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Review

Formulation & Evaluation of Oral Disintegrating Tablet of Atomoxetine

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Abstract

The present investigation aimed to formulate and evaluate oral disintegrating tablets (ODTs) of Atomoxetine hydrochloride to improve patient compliance and achieve rapid onset of action in attention-deficit/hyperactivity disorder (ADHD). ODTs were prepared by direct compression using Crospovidone, Sodium Starch Glycolate (SSG), and Croscarmellose Sodium (Ac-Di-Sol) at varying concentrations. Tablets were evaluated for physicochemical properties, including thickness, hardness, weight variation, friability, wetting time, dispersion time, disintegration time, drug content uniformity, and in vitro drug release. Compatibility studies using Differential Scanning Calorimetry (DSC) and Fourier Transform Infrared Spectroscopy (FTIR) confirmed the absence of drug–excipient interactions, indicating formulation stability. All formulations complied with pharmacopoeial requirements for ODTs. Among nine formulations, AXODT6 containing optimized SSG showed superior performance with the shortest wetting and disintegration times, highest drug content uniformity, and nearly complete drug release (≈99.33%). Dissolution studies demonstrated rapid drug release from all formulations, with SSG-based tablets outperforming Crospovidone and Ac-Di-Sol. Release kinetics predominantly followed First-order and Higuchi models, with Korsmeyer–Peppas analysis indicating non-Fickian diffusion. AXODT6 exhibited an excellent Zero-order release profile, suggesting controlled and predictable release. The study concludes that Atomoxetine ODTs can be successfully developed by direct compression, and AXODT6 represents a promising patient-friendly dosage form with improved compliance and therapeutic efficacy.

Keywords: Atomoxetine hydrochloride, Oral disintegrating tablets, Direct compression, SSG, Drug release kinetics.

Introduction

Oral drug delivery systems continue to be the most widely preferred route of administration due to their simplicity, patient convenience, cost-effectiveness, and suitability for large-scale manufacturing. However, conventional oral solid dosage forms such as tablets and capsules often present challenges, including difficulty in swallowing (dysphagia), delayed onset of action, and reduced patient compliance, particularly among pediatric, geriatric, and psychiatric populations.[1] These limitations may result in improper dosing, poor therapeutic outcomes, and reduced adherence to treatment regimens, especially in chronic disorders requiring long-term pharmacotherapy.

To overcome the drawbacks associated with conventional oral dosage forms, orally disintegrating tablets (ODTs) have been developed as an innovative and patient-friendly drug delivery system. ODTs are designed to disintegrate rapidly in the oral cavity, typically within seconds, without the need for water, thereby facilitating ease of administration and improving patient compliance.[2] This dosage form is particularly advantageous for patients who have difficulty swallowing, those with nausea, or individuals who require rapid onset of action.[3] By disintegrating quickly in saliva, ODTs allow for faster drug dissolution and absorption, which can enhance bioavailability and improve therapeutic efficacy.[4]

Orally disintegrating tablets employ a combination of superdisintegrants, hydrophilic excipients, and taste-masking agents to achieve rapid tablet breakup while maintaining adequate mechanical strength. Upon contact with saliva, superdisintegrants swell or wick moisture into the tablet matrix, leading to its rapid disintegration into fine particles.[5] This rapid dispersion increases the surface area of the drug exposed to dissolution media, thereby accelerating drug release and onset of action.[6] Additionally, ODTs enhance patient acceptability by reducing the risk of choking and eliminating the need for water during administration.[7]

Atomoxetine hydrochloride is a selective norepinephrine reuptake inhibitor primarily indicated for the treatment of attention-deficit/hyperactivity disorder (ADHD). It is widely prescribed for both pediatric and adult patients due to its non-stimulant nature and lower potential for abuse compared to traditional stimulant medications.[8] Despite its clinical benefits, atomoxetine therapy is often associated with compliance issues, particularly in children, due to difficulty in swallowing conventional tablets and the need for consistent daily dosing to maintain therapeutic plasma levels.[9]

