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Development and Optimization of Immediate Release Imipramine Hydrochloride Tablets Using Superdisintegrants by Direct Compression Technique

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Abstract: The present study aimed to develop and optimize immediate-release tablets of Imipramine Hydrochloride using Croscarmellose Sodium (CCS) as a superdisintegrant by the direct compression technique. Preformulation studies and Fourier-transform infrared spectroscopy (FTIR) analysis were performed to evaluate the physicochemical properties of the drug and its compatibility with the selected excipients. Nine formulations (F1–F9) containing varying concentrations of CCS were prepared and evaluated for pre-compression and post-compression parameters, including flow properties, weight variation, hardness, friability, drug content, disintegration time, and in-vitro drug release. All formulations exhibited satisfactory pharmaceutical characteristics. Among them, formulation F9 demonstrated the most desirable performance, with a drug content of $99.83 \pm 0.42\%$, friability of 0.526% , disintegration time of 2 min, and 96.23% drug release within 30 min. The optimized formulation was further evaluated using drug-release kinetic models and accelerated stability studies. The stability study showed no significant changes in the evaluated parameters during the study period. The findings demonstrate that direct compression is a suitable technique for the preparation of immediate-release Imipramine Hydrochloride tablets, while the concentration of CCS significantly influences tablet disintegration and drug-release performance. The optimized formulation exhibited rapid disintegration, satisfactory drug content, and efficient drug release, indicating its potential as an immediate-release tablet formulation.

Keywords: Imipramine Hydrochloride; Immediate-Release Tablets; Direct Compression; Croscarmellose Sodium; Superdisintegrant; Optimization; In-vitro Drug Release.

INTRODUCTION

Depression is a common psychiatric disorder that can substantially impair emotional, cognitive, social and occupational functioning. Pharmacological treatment remains an important component of management, particularly in moderate-to-severe disease. Imipramine Hydrochloride is a tricyclic antidepressant that produces its therapeutic effect mainly through inhibition of serotonin and norepinephrine reuptake.

Although newer antidepressants are widely used, Imipramine remains an established therapeutic agent [1-3].

Immediate-release solid oral dosage forms are designed to disintegrate and release the active pharmaceutical ingredient rapidly after administration. Direct compression is a comparatively simple tablet-manufacturing approach because it avoids wet-granulation processing and reduces the number of manufacturing steps. However, successful direct compression requires adequate powder flow, compressibility and rapid tablet disintegration [4,5].

Superdisintegrants are incorporated into immediate-release tablets to promote rapid breakup of the compact after contact with aqueous fluids. Croscarmellose Sodium is a cross-linked cellulose derivative with swelling and wicking characteristics that can facilitate water penetration, tablet breakup and drug dissolution. The concentration of a superdisintegrant can markedly influence tablet performance; therefore, systematic optimization is useful [6-8].

The objective of the present investigation was to formulate and optimize Imipramine Hydrochloride immediate-release tablets by direct compression using different concentrations of Croscarmellose Sodium and to evaluate their pre-compression and post-compression properties, in-vitro drug release, release kinetics and short-term accelerated stability.

MATERIALS AND METHODS

Materials

Imipramine Hydrochloride was obtained from Sun Pharma, Chennai. Croscarmellose Sodium and Polyvinylpyrrolidone K30 were obtained from Colorcon Asia Pvt. Ltd., Goa. Microcrystalline Cellulose was obtained from Loba Chemie Pvt. Ltd., Mumbai. Magnesium Stearate and Talc were obtained from Loba Chemie Pvt. Ltd., Mumbai.

Preformulation Studies

Preformulation studies involve the systematic assessment of the physical, chemical, and mechanical properties of a drug substance to facilitate formulation development. The findings provide valuable information for selecting appropriate excipients, manufacturing processes, and storage conditions, thereby supporting the development of a stable, safe, effective, and high-quality dosage form [9].

Organoleptic Characteristics

The drug sample was examined for its colour, odour, taste, and appearance, and the observations were recorded.

Determination of Melting Point

The melting point of Imipramine Hydrochloride was determined by the capillary tube method using a digital melting point apparatus. The temperature at which the drug completely melted was recorded. The test was performed in triplicate, and the mean melting point was calculated to assess the drug's identity and purity [10].

