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ORIGINAL ARTICLE

Formulation, Optimization and Assessment of Imipramine Hydrochloride an Immediate Released Tablet

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ABSTRACT
The present study was undertaken to formulate, optimize, and evaluate immediate released tablets of Imipramine Hydrochloride with the goal of achieving rapid drug release and immediate onset of therapeutic action. Imipramine Hydrochloride, a tricyclic antidepressant used in the treatment of depression, anxiety disorders, and nocturnal enuresis, was chosen to be the model medication. Superdisintegrants like Kyron T-314 and crospovidone were used in the direct compression method to produce the tablets in various concentrations. Optimization of the Central Composite Design (CCD) was used as a two-factor method for formulation variables. at three levels (32) using Design Expert Software and experimental trails were performed on all 9 formulations. FTIR analyses verified that the medication and excipients did not interact. Pre-compression tests revealed revealed the powder mixture had favorable flow properties. Hardness, thickness, friability, weight variation, drug content, wetting time, disintegration time, in-vitro dissolution study, stability study, and cell cytotoxicity were all assessed for the produced tablets. The optimized formulation showed satisfactory tablet properties, immediate disintegration with nearly full drug release within 30 minutes. The study concluded that the optimized combination of Kyron T-314 and crospovidone successfully produced an effective immediate released tablet formulation of Imipramine Hydrochloride with improved drug release and better tablet performance.
KEYWORDS: *Imipramine Hydrochloride, Immediate released, Superdisintegration, Direct Compression Method, FTIR, DSC, Cell Cytotoxicity.*

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INTRODUCTION

Oral administration is among the most well-known and often used drug delivery techniques because of its simplicity, safety, affordability, and high patient compliance [1,2]. Tablets represent the most popular oral dose form because to its precise dosage, stability, convenience of handling, production, and transportation [3,4]. Conventional types of solid dosage called immediate release tablets are made to quickly dissolve and release the medication following administration without requiring a modified-release mechanism, which speeds up drug absorption and the start of therapeutic activity [5]. A tricyclic antidepressant called imipramine hydrochloride is used to treat anxiety disorders, depression, and nocturnal enuresis. Imipramine hydrochloride immediate-release tablets were created to facilitate quicker tablet breakdown and quick drug release since quick beginning of action is crucial for increasing therapeutic efficacy and patient compliance. Kyron T-314 and Crospovidone were employed as superdisintegrants in this investigation to improve tablet breakdown and disintegration [6,7]. The Using the direct compression approach, manufacture tablets because it was easy to use, affordable, and appropriate for immediate-release formulas. To optimize the formulation variables and investigate their impact on drug release and disintegration time, a CCD, or Central Composite Design, was utilized [8,9]. To create an ideal and efficient immediate-release formulation of imipramine hydrochloride, the prepared Formulations were evaluated further for drug-excipient compatibility, pre- and post-compression parameters, in vitro dissolution studies, release kinetics, stability studies, and cytotoxicity studies.

MATERIAL AND METHODS

Materials

Imipramine Hydrochloride was collected from a Swapnroop Drugs and Pharmaceuticals. Another excipient such as Kyron T-314, Mannitol and Aspartame was received from Yarrow Chem Products Pvt, Ltd., Crospovidone was received from Rajesh Chemicals, Mumbai Pvt, Ltd, Talc and Magnesium stearate from Loba Chemie Pvt. Ltd., Palghar.

Instruments

The instrument and equipment used during the research work included an electronic digital balance (Shimadzu, AUY220), UV-Visible spectrophotometer (Jasco, V-630), Tablet compression machine (Goodwill), Melting point apparatus (Vego), Hardness tester (Monsanto), FTIR spectrophotometer (IRAffinity-1S, Shimadzu, Japan), Roche friabilator (Electrolab), Dissolution apparatus (Electrolab, TDT-08L), Disintegration apparatus (Electrolab ED-2L), Digital P^H meter (Henna instrument), Stability chamber (Remi Elektotechnik Ltd.), and Vernier caliper (Mitutoyo 500-196-30, Japan These tools have been used for the preparation, evaluation, and description of the immediate released tablets of Imipramine Hydrochloride throughout the study.

Determination of melting point

Imipramine Hydrochloride was placed in a capillary tube and Its melting point was determined using a melting point apparatus. The examination was conducted three times and the average value was recorded.

Drug-Excipients Interactions Studies

Compatibility studies using FTIR and DSC were performed to check interaction between Imipramine Hydrochloride and excipient. Polymers were selected based on being safe, non-taxic, tasteless, stable, inexpensive, and suitable for immediate disintegration without affecting drug performance.

FTIR Studies

The Fourier transform infrared spectrum of pure Imipramine Hydrochloride were compared with those of immediate release tablets to check for any changes in the drug or potential interactions between the medication and excipient used in formulation [10–12].

DSC Analysis

Pure imipramine hydrochloride's DSC thermogram revealed a sharp endothermic peak at 177°C, which matched its melting point and verified that it was stable and crystalline. The distinctive peak of the Impramine Hydrochloride tablet formulation was found at 163°C, with a small broadening and decrease in intensity. This change shows that the medication is uniformly dispersed throughout the excipient matrix and has less crystallinity. Nonetheless, the stability of imipramine hydrochloride in the formulation is confirmed by the persistence of the same characteristic peak without the emergence of any new peaks, suggesting no substantial drug excipient incompatibility [13,14].

Manufacturing of Imipramine Hydrochloride tablet

Direct compression Method

Using various super disintegrant ratios listed in the table, imipramine hydrochloride tablets were manufactured for nine batches, F1 through F9, while maintaining a constant tablet weight of 100 mg throughout all formulations. Using the recipe listed in the table, imipramine hydrochloride tablets were made applying the direct compression technique. Super disintegrants like Crospovidone and Kyron T-314 were used in varying amounts.