Variability in drug intake and delayed onset of action can adversely affect treatment outcomes in ADHD, where sustained symptom control is critical. Developing an orally disintegrating tablet of atomoxetine offers a promising approach to address these challenges by providing rapid disintegration, improved ease of administration, and enhanced patient adherence.[10] The quick disintegration in the oral cavity ensures faster drug availability, potentially leading to improved therapeutic response and better management of ADHD symptoms. Reduced dosing inconvenience further contributes to improved compliance and overall clinical effectiveness.[11]

Therefore, the present study aims to formulate and evaluate orally disintegrating tablets of atomoxetine using suitable superdisintegrants and excipients. The formulated ODTs were subjected to comprehensive evaluation, including physicochemical characterization, drug content uniformity, in vitro disintegration time, wetting time, in vitro dissolution studies, and release kinetics assessment, to determine their suitability as an effective and patient-compliant oral drug delivery system.[12]

Material:

All pharmaceutical-grade chemicals and excipients were procured from reputed suppliers in the Hyderabad region. Atomoxetine hydrochloride was obtained from Sun Pharmaceutical Industries Ltd.; Crospovidone from BASF India Ltd.; Croscarmellose sodium from Signet Chemical Corporation, Hyderabad; Sodium starch glycolate from Colorcon Asia Pvt. Ltd.; Mannitol from Roquette India Pvt. Ltd.; Microcrystalline cellulose (MCC PH 102) from FMC Biopolymer; Aspartame from Ajinomoto India Pvt. Ltd.; and Magnesium stearate from Loba Chemie Pvt. Ltd.

Methodology

Formulation of Oral Disintegrating Tablet of Atomoxetine by Direct Compression Method

Oral disintegrating tablets of Atomoxetine were prepared by the direct compression method using different concentrations of superdisintegrants. To obtain uniform particle size and ensure proper mixing, all raw materials were passed through a No. 100 mesh

sieve. Accurately weighed quantities of Atomoxetine, diluents (such as Mannitol and Microcrystalline Cellulose), superdisintegrant(s) (Sodium Starch Glycolate, Crospovidone, or Croscarmellose Sodium), and binder Povidone K-30 were thoroughly mixed in a glass mortar and pestle to obtain a uniform blend.[13] Sweetening agent Aspartame was then added and mixed uniformly to improve palatability. After proper blending, magnesium stearate and talc were added to the powder mixture as lubricants and mixed gently to ensure adequate flow properties. The final blend was compressed into tablets using a single-punch tablet compression machine (Cadmach, Ahmedabad, India) by the direct compression method.[14]

Table no. 1 Formulation Table for Oral Disintegrating Tablet of Atomoxetine

Formulation	**AXODT1**	**AXODT2**	**AXODT3**	**AXODT4**	**AXODT5**	**AXODT6**	**AXODT7**	**AXODT8**	**AXODT9**
Atomoxetine(mg)	40	40	40	40	40	40	40	40	40
Sodium Saccharine(mg)	49	43	37	49	43	37	49	43	37
Cross povidone(mg)	6	12	18	-	-	-	-	-	-
SSG(mg)	-	-	-	6	12	18	-	-	-
Ac-Di-Sol(mg)	-	-	-	-	-	-	6	12	18
Magnesium stearate(mg)	5	5	5	5	5	5	5	5	5
Total weight(mg)	**100**	**100**	**100**	**100**	**100**	**100**	**100**	**100**	**100**

AXODT= ***Atomoxetine Oral disintegrating Tablet***

Evaluation of Oral Disintegrating Tablet of Atomoxetine

Thickness:

Twenty tablets from the representative sample were randomly selected, and individual tablet thickness was measured using a digital vernier caliper. The average thickness and standard deviation were calculated to ensure uniformity among tablets.

