e, 100%) in 40 min only due to increased proportion of croscarmellose sodium as super disintegrant. From all the formulation (F1-F10) the F4, F7, F10 formulations shown higher percentage drug release than others due to increased proportions of super disintegrants at higher ratio (i.e, SSG, CP, CCS at 25mg). Among the formulations F4, F7 and F10, the formulation of optimised solid dispersion with CCS at 1:6:2ratio (i.e, F10) shown highest 100% percentage drug release in 40min. From the developed ten formulations, F10 showed higher 100% drug release at the end of 40 minutes than other formulation tablets and pure drug (Fig. 11) which might be due to the use of super-disintegrant (CCS) which absorb the medium and swells when exposed to dissolution medium and promote the rapid disintegration of tablets and also MCC and Mannitol prevent the aggregation of solid dispersion particles by coating on them and increase the absorption of dissolution medium and promote the faster disintegration (Zarmpi et al., 2017). Hence, it is concluded that F10 as the optimised fast disintegrating tablet formulation.

3.6.5 Stability Studies of Selected Formulation:

At predetermined time interval (3rd month and 6th month) the optimized tablet formulations (F10) samples were withdrawn from the stability chamber at 40°C /75% RH and evaluated for quality parameters. The obtained results (Table 6) meeting with initial results and no deviation observed.

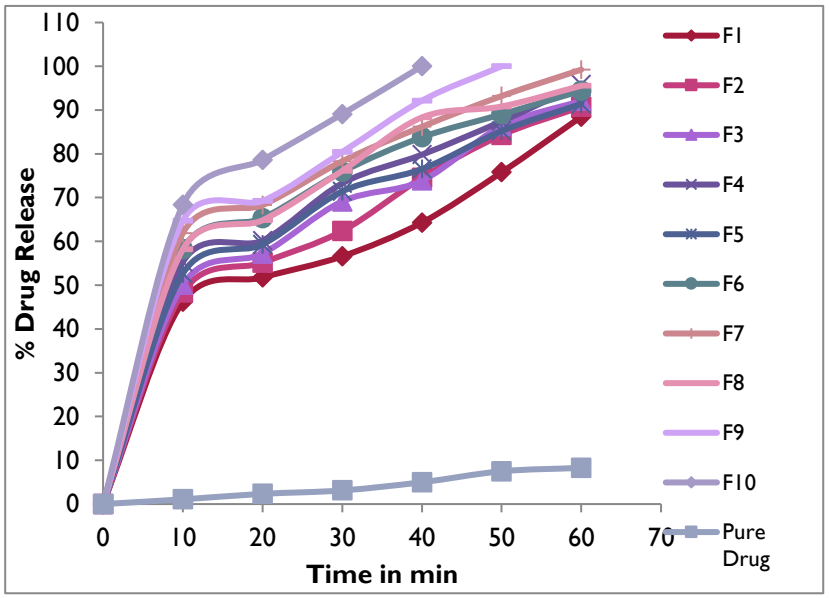

Figure 4. Dissolution profiles of FDTs (F1-F10)

Table 6. Stability Studies of optimized formulation (F10)

Test parameter	F10		
	Initial	3 month	6 month
Hardness (kg/cm2)	2.6±0.4	2.58±0.12	2.56±0.08
Disintegration time(sec)	23	22	20
Assay %	101.2±0.13	101.0±0.17	100.8±0.23
% Drug Release	100±0.10	99±0.18	98.10±0.21

4. CONCLUSION

With reference to our previous research work, solid dispersion 6SMSD3 was optimized (M.Vijaya laxmi et al., 2014). In present study, ternary solid dispersions of 6SMSD3 was formulated by adding solubilizes (Tween 80, SDS) in different proportions and its solubility and dissolution behavior is studied. In vitro dissolution of samples equivalent to 30 mg of pure drug was carried out in a USP apparatus II using pH 6.8 phosphate buffer as dissolution media.

In this experiment an attempt has been taken to evaluate effect of surfactants/ solubilizers on Lansoprazole release from the different formulations of binary and ternary Solid dispersions. Observations of In-vitro dissolution of the solid dispersion of Lansoprazole using pH 6.8 phosphate buffer as the media to study the drug release efficiency from the solid dispersions. These distorted solid dispersions may cause a wide variation in drug release pattern. Lansoprazole is a poorly water soluble drug. The present study was aimed to enhance the dissolution property of Lansoprazole. So this study was endeavored to observe release pattern of drug from the solid dispersion of Lansoprazole by using PEG 6000 as a carrier and Tween 80 and SDS as a surfactants or co-carriers. It was proposed that raising the proportion of the surfactant (SDS) would boost the dissolution rate, which was confirmed across all instances. The variables affecting drug dissolution was matrix property, hydrophilic excipients loading from the solid dispersion and also depend on the physicochemical property of the drug molecule. The major problem of poorly water soluble drugs especially for new molecules is bioavailability. Thus the main target is to increase the solubility of poorly water soluble drugs. So the present study reveals that ternary solid dispersions (with surfactant) may be an ideal means of drug delivery system for poorly water soluble drugs. Further study in this field is required to establish these drug delivery systems so that in future it can be used effectively in commercial basis.

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CONFLICTS OF INTEREST:

The author declares that there are no conflicts of interest regarding the publication of this article. Additionally, this article does not include any studies involving human subjects. This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

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