Procedure

Every part was weighed correctly and run through sieve number 60 independently. To create a homogenous powder mixture, imipramine hydrochloride, Kyron T-314, crospovidone, aspartame, mannitol, and talc were evenly combined. As Magnesium stearate was added as a lubricant and carefully combined with the mixture. A tablet compression machine equipped with a 2 mm punch was utilized to compress the prepared powder blend into tablets, which were then kept in airtight containers for additional assessment research.

Formulation of Imipramine Hydrochloride an immediate released

Table 1: Composition of Imipramine Hydrochloride tablet.

Sr. No	Ingredient	F1	F2	F3	F4	F5	F6	F7	F8	F9
1	**Imipramine Hydrochloride**	25	25	25	25	25	25	25	25	25
2	**Kyron T-314**	2	4	6	2	4	6	2	4	6
3	**Cospovidone**	3	3	3	5	5	5	7	7	7
4	**Aspartame**	3	3	3	3	3	3	3	3	3
5	**Talc**	1	1	1	1	1	1	1	1	1
6	**Magnesium Stearate**	2	2	2	2	2	2	2	2	2
7	**Mannitol**	64	62	60	62	60	58	60	58	56
Total weight (mg)		100	100	100	100	100	100	100	100	100

Pre-compression Parameters

Bulk Density

The powder's bulk density blend was established by transferring a known weight of powder into a graduated measuring cylinder and measuring the untapped volume. It was evaluated to evaluate the packing and flow properties of the blend used for preparation of Imipramine Hydrochloride immediate-release tablets [15,16].

Bulk Density: $\frac{\text{Weight of Powder}}{\text{Volume of powder}}$

Tapped Density

The mass to tapped volume ratio of granules following mechanical tapping is known as tapped density. Imipramine hydrochloride immediate-release tablet granules demonstrated adequate flow characteristics for tablet compression and good packing capabilities [17,18].

Tapped Density: $\frac{\text{Weight of powder}}{\text{Final tapped volume}}$

Angle of Repose

The repose angle is used to evaluate the flowability of granules in immediate release tablet formulation. It is determined by the fixed funnel method, where granules form a cone and its height (h) and radius (r) are measured [19,20]. It is calculated using:

$\tan \theta = h/r$

$\theta = \tan^{-1}(h/r)$

where the angle of repose is denoted by θ, the cone height by h, and the cone radius by r.

Compressibility Index (Carr's Index)

Carr's compressibility index is used to evaluate the flow properties of granules. It indicates the compressibility and packing ability of the powder blend. The Carr's index of Imipramine Hydrochloride immediate-release tablet granules showed good flow characteristics suitable for tablet compression [20,21].

Compressibility Index (%): $\frac{\rho t - \rho o}{\rho t} \times 100$

Were,

(Pt) = Tapped density

(Po) = Bulk density

Hausner's Ratio

Hausner's ratio is utilized to ascertain the flow properties of powders and granules by comparing tapped density with bulk density [20,21]. It is calculated using:

Hausner Ratio: $\frac{\text{Tapped Density}(\rho t)}{\text{Bulk Density}(\rho o)}$

Post compression parameters

Thickness

Ten randomly chosen tablets were measured for thickness in millimeters using a vernier calliper, and the standard deviation and mean were noted.

Hardness

The solid specimen's resistance to wear and fracture is correlated with the hardness 10 of a tablet. A Monsanto hardness tester can be used to measure tablet hardness, which is expressed in kg/cm2.

Friability

The Roche friabilator was utilized for test the tablet's friability 11. In a plastic chamber that rotates at 25 revolutions per minute and drops a tablet in a height of 6 inches for each revolution, this gadget exposes the tablet to the combined effects of abrasion and shock. A drug sample that had already been weighed was put within the friabilator and rotated 100 times. The tablets were reweighed after being dusted with a light muslin towel. The %friability (% F) is given by the formula**.**

$$\%F: \frac{W\,initial - W\,final}{W\,final} 100$$

In this case, W initial and W final represent the pill weights prior to (initial weight) and following (final weight) the test, respectively.

Weight Variation

Each of the twenty dosages was weighed using a Shimadzu digital scale for the weight variation test. Next, the average weight was determined and the weights of the individual tablets were contrasted to the average. After calculating the % weight deviation, it was compared to USP requirement**s.**

Disintegration test

Dissolution and disintegration tests were part of the in vitro assessment of Imipramine Hydrochloride immediate-release tablets. A USP Type II paddle apparatus (Electrolab) 900 milliliters of 0.1 N HCl at 37 ± 0.5°C and 50 rpm was utilized for the dissolution test [22,23]. Samples of five milliliters were collected out at prearranged intervals for up to thirty minutes, and a UV-visible spectrophotometer was used to measure the samples at 251 nm. The pills were observed to disintegrate in 30 minutes when tested using a USP disintegration device in distilled water kept at 37 ± 2°C.

Drug Content

After powdering each formulation contains three tablets. batch of Imipramine Hydrochloride immediate-release tablets, 100 mg of the medication was placed to a 100 mL volumetric flask and diluted to volume using 0.1 N HCl. A UV-visible spectrophotometer was used to measure the absorbance at 251 nm after an appropriate portion of this solution underwent additional dilution using 0.1 N HCl. The calibration curve generated in 0.1 N HCl functioned to process the concentration of imipramine hydrochloride.

