

Improving Solubility and Dissolution Characteristics of Dapoxetine Hydrochloride through the Lquisolid Compact Method

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ABSTRACT

This study aimed to enhance the solubility and dissolution properties of Dapoxetine hydrochloride (DXH) tablets by using of novel method i.e., liquisolid compact technology (LCT). A total of 9 formulations of DXH tablets were prepared by using carrier materials like microcrystalline cellulose and coating materials like lactose, silica, and starch. In out of nine formulations Super disintegrants like cross povidone (CP) in F1–F4 and Cross Carmellose Sodium in F5–F9 added. All formulations were evaluated for both pre compressional and post compressional evaluation parameters. Based on the evaluation parameters, the F6 formulation exhibited superior dissolution characteristics compared to others, indicating enhanced solubility rates. *In vitro* dissolution studies showed significantly improved release rates for DXH tablets. X-ray diffraction (XRD) analysis revealed a reduction in crystallinity, further supporting enhanced dissolution. Scanning electron microscopy (SEM) confirmed uniform dispersion of drug particles in the optimized formulation, leading to improved drug release. The absence of notable interactions between the drug and excipients was confirmed via FTIR analysis, ensuring formulation stability. In conclusion, LCT effectively enhanced the dissolution rate of DXH, demonstrating its potential as a promising approach for improving poorly water-soluble drugs.

Keywords: Liquisolid compact technology (LCT), Dapoxetine hydrochloride (DXH), Solubility, Dissolution Rate, FTIR
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INTRODUCTION

The development of innovative pharmaceutical formulations has considerably improved the treatment of various diseases. Approximately 40% of newly discovered pharmaceuticals demonstrate inadequate water solubility, presenting a significant obstacle to oral bioavailability¹. The gastrointestinal absorption of these medications is frequently constrained by insufficient dissolution, necessitating the investigation of novel methods to improve their solubility and bioavailability. Conventional approaches to enhance the solubility of weakly water-soluble pharmaceuticals encompass salt creation, co-solvent solubilization, particle size reduction, and solid dispersion methodologies. Although these methods have shown efficacy in particular instances, they frequently exhibit constraints such chemical instability, restricted scalability, and formulation intricacy. Consequently, the advancement of innovative medication delivery methods is essential for addressing these difficulties².

LCT has emerged as a viable alternative for enhancing the solubility and dissolution rate of poorly water-soluble pharmaceuticals. This process entails integrating a liquid

pharmaceutical or drug solution into a carrier material, subsequently coated with highly adsorptive excipients to produce a free-flowing, compressible powder. The notable enhancement in wetting characteristics and the augmented surface area of the drug particles facilitate improved dissolving rates and superior oral bioavailability³.

The LCT enables the effective formulation of BCS Class II medicines, characterized by low water solubility and high permeability, into solid dosage forms with enhanced dissolution characteristics. This approach has multiple benefits, such as manufacturing simplicity, economic efficiency, and compatibility with current tablet production methods. The choice of suitable excipients is essential for optimizing the formulation to maximize solubility enhancement while ensuring stability and compatibility^{4,5}.

This study aims to produce and assess liquisolid compact formulations of DXH, a selective serotonin reuptake inhibitor (SSRI) utilized in the treatment of premature ejaculation. Due of its inadequate solubility, LCT was investigated to augment its dissolving profile and improve therapeutic efficacy. Multiple formulation characteristics, such as the choice of carrier materials, coating agents, and

Table 1: Composition of different formulation of Liquisolid compacts tablets

S.NO	Ingredients in mgs	F1	F2	F3	F4	F5	F6	F7	F8	F9
1	DXH	50	50	50	50	50	50	50	50	50
2	PEG 400 (ml)	0.25	0.5	1	1.5	0.25	0.5	1	1.5	--
3	MCC	50	75	100	125	50	75	100	125	200
4	Starch	25	50	25	50	-	-	-	-	-
5	Lactose	-	-	-	-	25	50	25	50	-
6	Silica	10	20	30	40	10	20	30	40	-
7	CP	25	50	75	25	-	-	-	-	-
8	CCS	-	-	-	-	25	50	75	25	25
9	Talc	70	30	10	5	70	30	10	5	12.5
10	MS	70	25	10	5	70	25	10	5	12.5
	Total Weight	300	300	300	300	300	300	300	300	300

superdisintegrants, were optimized to identify the most effective composition for enhanced drug release⁶.

MATERIALS AND METHODS

Materials

DXH drug brought from Hetero Drugs, Hyderabad, Microcrystalline Cellulose, Starch, Silica, Lactose anhydrous, Talc Magnesium stearate from SD Fine, Mumbai, Sodium Starch Glycolate from Fisher Scientifics, Mumbai, Propylene glycol from LOBA CHEMIE, Mumbai. All chemicals and solvents are analytical grade.