Solubility Studies

The solubility of Imipramine Hydrochloride was evaluated in water, methanol, ethanol, and acetone by adding excess drug to each solvent and stirring at room temperature until equilibrium. The solutions were filtered, and the solubility characteristics were observed and recorded [11].

Drug-Excipient Compatibility Studies using FTIR Spectroscopy

Compatibility between Imipramine Hydrochloride and the selected excipients was evaluated by Fourier Transform Infrared (FTIR) spectroscopy. Physical mixtures of the drug and excipients were prepared in a 1:1 ratio and analyzed along with the pure drug using a Shimadzu FTIR spectrophotometer by the KBr pellet method. Samples were mixed with dry KBr (1:100) and compressed into pellets. The spectra were recorded over 4000–400 cm^{-1} and compared for changes in characteristic peaks, including peak shifting, disappearance, or appearance of new peaks, to identify possible drug–excipient interactions and confirm the compatibility of the formulation components [12].

Determination of λ_{max} of Imipramine Hydrochloride

A standard solution of Imipramine Hydrochloride was prepared using phosphate buffer (pH 6.8) and analyzed using a UV–Visible spectrophotometer. The solution was scanned over the wavelength range of 200–400 nm, with phosphate buffer (pH 6.8) serving as the blank. The wavelength at which the drug exhibited maximum absorbance was identified and recorded as its λ_{max} . The selected wavelength was subsequently employed for the construction of the calibration curve and the quantitative analysis of Imipramine Hydrochloride in subsequent studies. [13].

Preparation of 100 µg/mL Standard Stock Solution of Imipramine Hydrochloride Using Phosphate Buffer (pH 6.8)

A 100 µg/mL standard stock solution of Imipramine Hydrochloride was prepared by accurately weighing 10 mg of the drug, dissolving it in phosphate buffer (pH 6.8), and making the volume up to 100 mL with the same buffer. The stock solution was used to prepare working standard solutions for further analytical studies.

Calibration Curve of Imipramine Hcl Solution

Aliquots of 0.5–2.5 mL of the Imipramine Hydrochloride stock solution (100 µg/mL) were diluted to 10 mL with phosphate buffer (pH 6.8) to obtain concentrations of 5–25 µg/mL. The absorbance was measured at 255 nm using a UV–Visible spectrophotometer, with phosphate buffer as the blank. A calibration curve of concentration versus absorbance was constructed using the mean of triplicate measurements to assess linearity [14].

Formulation of Immediate-Release Imipramine Hydrochloride Tablet

Imipramine Hydrochloride tablets were prepared by direct compression using varying concentrations of croscarmellose sodium (4–20 mg/tablet). All ingredients were accurately weighed, and the drug, croscarmellose sodium, PVP K30, and microcrystalline cellulose were passed through sieve No. 40 and blended geometrically. Magnesium stearate and talc, previously passed through sieve No. 80, were added and blended for 3–5 min for lubrication. The final blend was evaluated for pre-compression parameters and compressed using a rotary tablet compression machine. The tablets were collected and stored in airtight containers for further evaluation.

Table 1: Formulation Table of Imipramine Hydrochloride Tablet

Ingredients	F1	F2	F3	F4	F5	F6	F7	F8	F9
Imipramine HCl	10	10	10	10	10	10	10	10	10
Croscarmellose Sodium	4	6	8	10	12	14	16	18	20
Polyvinylpyrrolidone K30	20	20	20	20	20	20	20	20	20
Microcrystalline Cellulose	173	171	169	167	165	163	161	159	157
Magnesium Stearate	2	2	2	2	2	2	2	2	2
Talc	1	1	1	1	1	1	1	1	1

Evaluation of Powder Blend (Pre-compression Parameters)

The powder blends were evaluated for flow and compression properties before tablet compression. Angle of repose, bulk density, tapped density, Carr's compressibility index, and Hausner's ratio were determined using standard pharmacopoeial procedures to assess the suitability of the blends for direct compression [15,16].