Studies on *in vitro* dissolution

Imipramine Hydrochloride immediate-release tablets were dissolved in vitro at 50 revolutions per minute with USP dissolution apparatus Type II (paddle method). 900 mL of 0.1 N HCl kept at 37 ± 0.5°C made up the dissolving media [5,23]. To maintain a constant volume, a 5 mL sample was taken out at intervals of 5, 10, 15, 20, 25, and 30 minutes and replaced with an equivalent volume of brand-new, preheated dissolving medium. A UV-visible spectrophotometer was used to measure the samples at 251 nm after they had been filtered via Whatman filter paper. The cumulative medication release percentage was computed.

Stability studies

Stability studies of the optimized batch were carried out according to ICH guidelines at 40 ± 2°C and 75 ± 5% RH for 90 days. The tablets were evaluated at predetermined periods for drug content, disintegration time, physical appearance, and in vitro drug release. The formulation showed no significant changes in evaluation parameters, indicating good stability under accelerated storage conditions.

Optimization of immediate release tablet of Imipramine Hydrochloride

The formulation was optimized using a Central Composite Design (CCD) of Imipramine Hydrochloride immediate release tablets using Design-Expert® software (Version 13.0, Stat-Ease Inc., USA). The experimental design comprised 9 formulation runs, including factorial and center points, to assess the impact of formulation variables and ensure the reliability of the developed quadratic model. Two independent variables were selected: Kyron T-314 (X_1) and Crospovidone (X_2), which were varied at different concentration levels.

The effect of these formulation factors was investigated on the dependent response, namely percentage drug release after 30 minutes (Y_1), in order to optimize the Immediate release characteristics of the tablet formulation.

Factor levels used in CCD design

Table 2: Factor combinations as per CCD.

Factor	Name	-1	0	+1
A	Kyron T-314	2	4	6
B	Crospovidone	3	5	7

Drug release kinetics study

Various kinetic models, including zero-order, first-order, Higuchi, Hixson–Crowell, and Korsmeyer–Peppas models, were applied to evaluate the in-vitro drug release profile of Imipramine Hydrochloride immediate-release tablets. The release mechanism was interpreted based on the regression coefficient (R^2) variables that come from each kinetic model [24,25].

Analysis of Imipramine Hydrochloride Tablets' Cytotoxicity and Biocompatibility

MDA-MB-231 cell lines of human breast cancer were used in the MTT assay to assess the cytotoxicity and biocompatibility of the proposed Imipramine Hydrochloride immediate-release tablet formulation. Under usual conditions of 37°C and 5% CO2, the cells were grown in MEM supplemented with NEAA and fetal bovine serum. 96-well plates were planted with cells were exposed to various quantities of the sterile formulation for a full day. When the MTT reagent was applied after the incubation period, purple formazan crystals formed, indicating the existence of live cells. A microplate reader was utilized to measure absorbance measured at 570 nm, and IC^2_0 values and percentage cell viability were computed. The study found that when drug as the concentration increased, cell viability sinkte in a concentration-dependent manner. Even at higher doses, a sizable number of live cells were observed, implying that the prepared immediate-release tablets had acceptable biocompatibility and moderate cytotoxicity.

RESULT AND DISCUSSION

Drug excipient compatibility study

The FTIR spectrum of Imipramine Hydrochloride exhibited characteristic absorption peaks at 3320 cm^{-1} corresponding to –OH/–NH stretching, 1594 cm^{-1} for C=N/C=C stretching, 1479 cm^{-1} for C–H bending, 1284 cm^{-1} for C–N/C–O stretching, and 762 cm^{-1} indicating out-of-plane ring deformation. The FTIR spectrum of the medication in its pure form, excipients, and their physical mixture were analysed for compatibility assessment. The physical mixture's spectrum retained all the major characteristic peaks of the drugs without any noticeable shift or disappearance. This confirms that no significant interaction occurred between the drug and excipients, confirming their suitability for the formulation of Imipramine Hydrochloride immediate-release tablets.