Method of Preparation of Liquisolid Compacts

The formulation of liquisolid compacts entailed dissolving DXH in PEG-400 to form a drug solution. The solution was subsequently combined with microcrystalline cellulose, serving as a carrier, utilizing a high-shear granulator to achieve uniform dispersion. Coating agents, including silica and starch, were incrementally included into the mixture to enhance the powder's flow characteristics and compressibility⁷. To improve disintegration and medication release, super disintegrants such as Cross Povidone or Cross Carmellose Sodium were included into the formulation and mixed well⁸. Subsequently, lubricants and diluents were incorporated into the blend and stirred for a designated period to attain a homogeneous powder mixture. The resulting mixture was further sieved to guarantee uniform particle size distribution and dried with a vacuum tray dryer at an appropriate temperature⁹. Upon drying, the granules underwent direct compression using a tablet press, resulting in the formation of liquisolid compact tablets¹⁰.

Evaluation of Pre-Compression and Post-Compression Parameters¹¹⁻¹³

Bulk Density

The mixture was poured into a graduated cylinder to determine the apparent bulk density. The following formula was used to determine the bulk density.

$$\text{Bulk Density} = \frac{\text{Bulk mass}}{\text{Bulk Volume}}$$

Tapped Density

An established number of taps were done on a measuring cylinder with a known amount of powder blend using USP apparatus-II. The lowest volume that the powder occupied after it was tapped was measured.

$$\text{Tapped Density} = \frac{\text{Bulk mass}}{\text{Tapped Volume}}$$

Compressibility Index

Table 2: Solubility data of API and Optimized Formulation

Solvent	Solubility ($\mu\text{g/mL}$)
Distilled Water	5
0.1 N HCl	13.2
Ethanol	22.10
Methanol	28.5
Acetone	31.5
PEG 400	42.5

A powder with strong flow properties is indicated by a score around 15%, whereas a number over 25% indicates poor flow ability.

$$CI = \frac{\text{Tapped density} - \text{Bulk density}}{\text{Tapped density}} \times 100$$

Hausner's Ratio

This is a calculated, oblique indicator of powder flow easiness. Good flow characteristics are indicated by a Hausner's ratio of less than 1.25, whereas poor flow characteristics are indicated by a ratio greater than 1.5.

$$\text{Hausner's Ratio} = \frac{\text{Tapped Density}}{\text{Bulk Density}}$$

Angle of Repose

The funnel method was utilized to determine the angle of repose. A funnel that could rise vertically was used to pour the mixture through until the maximum cone height (h) was reached. We measured the heap's radius (r) and computed its angle of repose.^[25]

$$\theta = \tan^{-1} \frac{h}{r}$$

Compression of Tablets

The final blended powder combination was compacted into tablets with a twelve-station rotary tablet press fitted with 7 mm flat punches. Magnesium stearate was utilized as a lubricant to facilitate smooth compression and avert tablet adhesion. The compression force was meticulously calibrated to produce tablets with consistent hardness and weight. Each batch had at least 20 tablets, and the compression process was overseen to ensure uniformity in tablet size, hardness, and weight fluctuation. The compressed tablets underwent post-compression examination, which included hardness testing, friability assessment, disintegration time measurement, and study of drug content homogeneity.

Evaluation of Liquisolid Compact Tablets¹⁴⁻¹⁸

Weight Variation

Table 3: Flow Properties of liquisolid compact mixture

Formulation Batch	Bulk density* (g/cc)	Tapped density *(g/cc)	Carr's Index* (%)	Hausner's Ratio*	Angle of Repose* (Degrees)
F1	0.56± 0.13	0.65± 0.22	13.84± 0.25	1.14± 0.22	33± 0.22
F2	0.66± 0.15	0.74± 0.55	10.8± 0.65	1.12± 0.65	34± 0.34
F3	0.69± 0.16	0.79± 0.88	19.12± 0.85	1.08± 0.33	29± 0.77
F4	0.55± 0.66	0.64± 0.23	13.16± 0.57	1.15± 0.28	26± 0.54
F5	0.64± 0.88	0.72± 0.54	11.31± 0.68	1.16± 0.68	28± 0.56
F6	0.68± 0.19	0.76± 0.26	12.34± 0.27	1.08± 0.82	22± 0.31
F7	0.53± 0.66	0.84± 0.58	17.18± 0.69	1.2± 0.55	36± 0.58
F8	0.62± 0.33	0.96± 0.88	16.78± 0.77	1.12± 0.44	38± 0.21
F9	0.65± 0.11	0.78± 0.25	18.46± 0.58	1.36± 0.88	32± 0.77

* n = SD±3

Table 4: Evaluation of Post compressional Parameters of Liquisolid compact tablets