Hardness:

The hardness of tablets was determined using a Monsanto hardness tester. Six tablets from each batch were tested, and the average value along with standard deviation was recorded to ensure mechanical strength of the tablets.[15]

Friability Test:

Ten tablets from each batch were accurately weighed and placed in a Roche friabilator. The friabilator was operated at 25 rpm for 4 minutes (100 revolutions). The tablets were dedusted and reweighed. The percentage weight loss (friability) was calculated, and tablets with less than 1% weight loss were considered acceptable.[16]

Weight Variation Test

To assess weight variation, the individual weight (WI) of 20 tablets was determined using an electronic balance. The average weight (WA) was calculated, and the percentage deviation for each tablet was computed using the formula:
% weight variation = (WA – WI) × 100 / WA
As per IP (1996), for tablets weighing 120 mg, a ±7.5% deviation is allowed for not more than two tablets. According to USP (2004), a ±10% variation is permissible for not more than two tablets out of twenty.[17]

Wetting time:

Wetting time was measured by placing a folded tissue paper (12 cm × 10.75 cm) in a Petri dish (ID = 6.5 cm) containing 6 mL of Sorenson's buffer (pH 6.8). A tablet was placed on the paper, and the time required for complete wetting was recorded. Wetting time indicates the speed of liquid uptake by the tablet and correlates with disintegration efficiency.[18]

In Vitro Dispersion Time:

The dispersion time of the tablets was measured by placing a tablet in a glass cylinder containing 6 mL of Sorenson's buffer (pH 6.8). Six tablets were tested randomly from each formulation, and the time taken for complete dispersion was recorded.

Drug Content (Assay):

Drug content was determined to ensure uniform distribution of Atomoxetine in the tablets. Ten tablets were weighed and powdered. A portion equivalent to 100 mg of Atomoxetine was transferred to a 100 mL volumetric flask containing 70 mL of 0.1N HCl and shaken for 1 hour using a mechanical shaker. The solution was filtered through Whatman filter paper No. 1 and diluted to 100 mL with 0.1N HCl. From this solution, 1 mL was further diluted to 50 mL with 0.1N HCl, and absorbance was measured using a UV-visible spectrophotometer at the λmax of Atomoxetine against blank.[19] The content was considered acceptable if it ranged between 90% to 110%.

In Vitro Drug Release Characteristics:

Dissolution studies were carried out using USP type II (paddle) dissolution apparatus at 100 rpm. The medium used was 500 mL of 0.1N HCl for the first 2 hours, followed by phosphate buffer (pH 6.8) for up to 12 hours, maintained at 37°C ± 0.5°C. At predetermined time intervals, 5 mL of sample was withdrawn, filtered through Whatman filter paper No. 1, and replaced with an equal volume of fresh medium. Drug release was analysed spectrophotometrically using a UV-visible spectrophotometer.[20]

Drug Release Kinetics:

To determine the drug release mechanism and kinetics, the dissolution data of the optimized formulations were fitted into various kinetic models—zero-order, first-order, Higuchi, and Korsmeyer-Peppas models. The best-fit model was identified by comparing the correlation coefficient (R^2) values, where a value closest to 1 indicated the most suitable release profile. Atomoxetine FDTs typically followed zero-order or Higuchi release, indicating a sustained release behavior due to polymer matrix diffusion.

Results & Discussion

DSC (Differential scanning calorimetry):

Differential Scanning Calorimetry excipients are utilised (**Fig:1**) for determination of presence of any interaction between drug & the excipients, as well as any changes in the crystallinity of drug. It measures the enthalpic changes that occur during endothermic or exothermic events. The melting point & heat of fusion is the device which is calibrated through indium (calibration standard, purity > 99.99%). In typical aluminium pans, 5-15 mg of drug sample was obtained for examination. As a guide, the empty pan is used. The heating rate is mostly nitrogen, which was used as a purged gas, and the system was cooled by liquid nitrogen. This was accomplished using a differential thermal analyzer. The peak is observed at 170 °C as referred to the standard.