Angle of Repose

The angle of repose was determined by the fixed-funnel method. The height and radius of the powder heap were measured, and the angle of repose was calculated as

$$\tan \theta = h/r$$

Bulk Density

A known quantity of powder was transferred into a graduated cylinder, and the untapped volume (V_0) was recorded. Bulk density was calculated as

$$\text{Bulk density} = \text{Weight of powder} / \text{Bulk volume}$$

Tapped Density

The powder-filled cylinder was mechanically tapped to constant volume, and the tapped volume (V_t) was recorded. Tapped density was calculated as

$$\text{Tapped density} = \text{Weight of powder} / \text{Tapped volume}$$

Carr's Compressibility Index

The index was calculated from bulk and tapped densities using

$$\text{Carr's Index (\%)} = [(\text{Tapped density} - \text{Bulk density}) / \text{Tapped density}] \times 100$$

Hausner's Ratio

Hausner's ratio was determined using

$$\text{Hausner's ratio} = \text{Tapped density} / \text{Bulk density}$$

These parameters were used to assess the flow and compressibility characteristics of the powder blends.

Evaluation of Compressed Tablets (Post-compression Parameters)

The prepared tablets were evaluated for weight variation, thickness, hardness, friability, drug content uniformity, and disintegration time using standard pharmacopoeial methods to assess their quality, mechanical strength, and suitability for immediate-release drug delivery [17].

Weight Variation: Twenty tablets from each formulation were individually weighed using a calibrated analytical balance. The mean weight and percentage deviation from the mean were calculated and compared with IP limits.

Table 2: Weight Variation Limit

Average Weight of Tablet	% Deviation
≤ 80 mg	± 10.0
80–250 mg	± 7.5
≥ 250 mg	± 5.0

Thickness: The thickness of six randomly selected tablets was measured using a calibrated digital Vernier caliper and expressed in millimetres. Mean thickness and standard deviation were calculated.

Hardness: The crushing strength of six tablets from each formulation was determined using a Monsanto hardness tester and expressed in kg/cm^2 . The mean hardness was calculated.

Friability: Twenty tablets were weighed and subjected to 100 revolutions in a Roche friabilator at 25 rpm for 4 min. The tablets were dedusted and reweighed, and percentage friability was calculated from the weight loss. A value below 1% was considered acceptable.

$$\% \text{Friability} = \frac{\text{Initial weight} - \text{Final weight}}{\text{Initial weight}} \times 100$$

Drug Content Uniformity: Ten tablets were powdered, and a quantity equivalent to 10 mg of Imipramine Hydrochloride was dissolved in phosphate buffer (pH 6.8), filtered, and appropriately diluted. Absorbance was measured at 255 nm using a UV–Visible spectrophotometer, and drug content was calculated from the calibration curve and expressed as a percentage of the labeled claim.

In-Vitro Disintegration Time: Six tablets were evaluated using a USP digital disintegration apparatus with phosphate buffer (pH 6.8) maintained at $37 \pm 0.5^\circ\text{C}$. The time required for complete disintegration was recorded in seconds, and the mean disintegration time was calculated.

In-Vitro Dissolution Studies: Dissolution studies were performed using a USP Type II (paddle) apparatus in 900 mL phosphate buffer (pH 6.8) at $37 \pm 0.5^\circ\text{C}$ and 50 rpm for 30 min. Samples (5 mL) were withdrawn at 5, 10, 15, 20, 25, and 30 min and replaced with an equal volume of fresh medium. After filtration, absorbance was measured at 255 nm, and cumulative percentage drug release was calculated using the calibration curve. The dissolution profiles were compared to identify the optimized formulation.

Optimization of Formulation: The optimized formulation was selected based on pre- and post-compression characteristics, disintegration time, and in-vitro drug release. The formulation exhibiting

satisfactory tablet properties, rapid disintegration, and maximum drug release was selected for stability evaluation.

Stability Studies: The optimized formulation was subjected to accelerated stability testing according to ICH guidelines at $40 \pm 2^\circ\text{C}$ and $75 \pm 5\%$ relative humidity for one month. The tablets were evaluated for appearance, hardness, drug content, disintegration time, and in-vitro drug release, and the results were compared with the initial values [18].

RESULTS AND DISCUSSION

Organoleptic Characteristics

Imipramine Hydrochloride was observed as a white to off-white, odourless, bitter, crystalline and free-flowing powder. The observations were consistent with the reported characteristics of the drug.

Table 3: Organoleptic Characteristics of Imipramine Hydrochloride

Parameter	Observation
Appearance	White to off-white crystalline powder
Colour	White to off-white
Odour	Odourless
Taste	Bitter
Physical Nature	Crystalline, free-flowing powder

Melting Point

The melting point of Imipramine Hydrochloride was determined by the capillary tube method and found to be $270\text{--}274^\circ\text{C}$.