Formulation	Weight Variation (mg)	Hardness (Kg/Cm ²)	Friability (%)	Drug Content	Disintegration Studies (mins)
F1	301±0.15	4.5±0.18	0.48 ± 0.18	99.18 ± 0.12	19.76
F2	298 ± 0.20	3.8 ± 0.14	0.37 ± 0.19	102.14 ± 1.8	14.58
F3	302 ± 0.36	3.45 ± 0.24	0.47 ± 0.13	98.25 ± 1.4	22.58
F4	295 ± 0.24	3.85 ± 0.31	0.42 ± 0.14	98.56 ± 0.63	12.48
F5	300 ± 0.18	3.68± 0.35	0.4 ± 0.16	97.78± 0.35	25.27
F6	299 ± 0.19	3.63± 0.33	0.32 ± 0.13	100.12 ± 0.21	9.25
F7	298 ± 0.64	3.84± 0.31	0.37 ± 0.28	95.48± 0.43	13.25
F8	287 ± 0.35	4.23± 0.38	0.43 ± 0.13	91.25 ± 0.98	12.82
F9	307 ± 0.65	4.98± 0.35	0.38 ± 0.17	98.98± 0.68	22.23

*n = SD±3

After randomly selecting twenty pills from each batch and weighing each one separately, the average weight and standard deviation of five tablets were calculated.

Hardness

Tablet crushing strength (Fc), or the force required to break a tablet in a diametric compression, was evaluated using a MONSANTO Tester to determine the hardness of the tablets.

Friability

The Roche friability (USP) was used to assess the friability of tablets. A tablet sample that had been previously weighed was put in the friability and spun 100 times at 25 revolutions per minute. A gentle muslin cloth was used to dust the tablets.

Drug Content

From each formulation, three exactly weighed and powdered pills were used. After dissolving 100 mg of powdered dapoxetine hydrochloride in 20 milliliters of alcohol, the volume was raised to 100 milliliters by adding 0.2% w/v SLS. A UV spectrophotometer set to 290 nm was used to measure the drug after the resultant solution had been diluted with pure water. Using the calibration curve, the absorbance is measured to determine the drug content.

In vitro Dissolution Studies

A paddle was used to measure the dissolution rate of DXH in all formulations—900 milliliters of PH 1.2 buffer was used as the dissolving fluid. Using a temperature of 37°C and a speed of 50 rpm, each test was conducted. Samples of the dissolving medium (5 mL) were taken out at various intervals (5, 10, 20, 30, 45, and 60 min), appropriately diluted, and tested for the presence of DXH by using a UV spectrophotometer to measure the absorbance at 290 nm.

Characterization of DXH Liquisolid Compact Tablets¹⁶⁻¹⁸

SEM Studies

SEM was used to examine the diameter and exterior surface morphology of Liquisolid Compacts. Using a SEM, the Liquisolid Compacts were examined. The results are shown in Figures 8–10, consist of directly attaching the samples to the SEM sample stub using double-sided sticky tape and covering them with a 200 nm thick gold layer at 0.0001 mm of Hg pressure.

X-Ray Diffraction

Long-range order material can be qualitatively identified via powder X-ray diffraction. The crystalline material is indicated by sharper diffraction peaks.

FTIR Spectroscopy Studies

FTIR spectra of improved batches of Liquisolid Compacts containing Dapoxetine hydrochloride were examined to make sure the API was compatible with the excipients. The FTIR spectrophotometer (Bruker) was used to get FTIR spectroscopy utilizing the potassium bromide pellets. The scanning time was one minute, and the scanning range was 4400 to 400 cm⁻¹.

RESULTS AND DISCUSSIONS

Solubility Studies

The solubility of DXH was assessed in several solvents. The medication demonstrated limited solubility in distilled water (5µg/mL) but exhibited considerable enhancement in PEG 400 (42.5µg/mL). This improvement was ascribed to the enhanced wetting and solubilizing characteristics of PEG 400, which promoted superior drug dispersion in the formulation.

Evaluation of Pre Compressional Parameters

Pre-compression assessments demonstrated favorable flow characteristics, crucial for consistent die filling and

compression. The formulations demonstrated bulk density and tapped density values that indicated favorable flow ability. The compressibility index values were within acceptable parameters, with Hausner's ratios under 1.15 and angles of repose below 25° , validating the blends' appropriateness for tablet compression.

Evaluation of Post Compressional Parameters

The weight variation of the developed formulations adhered to permitted limits according to pharmacopeial standards. The results varied from 287 ± 0.35 mg to 307 ± 0.65 mg.

The minor discrepancies in the weight of various formulations can be ascribed to the consistency in powder flow characteristics and the compression procedure. All batches satisfied the weight uniformity criterion, guaranteeing constant tablet composition. The tablet hardness varied from 3.45 ± 0.24 Kg/cm² to 4.98 ± 0.35 Kg/cm². Formulations with elevated hardness values, such as F8 and F9, demonstrated enhanced mechanical strength, rendering them more resilient to breakage during handling and transit. All formulations, however, preserved an optimal equilibrium between hardness and friability, guaranteeing sufficient tablet strength while facilitating appropriate disintegration. The friability values for all formulations were within the permitted limit of under 1%, signifying robust mechanical integrity. The minimal friability was noted in formulation F6 ($0.32 \pm 0.13\%$), indicating enhanced tablet durability. The maximum friability ($0.48 \pm$

0.18%) was observed in F1, remaining within acceptable parameters, so guaranteeing that the tablets would not disintegrate under standard handling conditions.