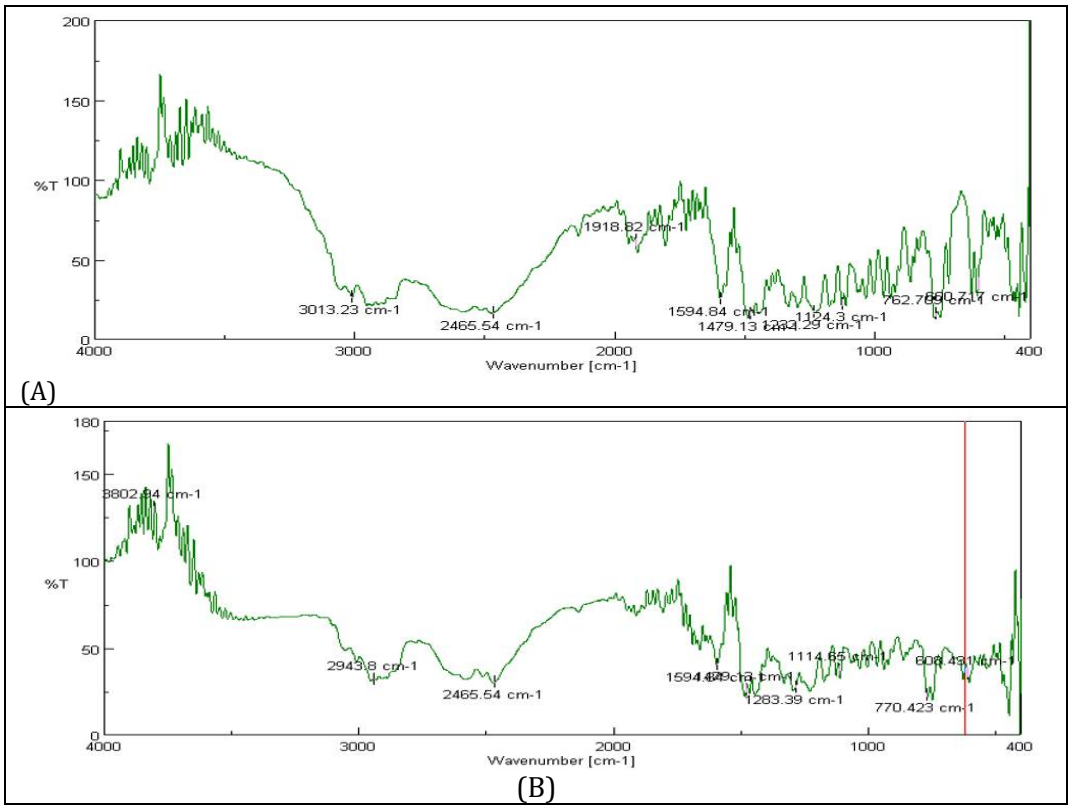

Figure 1: FTIR Studies of (A) Pure Drug Imipramine Hydrochloride (B) Imipramine Hydrochloride Tablet and Excipients.

Differential Scanning Calorimetric Study

The DSC study confirms that Imipramine Hydrochloride is a crystalline and pure compound with a sharp melting point at approximately 177°C and demonstrates strong thermal stability without any sign of degradation or polymorphic transformation

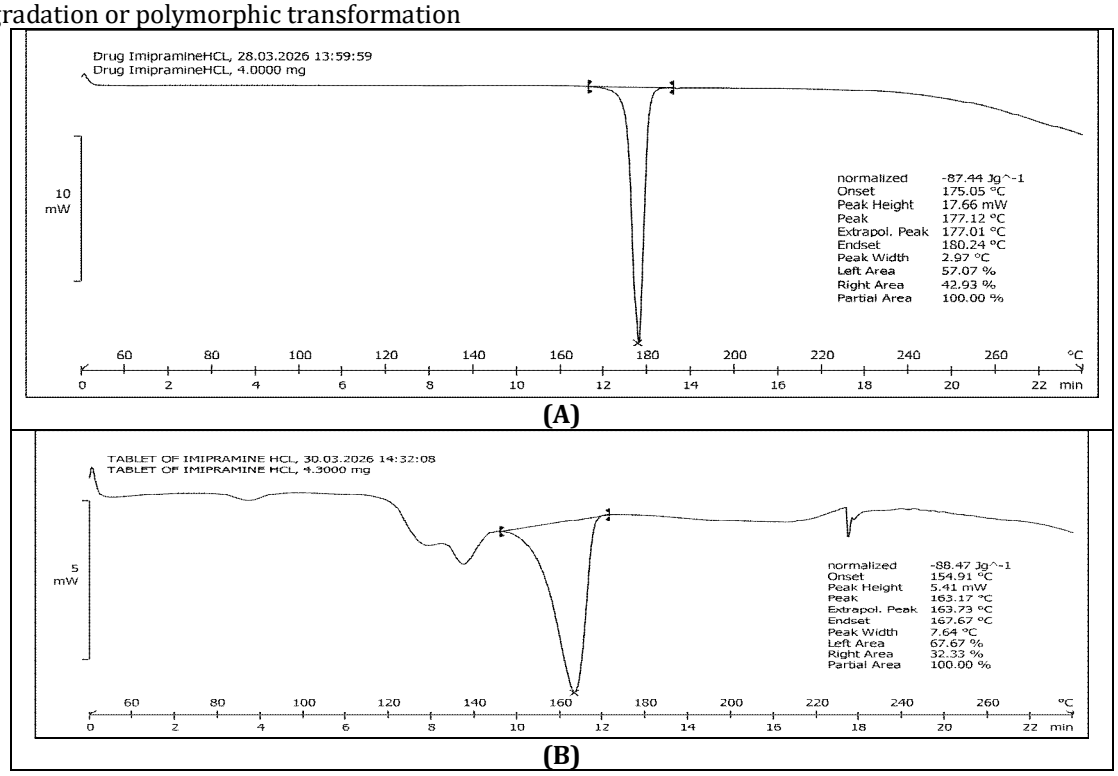

Figure 2: DSC analysis thermograms of (A) Imipramine Hydrochloride (B) Imipramine Hydrochloride Table

The thermogram for DSC of the Imipramine Hydrochloride tablet exhibited an endothermic peak at 163.17°C, which was less than that of the pure drug, indicating the impact of excipients on the thermal activity of the formulation. The existence of the characteristic peak verified the existence of the drug in the formulation, while the shift in melting temperature and broadening of the peak suggested reduced crystallinity and uniform dispersion of the drugs within the excipient matrix. No disappearance of the distinctive peak was seen, signifying the lack of significant drug–excipient incompatibility.

Pre-Compression Parameters

Table 3: Evaluation of Bulk density, Tapped density, Carr's Index, Hausner's Ratio and Angle of Repose (θ) of Formulated Batches.

Formulation Code	Bulk Density (g/cm^3)	Tapped Density (g/cm^3)	Carr's Index (%)	Hausner's Ratio	Angle of Repose (θ)
F1	0.52±0.01	0.62±0.02	16.1±0.3	1.19±0.02	27.8±0.50
F2	0.53±0.01	0.63±0.01	15.9 ±0.2	1.18±0.01	27.2±0.33
F3	0.51±0.02	0.61±0.02	16.4 ±0.4	1.20±0.02	26.0±0.27
F4	0.54±0.01	0.64±0.01	15.6 ±0.3	1.18±0.01	28.0±0.44
F5	0.52±0.02	0.63±0.02	17.0 ±0.5	1.21±0.02	27.5±0.71
F6	0.53±0.01	0.64±0.01	16.2±0.3	1.20±0.01	27.9±0.52
F7	0.52±0.01	0.61±0.02	14.8±0.2	1.17±0.01	26.5±0.34
F8	0.53±0.01	0.62±0.01	15.2±0.3	1.17±0.01	26.8±0.12
F9	0.52±0.62	0.63±0.02	14.9±0.2	1.16±0.01	27.3±0.23

Post Compression study of Immediate release tablet

Table 4: Evaluation of Thickness, Weight Variation, Hardness, Friability and Drug content of Formulated Batches.