Solubility Studies

Imipramine Hydrochloride was freely soluble in water, ethanol, and methanol; soluble in acetone; and insoluble in ether and benzene. Its aqueous solubility supported its suitability for immediate-release formulation. Phosphate buffer (pH 6.8) was selected as the dissolution medium for subsequent analytical and *in-vitro* dissolution studies.

Drug–Excipient Compatibility Studies by FTIR

Compatibility of Imipramine Hydrochloride with the selected excipients was evaluated by FTIR spectroscopy. KBr, the drug, and excipients were dried at 105°C for 1 h, mixed with spectroscopic-grade KBr, triturated, and compressed into pellets. Spectra of the pure drug, physical mixture, and optimized formulation were recorded over $4000\text{--}400\text{ cm}^{-1}$ and compared for changes in characteristic peaks. The absence of significant peak shifts, disappearance, or appearance of new peaks indicated no appreciable drug–excipient interaction, confirming compatibility.

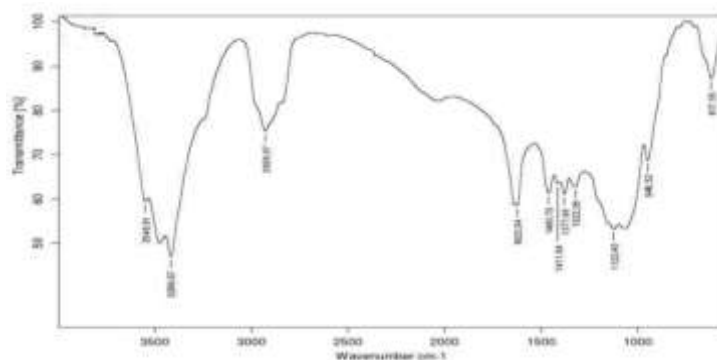


Fig 1: FTIR Spectra of Pure Drug Imipramine Hydrochloride

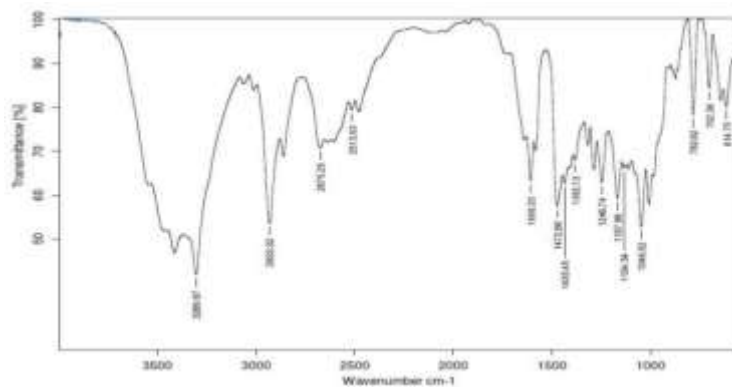


Fig 2: FTIR Spectra of Optimised Formulation

Table 4: FTIR interpretation

Functional Group	Imipramine Hydrochloride (cm ⁻¹)	Croscarmellose Sodium (cm ⁻¹)	Polyvinylpyrrolidone K30 (cm ⁻¹)	Microcrystalline Cellulose (cm ⁻¹)
O–H stretching	-	3200–3600	-	3200–3600
N–H stretching	3300–3400	-	-	-
Aromatic C–H stretching	3000–3100	-	-	-
Aliphatic C–H stretching	2850–2950	2900–2930	2940–2960	2890–2930
C=O stretching	-	1600–1650	1650–1680	-
Aromatic C=C stretching	1450–1600	-	-	-
C–N stretching	1200–1350	-	1280–1300	-
C–O stretching	-	1020–1160	-	1020–1160
COO ⁻ stretching	-	1580–1610, 1400–1450	-	-

Determination of λ_{max}

Imipramine Hydrochloride exhibited a maximum absorption at **255 nm** in phosphate buffer (pH 6.8). Therefore, 255 nm was selected as the analytical wavelength for calibration curve and drug content estimation.