The drug concentration in the formulations was evaluated to ascertain consistent drug distribution within the tablets. The drug concentration varied from $91.25 \pm 0.98\%$ to $102.14 \pm 1.8\%$ indicating that all formulations adhered to pharmacopeial standards (95–105%). The modest discrepancies in drug content may result from slight variances in mixing efficiency throughout the formulation process. Disintegration tests are crucial for assessing the rate at which the tablet dissolves in the gastrointestinal tract, influencing medication release and absorption. The disintegration times exhibited considerable variation across formulations, spanning from 9.25 minutes to 25.27 minutes. Formulation F6 demonstrated the briefest disintegration time, signifying swift decomposition in the dissolving medium, presumably attributable to an optimal proportion of superdisintegrants and excipients. In contrast, formulation F5 had the longest disintegration time, likely attributable to a greater concentration of hydrophobic excipients, which may have impeded water absorption. All the post compressional evaluation parameters were noted in the table 4.

In vitro Drug Release Studies

The dissolution profiles of formulations F1, F2, and F3 (Figure 1) exhibit notable disparities in drug release rates. Of the three formulations, F3 demonstrated the greatest cumulative drug release, signifying enhanced solubility and dissolving properties. The swift drug dissolution in F3 may be ascribed to the use of a suitable carrier, which improves the drug's wettability and dispersibility. F1 demonstrated a moderate dissolution rate, but F2 displayed the slowest drug release, maybe attributable to differences in tablet hardness, excipient composition, or the compression force utilized during tablet production. The delayed release of F2 indicates a possible requirement for adjustment of formulation parameters to enhance bioavailability.

The dissolution characteristics of formulations F4, F5, and F6 (Figure 2) underscore the influence of formulation parameters on drug release. F6 had the highest dissolving rate, attaining practically whole drug release in a brief timeframe, signifying enhanced disintegration and