Batch	Thickness (mm)±SD	Average weight (mg)±SD	Hardness (kg/cm²) ±SD	Friability (%) ±SD	Drug Content (%) ±SD
F1	2.05 ± 0.03	100.2 ± 0.8	3.2 ± 0.2	0.52	96.2±1.8
F2	2.08 ± 0.02	99.8 ± 0.7	3.4 ± 0.3	0.42	97.4±1,6
F3	2.02 ± 0.04	100.5 ± 0.9	3.5 ± 0.2	0.40	98.1±1.5
F4	2.10 ± 0.02	100.1 ± 0.6	3.6 ± 0.3	0.38	98.9±1.3
F5	2.06 ± 0.03	99.6 ± 0.8	3.3 ± 0.2	0.44	99.3±1.2
F6	2.12 ± 0.03	100.3 ± 0.7	3.7 ± 0.3	0.36	99.7±1.1
F7	2.04 ± 0.02	99.9 ± 0.6	3.5 ± 0.2	0.41	100.1±1.0
F8	2.07 ± 0.04	100.4 ± 0.8	3.6 ± 0.3	0.37	100.4±0.9
F9	2.09 ± 0.03	100.0 ± 0.7	3.4 ± 0.2	0.39	100.8±0.7

In-vitro dissolution study

A USP Type II (paddle) dissolution equipment operating at 50 rpm in 900 ml of 0.1 N HCl kept at 37°C ± 0.5°C was used to conduct drug release tests of Imipramine Hydrochloride instant release tablets. Samples were taken out at certain intervals and examined at 250–254 nm using a UV spectrophotometer. The dissolution profile was determined by calculating the cumulative percentage drug release. These investigations validated the formulation's potential for prompt therapeutic action, guaranteed batch-to-batch uniformity, and proved rapid drug release.

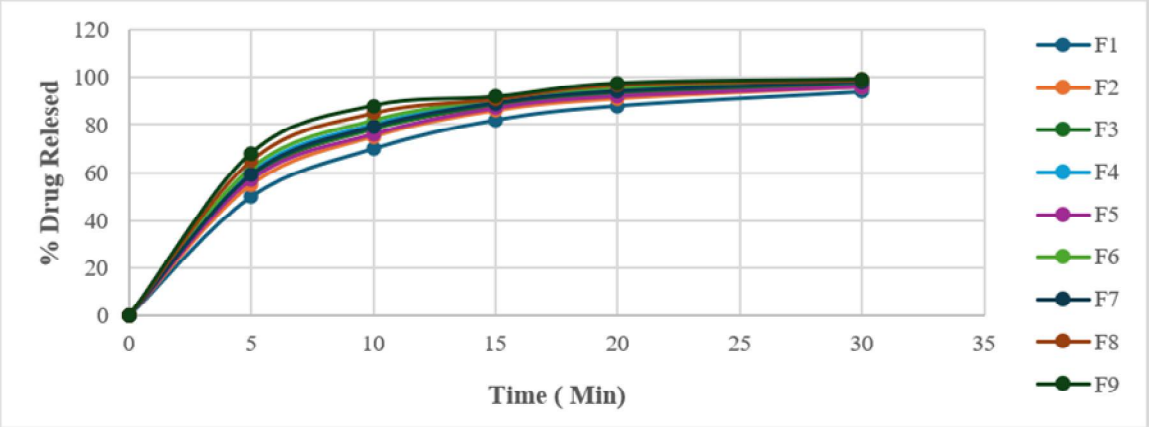

Figure 3: Cumulative % profile of release of drugs Imipramine Hydrochloride immediate release formulation as per experimental design.

Optimization of formulation

Time of Disintegration (Y_1)

Good agreement between the experimental and anticipated responses was demonstrated by the model's strong R2 adjusted R2 and predicted R2 values. Kyron T-314 (A) and Crospovidone (B) both had a major impact on how quickly the tablets disintegrated. The disintegration time reduced as The level of focus of both superdisintegrants increased, In line with the negative coefficients of the linear terms. Of the two, Kyron T-314 produced faster tablet disintegration and had a relatively stronger effect than Crospovidone. The disintegration time regression equation was:

$$(Y_1) = 19.24 - 10.03A - 5.17B + 0.9000AB + 5.43A^2 + 2.83B^2$$

The positive quadratic coefficients suggested a nonlinear relationship between the independent variables and response. At higher concentrations, the decrease in disintegration time was not directly proportional, indicating an ideal range of concentrations for both superdisintegrants. The interaction effect between Kyron T-314 and Crospovidone was less significant compared to their individual effects. Contour and 3D surface plots demonstrated that formulations containing moderate to higher levels of Kyron T-314 and Crospovidone showed rapid tablet disintegration.