Calibration Curve of Imipramine Hcl Solution

The UV spectrophotometric calibration curve of Imipramine Hydrochloride in phosphate buffer (pH 6.8) showed a linear relationship between concentration and absorbance over the range of **10–50 $\mu\text{g/mL}$** , following Beer–Lambert’s law. Absorbance increased with increasing drug concentration, confirming the

suitability of the method for quantitative drug estimation in content uniformity and *in-vitro* dissolution studies.

Table 5: Calibration Curve of Imipramine Hydrochloride

Concentration ($\mu\text{g/mL}$)	Absorbance at 255 nm
0	0.000
10	0.155
20	0.342
30	0.454
40	0.589
50	0.870

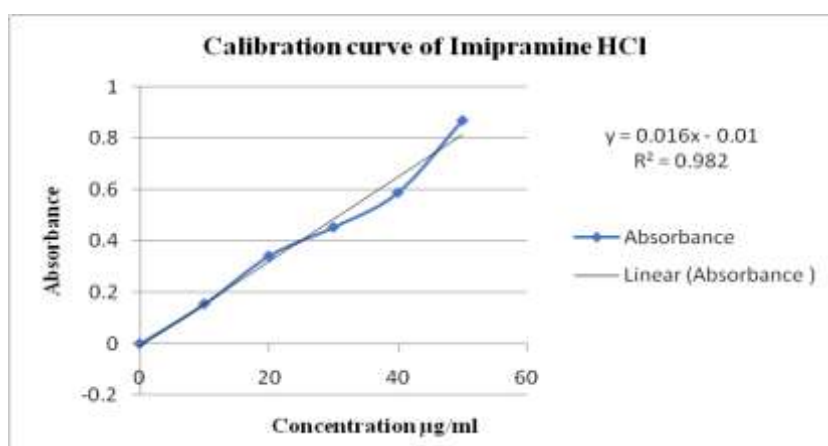


Fig 3: Calibration Curve of Imipramine Hydrochloride

Evaluation of Powder Blend (Pre-compression Parameters)

Table 6: Flow properties of granules prepared by different techniques

Formulation	Angle of repose ($^{\circ}$)	Bulk density (gm/ml)	Tapped density (gm/ml)	Carr's index (%)	Hausner's ratio
F1	25.38 $\pm$ 0.13	0.36 $\pm$ 0.02	0.44 $\pm$ 0.02	18.56 $\pm$ 0.13	1.22 $\pm$ 0.01
F2	25.52 $\pm$ 0.28	0.37 $\pm$ 0.02	0.45 $\pm$ 0.03	17.74 $\pm$ 0.13	1.21 $\pm$ 0.01
F3	26.19 $\pm$ 0.19	0.36 $\pm$ 0.02	0.44 $\pm$ 0.03	18.18 $\pm$ 0.13	1.22 $\pm$ 0.02
F4	25.51 $\pm$ 0.16	0.37 $\pm$ 0.01	0.45 $\pm$ 0.01	19.53 $\pm$ 0.15	1.18 $\pm$ 0.01
F5	25.61 $\pm$ 0.21	0.37 $\pm$ 0.01	0.45 $\pm$ 0.00	18.25 $\pm$ 0.05	1.12 $\pm$ 0.02
F6	24.38 $\pm$ 0.13	0.36 $\pm$ 0.02	0.46 $\pm$ 0.02	18.56 $\pm$ 0.13	1.22 $\pm$ 0.01
F7	23.52 $\pm$ 0.28	0.37 $\pm$ 0.02	0.46 $\pm$ 0.03	17.74 $\pm$ 0.13	1.21 $\pm$ 0.01
F8	23.19 $\pm$ 0.19	0.38 $\pm$ 0.02	0.44 $\pm$ 0.03	18.18 $\pm$ 0.13	1.22 $\pm$ 0.02
F9	22.51 $\pm$ 0.16	0.37 $\pm$ 0.01	0.43 $\pm$ 0.01	15.53 $\pm$ 0.15	1.18 $\pm$ 0.01

The pre-compression parameters of formulations F1–F9 showed satisfactory flow and compressibility characteristics. The angle of repose ranged from 22.51 $\pm$ 0.16 $^{\circ}$ to 26.19 $\pm$ 0.19 $^{\circ}$, while bulk and tapped densities ranged from 0.36 $\pm$ 0.02 to 0.38 $\pm$ 0.02 g/mL and 0.43 $\pm$ 0.01 to 0.46 $\pm$ 0.03 g/mL, respectively. Carr's index ranged from 15.53 $\pm$ 0.15% to 19.53 $\pm$ 0.15%, and Hausner's ratio from 1.18 $\pm$ 0.01 to 1.22 $\pm$

0.02, indicating good flow and compressibility. Overall, all powder blends were suitable for direct compression.