DISSOLUTION PROFILE OF F1,F2,F3

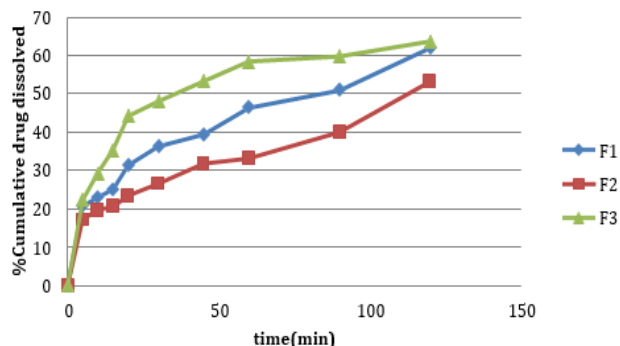


Figure 1: Dissolution profile of F1, F2, F3

DISSOLUTION PROFILE OF F4,F5,F6

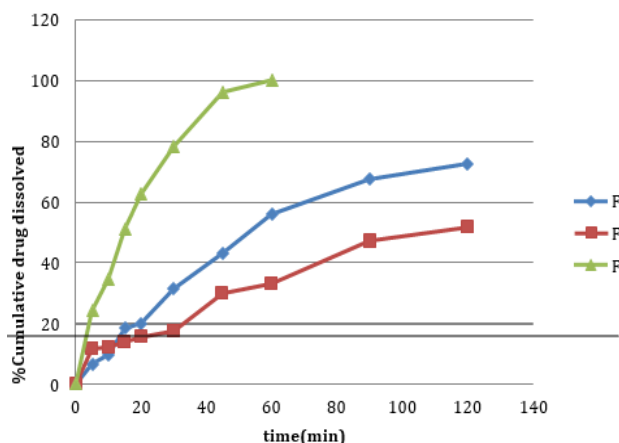


Figure 2: Dissolution profile of F4, F5, F6

DISSOLUTION PROFILE OF F7,F8,F9

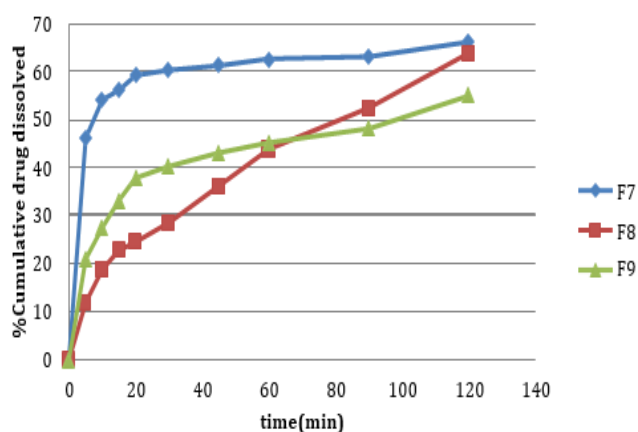


Figure 3: Dissolution profile of F7, F8, F9

Dissolution profile of Pure drug Conventional tablets, F6

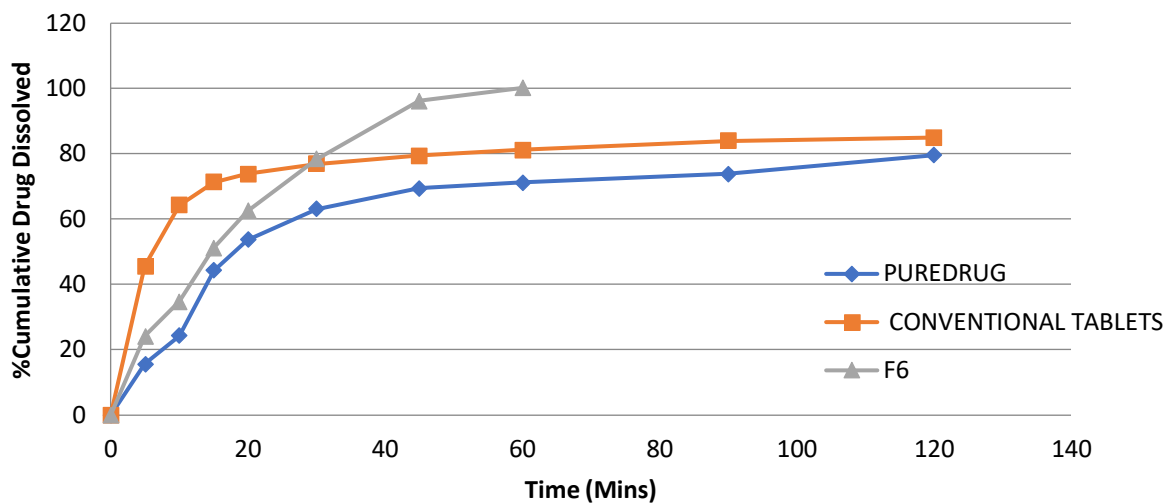


Figure 4: Dissolution profile of Optimized Formulation F6, Conventional tablet

solubility. This may be ascribed to an optimized excipient ratio, which enhanced drug release by boosting wettability and diminishing crystallinity. F4 demonstrated a moderate dissolving rate, whilst F5 revealed the slowest drug release of the three formulations. The diminished dissolving rate of F5 may be linked to heightened tablet hardness and decreased porosity, which obstructed the ingress of

dissolution medium, resulting in a decelerated drug diffusion. The enhanced performance of F6 indicates that the formulation approach employed markedly improved the medication dissolving profile.

The dissolution profile of formulations F7, F8, and F9 (Figure 3) demonstrates considerable changes in drug release behavior, suggesting the influence of formulation