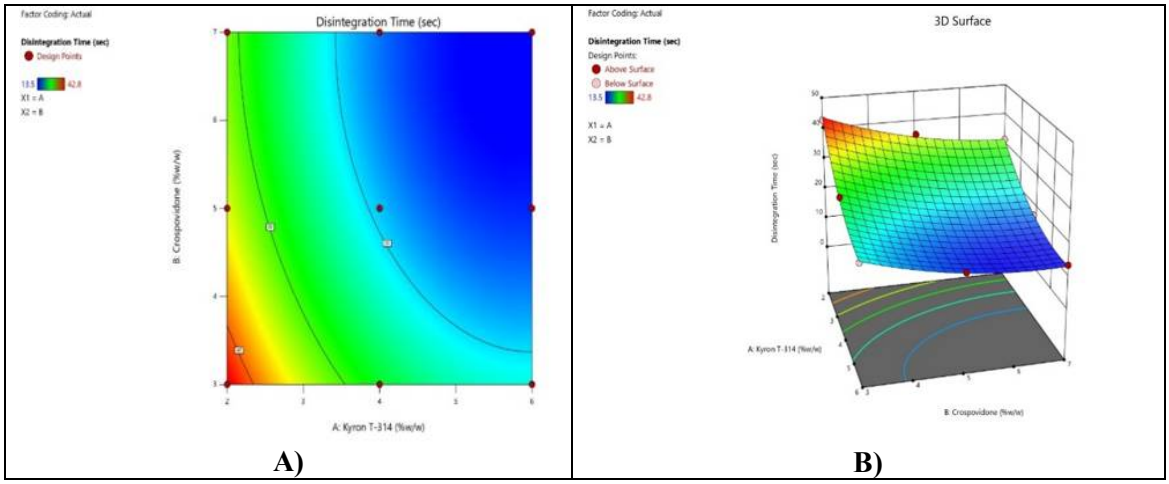

Figure 4: (A) The disintegration time contour plot shows that the disintegration time gradually rose when the concentration of Kyron T-314 and Crospovidone increased. An increase in disintegration time from lower to higher levels of superdisintegrants is represented by the color shift from blue to red. (B) Three-dimensional surface map illustrating how Kyron T-314 and Crospovidone affect disintegration time. The reaction surface shows that both superdisintegrants had a major impact on the behavior of tablet disintegration and helped Imipramine Hydrochloride immediate-release tablets break apart quickly and release the medication right away.

% Drug Release (Y_2)

Good model fitting and satisfactory consensus between the expected and experimental responses were demonstrated by the Quadratic model for drug release %. Drug release was greatly impacted by both Kyron T-314 (A) and Crospovidone (B), with Kyron T-314 having a larger effect. Increasing the concentration of both superdisintegrants improved the percentage drug release, according to the positive coefficients of the linear terms. Crospovidone exhibited a positive effect within the investigated range, while sodium starch glycolate showed a suppressive effect on the release of drugs at greater doses. Regarding the proportion of drug release, the regression equation was:

$$(Y_2) = 85.89 + 7.10A + 4.80B - 1.00AB - 3.13A^2 - 1.83B^2$$

The reaction was not considerably impacted by the interaction term (AB). Formulations with modest doses of both superdisintegrants provided maximum drug release within 15 minutes, as shown by contour and 3D surface plots. In comparison to Crospovidone, Kyron T-314 generally made a greater contribution to quick drug release.

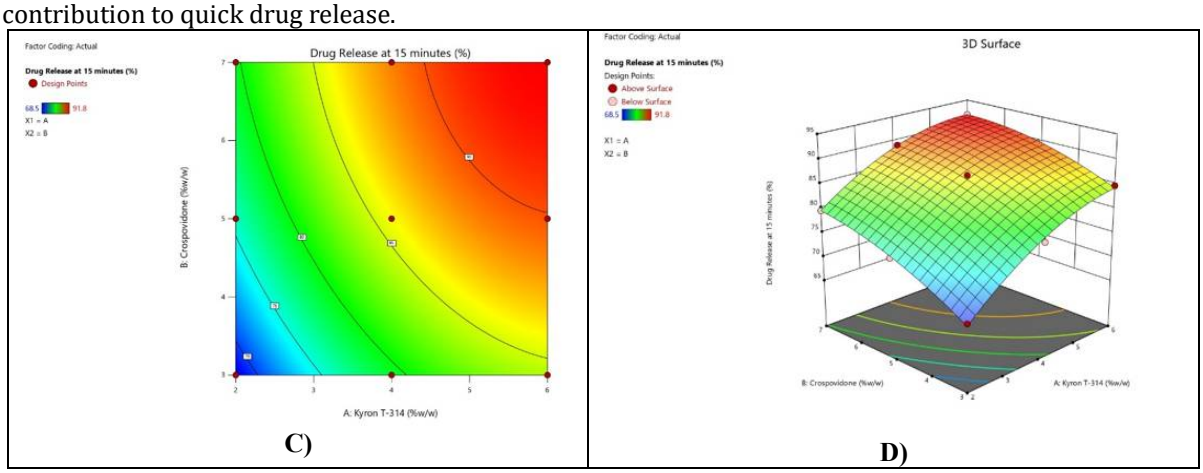

Figure 5: (C) The red area in the drug release contour plot represents the maximal release at optimal levels of Kyron T-314 and Crospovidone. (D) 3D surface plot showing a quadratic influence on drug release from Imipramine Hydrochloride immediate-release tablets, where optimal amounts of both superdisintegrants increased drug release

Results of release kinetics

The improved Imipramine Hydrochloride immediate-release formulation's The kinetics of medication release were evaluated using Higuchi, Korsmeyer-Peppas, Zero-order, and First-order models. Using a correlation coefficient of R2 = 0.9985, the Zero-order model demonstrated the greatest match among

them, suggesting that the medication was released at a fairly constant rate during the 30-minute trial period.