Evaluation of Compressed Tablets (Post-compression Parameters)

Table 7: Evaluation of Physical parameters

Formulation	Weight Variation	Thickness (mm)	Hardness (Kg/cm ²)	Friability (%)	Drug Content Uniformity (%)	In-Vitro Disintegration Time (mins)
F1	196±1.02	2.80±0.01	2.8±0.06	0.632	97.24±0.22	4
F2	197±0.08	2.95±0.00	2.7±0.06	0.646	96.57±0.42	3
F3	198.002	2.75±0.01	2.6±0.00	0.686	97.43±0.13	3
F4	197±0.003	2.68±0.01	2.7±0.06	0.675	97.83±0.42	3
F5	196±0.08	2.52±0.01	2.5±0.10	0.646	97.86±0.32	3
F6	198±1.02	2.50±0.01	2.5±0.06	0.632	98.24±0.22	3
F7	198±0.08	2.45±0.00	2.6±0.06	0.646	97.57±0.42	3
F8	201±0.02	2.3±0.01	2.5±0.00	0.686	9.843±0.13	2
F9	200±0.003	2.28±0.01	2.5±0.06	0.526	99.83±0.42	2

The post-compression parameters of formulations F1–F9 were evaluated to assess tablet quality. The average tablet weight ranged from 196 ± 1.02 to 201 ± 0.02 mg, and all formulations complied with pharmacopeial limits. Tablet thickness ranged from 2.28 ± 0.01 to 2.95 ± 0.00 mm, while hardness ranged from 2.5 ± 0.00 to 2.8 ± 0.06 kg/cm², indicating acceptable dimensional uniformity and mechanical strength. Friability ranged from 0.526% to 0.686%, remaining below the 1% limit. Drug content ranged from 96.57 ± 0.42% to 99.83 ± 0.42%, confirming satisfactory drug uniformity. The *in-vitro* disintegration time was 2–4 min, indicating rapid disintegration suitable for immediate-release tablets. Overall, all formulations exhibited satisfactory post-compression characteristics.

In-Vitro Drug Dissolution Studies

The *in-vitro* dissolution profiles of formulations F1–F9 showed a progressive increase in cumulative drug release with time. At 30 min, drug release ranged from 56.42% (F1) to 96.23% (F9). Increasing the concentration of croscarmellose sodium enhanced drug release, which may be attributed to its swelling and wicking properties, promoting rapid disintegration and dissolution. Formulation F9 exhibited the highest drug release (96.23%), followed by F8 (89.53%) and F5 (83.32%). Based on its drug release and disintegration characteristics, F9 was selected as the optimized formulation for further evaluation.

Table 8: In-vitro Drug Release Data

Time in mins	F1	F2	F3	F4	F5	F6	F7	F8	F9
0	0	0	0	0	0	0	0	0	0
5	10.42	11.23	13.52	15.62	21.32	34.52	37.32	40.52	45.65
10	21.20	25.56	31.62	45.32	45.62	47.52	49.52	53.53	65.26
15	26.12	32.21	43.85	48.65	50.31	56.12	58.13	65.27	74.56
20	32.32	45.32	52.59	56.56	60.61	69.46	70.42	76.62	80.26
25	43.13	54.32	62.87	68.53	70.65	58.65	65.65	78.56	90.65
30	56.42	69.23	74.59	80.59	83.32	66.32	77.23	89.53	96.23