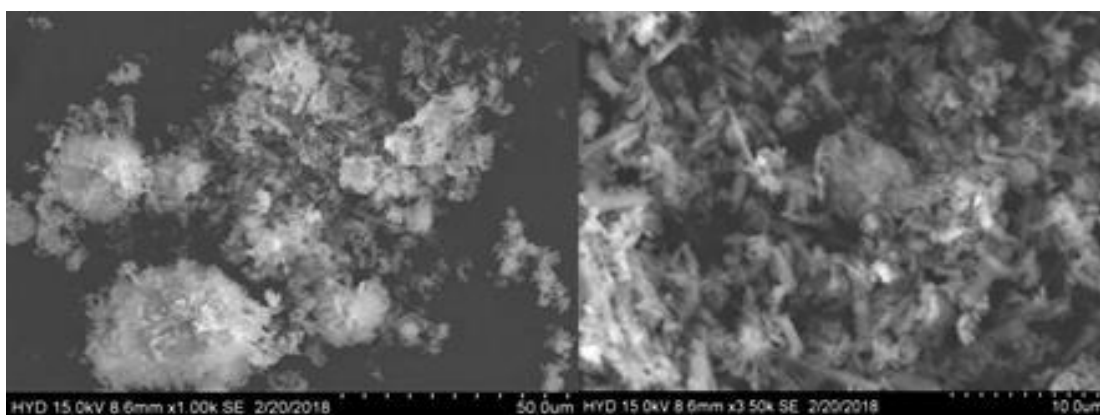


Figure 5: SEM Image of Dapoxetine hydrochloride drug

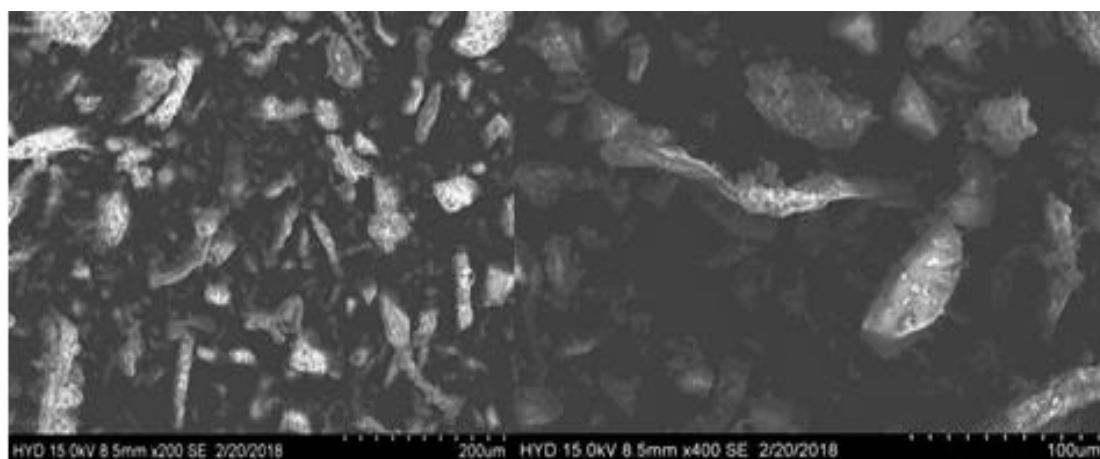


Figure 6: SEM Image of Conventional Tablets

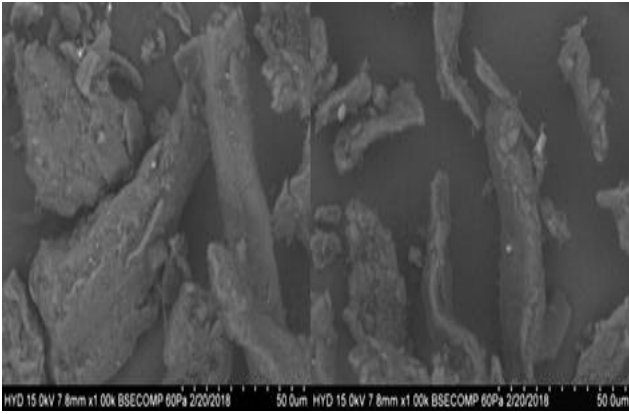


Figure 7: SEM Image of Optimized Formulation (F6)

parameters on dissolution kinetics. F7 had the highest dissolving rate of the three formulations, with over 60–70% cumulative drug release in 20 minutes. F7 fast release indicates improved wettability, drug dispersion, and solubility due to modified excipients. The faster dissolve rate may be due to a more efficient carrier system that improved medication dissolution. F8 had a slower drug

release profile than F7 and a moderate disintegration rate. The gradual dissolution increase suggests that the formulation may have had excipients with controlled-release qualities or a stronger compression force, resulting to reduced porosity and slower penetration of the dissolution medium. F9 had the slowest drug disintegration of the three. The dissolving curve indicates a constant increase, indicating a possible increased degree of crystallinity or inadequate wetting of the drug particles. The formulation's composition may have caused a decreased dissolving rate, poor disintegration, and delayed release. The comparative dissolution analysis of the pure medication, standard tablets, and the optimized formulation F6 (Figure 4) substantiates the efficacy of formulation strategies in improving drug solubility. The unadulterated medication demonstrated the most sluggish dissolving rate, signifying its inadequate aqueous solubility and restricted bioavailability. Conventional tablets had enhanced solubility relative to the pure medication; yet, they displayed a delayed release compared to F6. The optimized formulation F6 exhibited the quickest and most effective drug release, indicating that the formulation strategy,