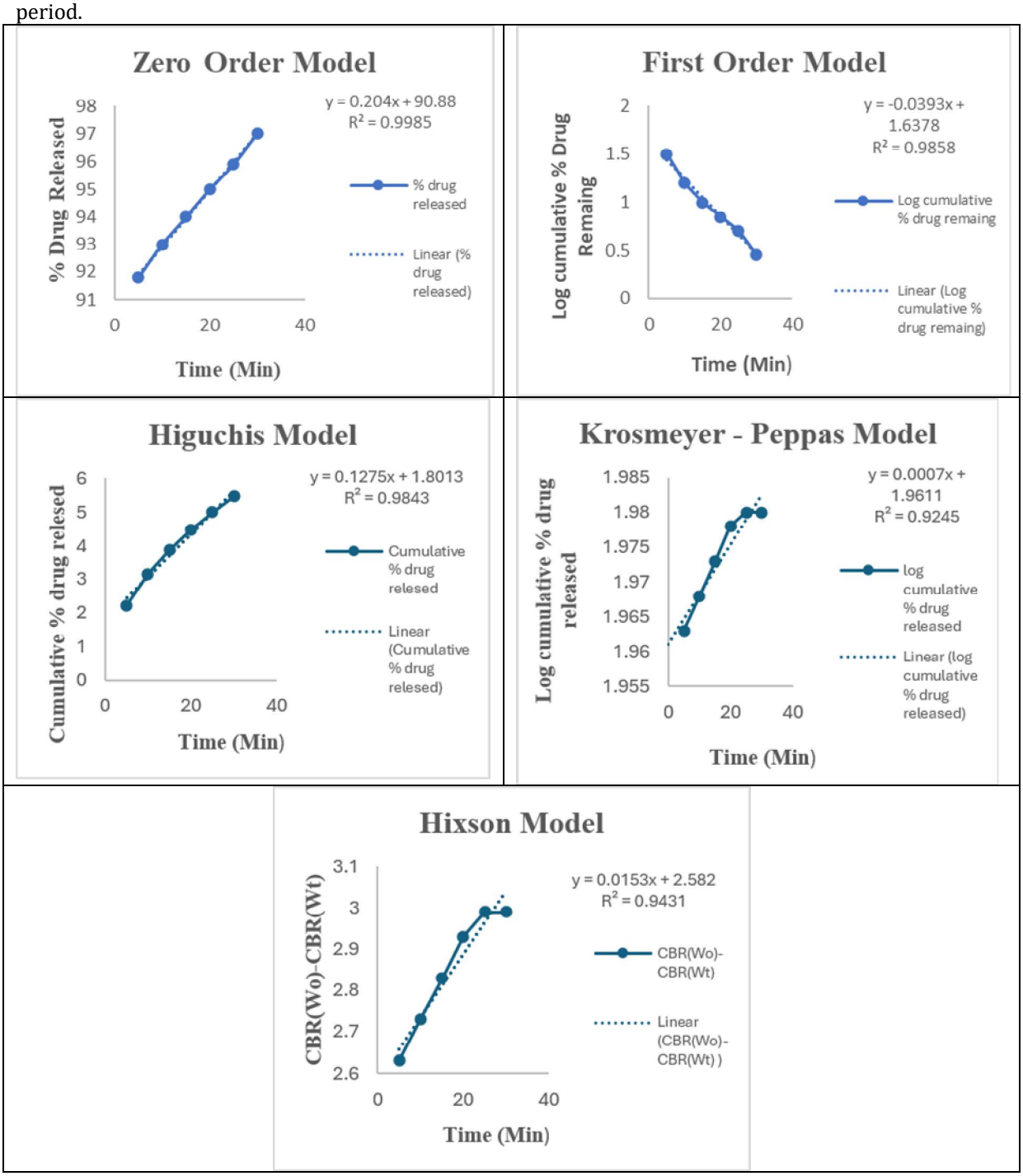

Figure 6: Kinetics modeling the release of drugs from optimized Imipramine Hydrochloride immediate Release Tablet

MTT assay result

Under usual conditions of 37°C and 5% CO2, the cells were grown in MEM supplemented with NEAA and fetal bovine serum. After being seeded in 96-well plates, cells were exposed to varying doses of the sterilized formulation for a whole day. When the MTT reagent was applied after the incubation period, purple formazan crystals formed, indicating the presence of live cells. A microplate reader was used to measure absorbance at 570 nm, and IC^2_0 values and percentage cell viability were computed. The study found that when drug Cell viability declined as concentration raised in a concentration-dependent manner. Even at higher doses, a sizable number of live cells were seen, indicating that the prepared immediate-release tablets had acceptable biocompatibility and moderate cytotoxicity.

Table 5: Effect of test sample on cell viability assessed by MTT assay at various concentration

Concentration (ug/mL)	Average % Cell Survival
CTRL	100.00
5	95.02
10	87.84
40	92.51
100	79.40
150	77.27
250	54.67
500	18.38

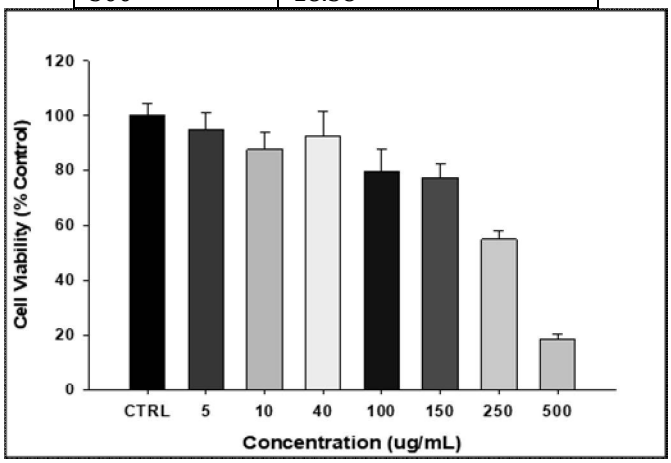

Figure 7: Effect of Imipramine Hydrochloride Immediate-Release Tablets on MDA-MB-231 Cell Viability at Varying Concentrations Assessed by MTT Assay