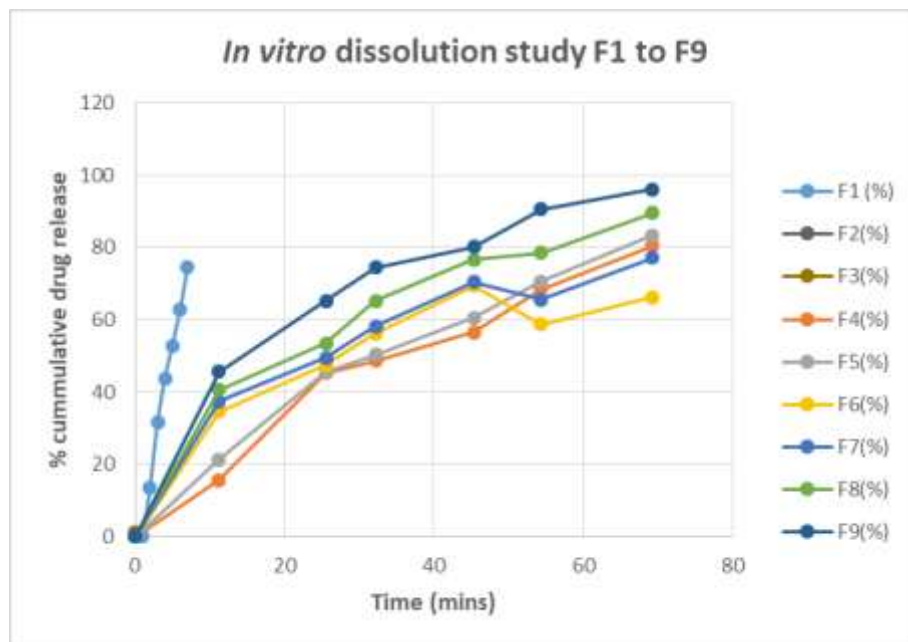


Fig 4: *In-vitro* Release Profile of Formulations F1 - F9

***In vitro* Drug Release Kinetic Study**

In-Vitro Drug Release Kinetic Study: The *in-vitro* drug release data of the optimized formulation F9 were analyzed using Zero-order, First-order, Higuchi, Korsmeyer–Peppas, and Hixson–Crowell kinetic models to determine the drug release mechanism. F9 showed 96.23% cumulative drug release within 30 min. The required parameters, including cumulative percentage drug release, log time, square root of time, log % drug release, percentage drug remaining, and log % drug remaining, were calculated from the dissolution data. The corresponding kinetic plots were constructed, and the correlation coefficient (R^2) was determined for each model. The model showing the highest R^2 value was considered the best fit for describing the release behavior of the optimized formulation. The kinetic analysis indicated a rapid drug release profile consistent with the intended immediate-release characteristics of Imipramine Hydrochloride tablets.

Table 9: *In vitro* Release Kinetics of Imipramine Hydrochloride from F9

Time in mins	% Cumulative Drug Release	Log Time	$\sqrt{\text{Time}}$	Log %CDR	% Drug Remaining	Log % Drug Remaining
0	0.00	0.00	0.00	0.00	100.00	2.000
5	45.65	0.699	2.236	1.659	54.35	1.735
10	65.26	1.000	3.162	1.815	34.74	1.541
15	74.56	1.176	3.873	1.873	25.44	1.406
20	80.26	1.301	4.472	1.905	19.74	1.295
25	90.65	1.398	5.000	1.957	9.35	0.971
30	96.23	1.477	5.477	1.983	3.77	0.576