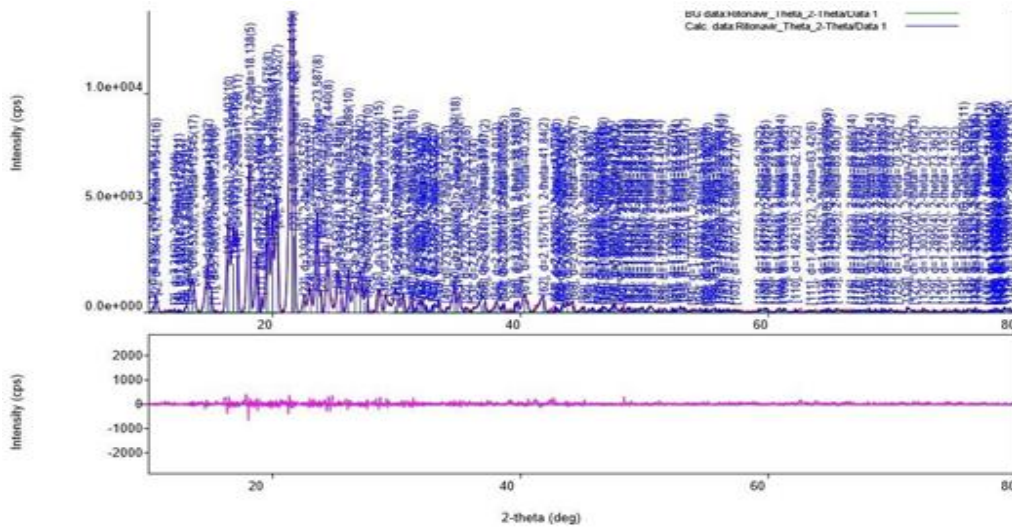


Figure 8: XRD of Dapoxetine hydrochloride drug

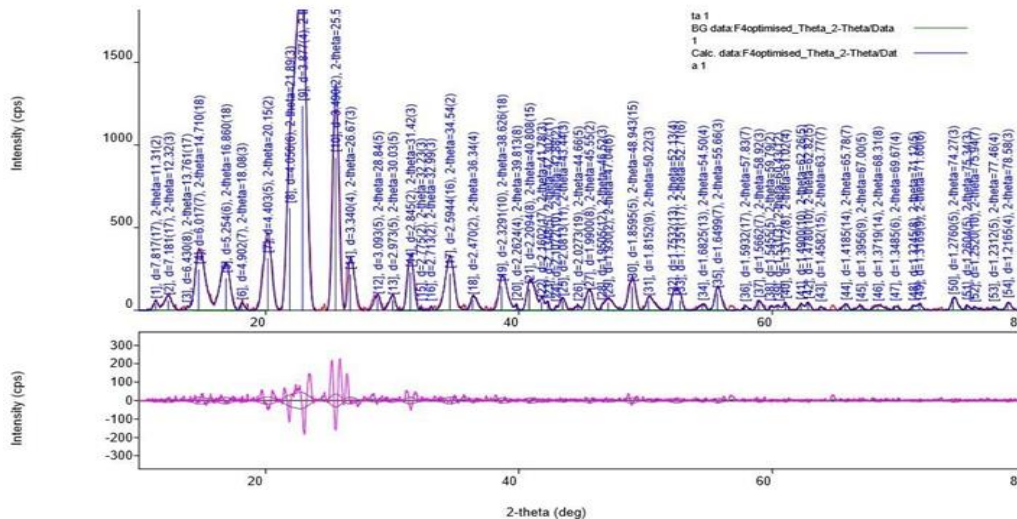


Figure 9: XRD of Optimized Formulation (F6)

potentially incorporating a liquisolid system or solubility-enhancing excipients, effectively improved the drug's dissolving properties. The notable enhancement in F6's dissolving characteristics is due to the incorporation of appropriate carriers and excipients that expedited drug dissolution and absorption, rendering it a promising candidate for enhanced bioavailability.

Characterization of DXH Liquisolid Compact Tablets

SEM Studies

Figure 5 shows a highly crystalline and aggregated structure. Agglomeration may affect medication solubility and dissolution rate, as shown in big, irregular clusters. The uneven surface morphology suggests excipients may have affected particle dispersion.

Figure 6 shows a medium crystalline, scattered form. The rod- and plate-like formations suggest a crystalline character, which may impede disintegration compared to amorphous forms. Better particle dispersion may improve solubility.

Figure 7 illustrates broken and porous structures, signifying an increased surface area. This shape enhances medication dispersion, as greater porosity promotes improved water penetration and solubility. The fractured and uneven forms indicate mechanical processing impacts that may have enhanced the dissolution profile observed in F6.

XRD Studies

Figure 8 has pronounced and powerful peaks, signifying a highly crystalline structure. The existence of numerous diffraction peaks indicates robust intermolecular interactions and organized lattice structures. Figure 9 illustrates a decrease in peak strength and the partial absence of certain distinctive peaks, signifying a shift towards an amorphous or less crystalline state. The pronounced peaks in the pure substance indicate its elevated crystallinity, which correlates with diminished water solubility. The improved formulation exhibits a reduction in peak intensity, indicating effective amorphization or molecule dispersion within the carrier system. Decreased crystallinity enhances solubility, bioavailability, and therapeutic efficacy.

FTIR Studies

The FTIR spectrum of the pure medication, illustrated in figure 10, exhibits characteristic absorption bands associated with functional groups including hydroxyl (-OH), carbonyl (C=O), and amine (-NH). These peaks validate the molecular integrity of the pharmaceutical compound. Figure 11 illustrates that the spectrum of the improved formulation preserves the majority of the distinctive peaks of the pure medication, signifying the absence of substantial chemical interaction or degradation.