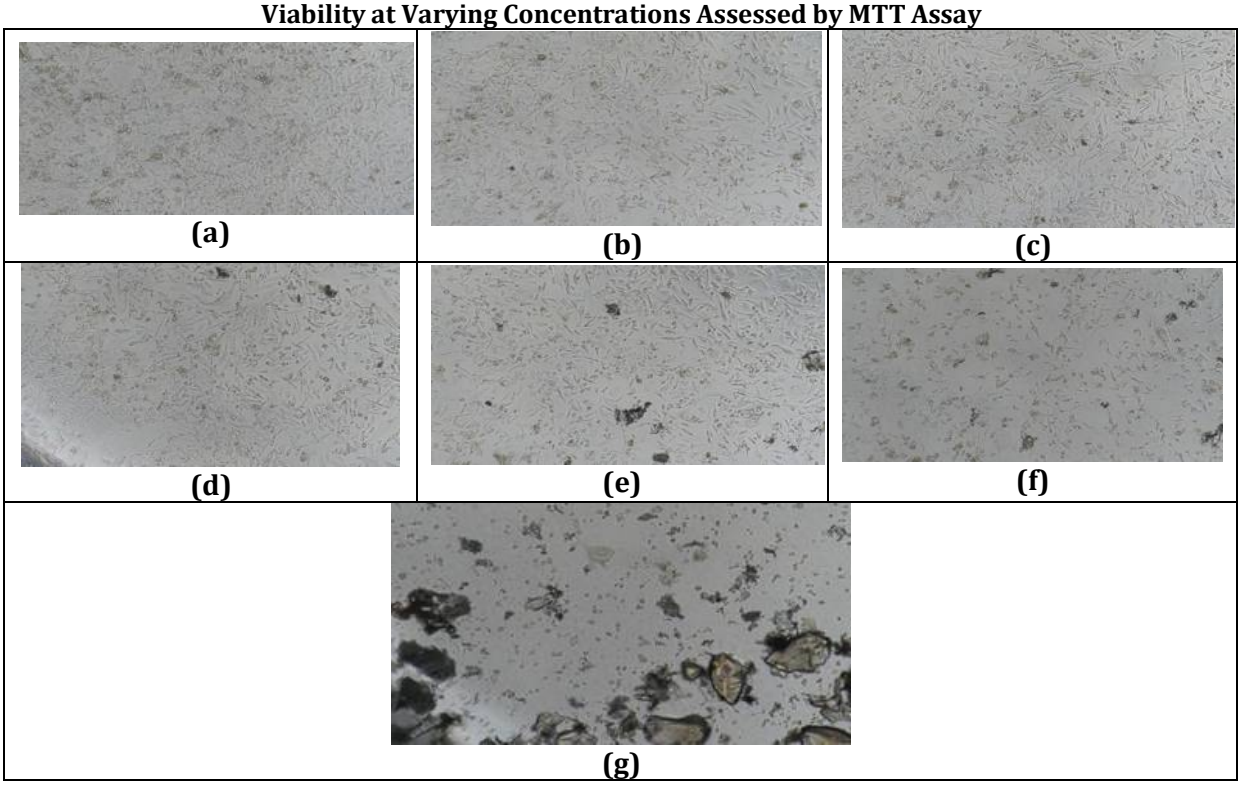

Figure 8: Microscopic images of MDA-MB-231 cells treated with optimized Imipramine Hydrochloride immediate-release tablet formulation at various concentrations after 24 hours of incubation: (a) 1 µg/mL, (b) 5 µg/mL, (c) 25 µg/mL, (d) 50 µg/mL, (e) 100 µg/mL, (f) 250 µg/mL, and (g) 500 µg/mL.

Stability Study

In accordance with ICH Q1A (R2) recommendations, an accelerated stability study of optimized batch F9 was conducted for 90 days at 40°C ± 2°C and 75% RH ± 5% RH. At 0, 30, 60, and 90 days, the formulation's physical characteristics, drug content, disintegration time, and in-vitro drug release were assessed. The stability of Imipramine Hydrochloride immediate-release tablets under accelerated settings was confirmed by the little variations in hardness and weight fluctuation that were noted, all of which stayed within acceptable bounds.

Table 6: Enhanced Stability of Optimized Batch F9 (40±2oC/75±5%)

Study Duration	Appearance	Hardness (kg/cm²)	Weight Variation(mg)	Drug Release (%)
Initial	White, Smooth tablet	2.5 ± 0.12	100 ± 1.2	98.6 ± 0.82
1 Month	No change	2.4 ± 0.10	100 ± 1.4	98.1 ± 0.44
2 Months	No change	2.3± 0.15	99.8 ± 1.5	97.4 ± 0.35
3 Months	No change	2.2 ± 0.11	98.7 ± 1.8	96.1 ± 0.38

All values are expressed as mean ±SD (Where n=3)

CONCLUSION

The present study successfully developed and optimized Imipramine hydrochloride immediate-release tablets, manufactured using direct compression with Kyron T-314 and Crospovidone as superdisintegrants. The optimized formulation F9 showed excellent powder flow properties, uniform drug content, and satisfactory mechanical strength with low friability, indicating good tablet integrity. Among all prepared batches, F9 exhibited the fastest disintegration, shortest wetting time, and maximum in vitro drug release, following a rapid release profile suitable for immediate therapeutic action. Compatibility studies confirmed no significant interaction between a drug and excipients. Studies on stability to rapid conditions showed that the optimized formulation remained physically and chemically stable without significant changes in drug content or dissolution behavior. Overall, the optimized F9 formulation of Imipramine Hydrochloride immediate release tablets demonstrated rapid drug release, good stability, and improved performance, making it a promising dose form for a quicker start to action and enhanced patient compliance.

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