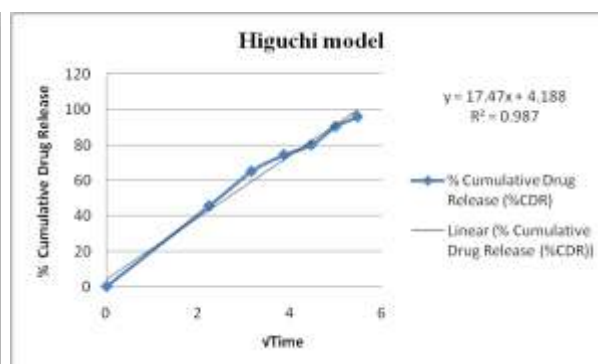
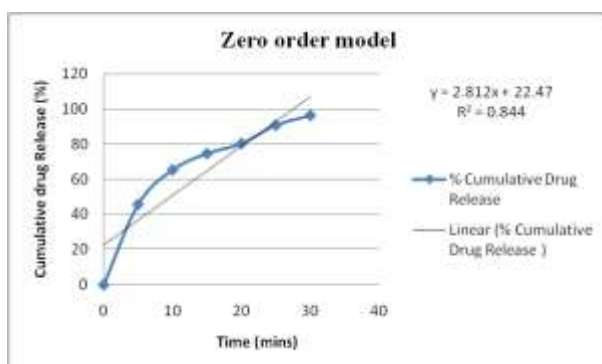
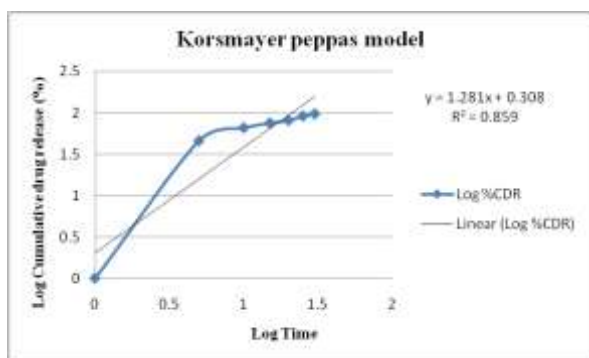
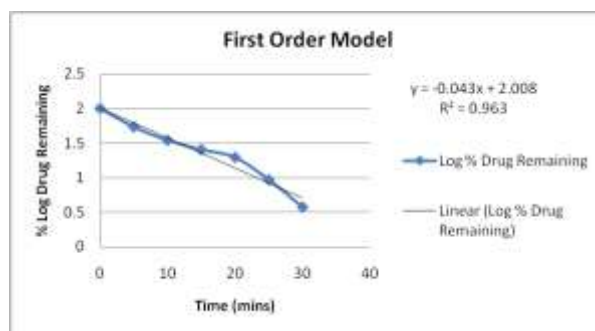


Fig 5: Zero-Order Release Kinetic Plot**Fig 7:** Korsmayer-Peppas Release Kinetic Plot**Fig 6:** Higuchi Release Kinetic Plot**Fig 8:** First Order Release Kinetic Plot

Stability Studies

The optimized formulation F9 was subjected to accelerated stability testing at $40 \pm 2^\circ\text{C}/75 \pm 5\% \text{ RH}$ for 30 days in accordance with ICH guidelines. The formulation was evaluated at 0, 15, and 30 days for hardness, *in-vitro* disintegration time, and cumulative drug release. Drug release showed only a slight decrease from 96.23% at day 0 to 95.72% at day 30, while hardness remained essentially unchanged at approximately 2.5 kg/cm². The disintegration time remained constant at 2 min throughout the study. These results indicate that F9 maintained its physical and performance characteristics during the accelerated storage period, demonstrating satisfactory stability under the tested conditions. The results are presented in Table 24.

Table 10: Stability Study of Optimized Formulation (F9) Stored at $40 \pm 2^\circ\text{C} / 75 \pm 5\% \text{ RH}$

Days	Drug Release (%)	Hardness (kg/cm ²)	Disintegration Time (min)
0	96.23	2.5 ± 0.06	2
15	95.98	2.5 ± 0.05	2
30	95.72	2.5 ± 0.04	2

Conclusion

The present study successfully developed and optimized immediate-release Imipramine Hydrochloride tablets using Croscarmellose Sodium (CCS) as a superdisintegrant by the direct compression technique. Preformulation and FTIR studies confirmed the suitability and compatibility of the drug and selected excipients. All formulations exhibited satisfactory pre- and post-compression characteristics. Variation in CCS concentration influenced tablet disintegration and drug-release performance, with F9 identified as the optimized formulation. F9 exhibited $99.83 \pm 0.42\%$ drug content, 0.526% friability, $2.5 \pm 0.06 \text{ kg/cm}^2$ hardness, a disintegration time of 2 min, and 96.23% cumulative drug release within 30 min. The optimized formulation maintained comparable hardness and disintegration characteristics during the 30-day accelerated stability study at $40 \pm 2^\circ\text{C}/75 \pm 5\% \text{ RH}$, with drug release showing only a slight decrease from 96.23% to 95.72%. Overall, the findings demonstrate that appropriate optimization of CCS concentration can facilitate rapid disintegration and enhanced drug release from directly compressed Imipramine Hydrochloride immediate-release tablets. Further studies involving long-term stability, scale-up, comparative dissolution, analytical method validation, and *in-vivo* bioavailability evaluation are warranted to establish the formulation's performance beyond the laboratory scale.

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