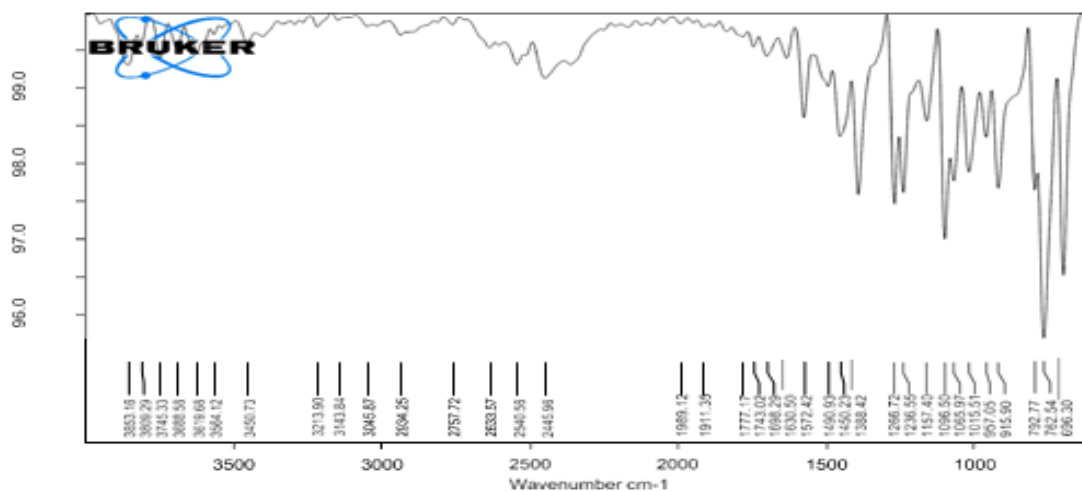


Figure 10: Fourier transform infrared spectra of Dapoxetine Hydrochloride

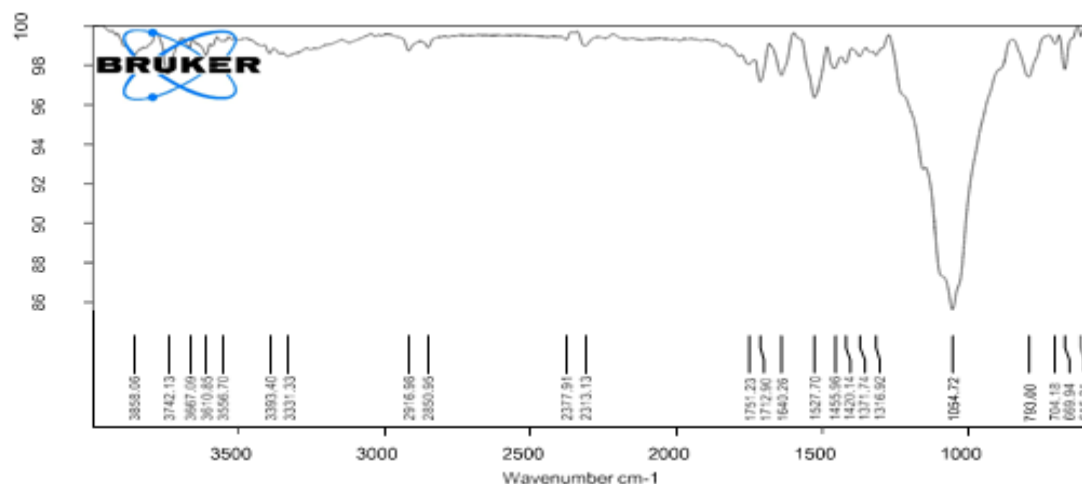


Figure 11: Fourier transform infrared spectra of Optimized Formulation (F6)

Minor variations and intensity alterations in specific peaks indicate possible hydrogen bonding or intermolecular interactions with excipients, which may enhance medication solubility and stability.

CONCLUSION

The current study effectively generated and improved a medication formulation, thereafter undergoing comprehensive characterisation by several analytical techniques. Pre-compression analyses verified that the powder mixture demonstrated superior flow characteristics and compressibility, guaranteeing consistent die filling and tablet production. Post-compression assessments revealed that the optimized tablets satisfied all pharmacopeial standards, encompassing hardness, friability, thickness, and weight fluctuation, signifying substantial mechanical integrity and consistency. XRD measurement indicated a decrease in crystallinity in the revised formulation, implying improved solubility and dissolving capacity. FTIR analyses validated the chemical stability of the drug, revealing no significant interactions between the medication and excipients. SEM investigation revealed alterations in surface morphology within the formulation, enhancing dissolving behavior. *In vitro* dissolution experiments demonstrated a markedly superior drug release profile from the optimized formulation relative to the pure medication, underscoring its potential for improved bioavailability. The formulation technique effectively enhanced the physicochemical properties of the medication, ensuring greater processability and therapeutic efficacy. In future work, will concentrate on *in vivo* pharmacokinetic investigations to enhance its validation and therapeutic relevance.

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