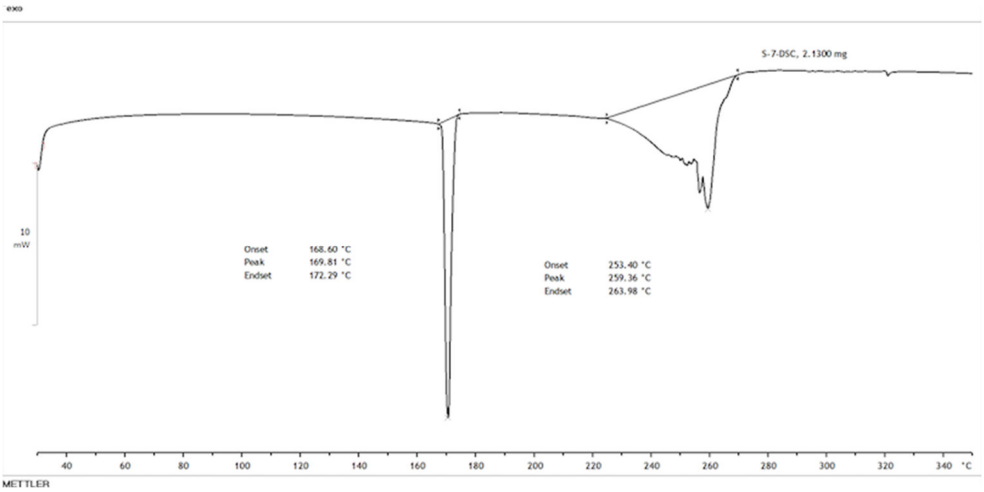


Figure no. 1: DSC of Pure Drug

FTIR

Pure Atomoxetine IR spectra are displayed in (**Fig:2**). Atomoxetine's spectra exhibit peaks at 1755.28 C= O cm 1 for NH- stretching, 1618.33 cm 1 for C=C stretching, 1276.92 cm 1 for C-N amine bond, 516.94 cm 1 for halogen compound (C-Cl) link, 2997.48 (alkane compound), 2947.33, 2883.68 with O-H bond, and 1188.19 with C-N bond. Atomoxetine-formulated NLC spectra exhibit a shift in the pure drug's spectral peaks, proving the presence of drug in these formulations.

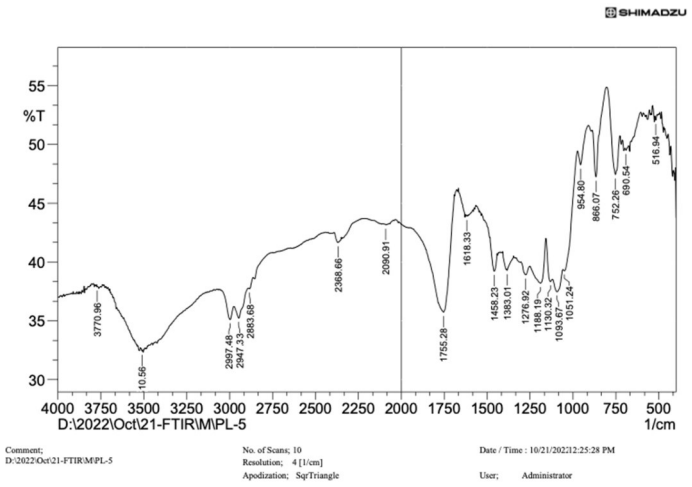


Figure no. 2 FTIR of Pure Drug

Table no. 2 Characterization of Atomoxetine Fast dissolving tablets

Formulation	Thickness(mm)	Weight variation (%)	Hardness(kg/cm2)	Friability
AXODT1	3.06	1.89	5.12	0.321
AXODT2	3.02	1.91	5.23	0.421
AXODT3	3.05	1.87	5.27	0.432
AXODT4	3.04	1.90	5.31	0.471

AXODT5	3.11	1.88	5.26	0.512
AXODT6	3.04	1.95	5.32	0.312
AXODT7	3.07	1.92	5.48	0.782
AXODT8	3.01	1.88	5.44	0.861
AXODT9	3.02	1.95	5.55	0.751

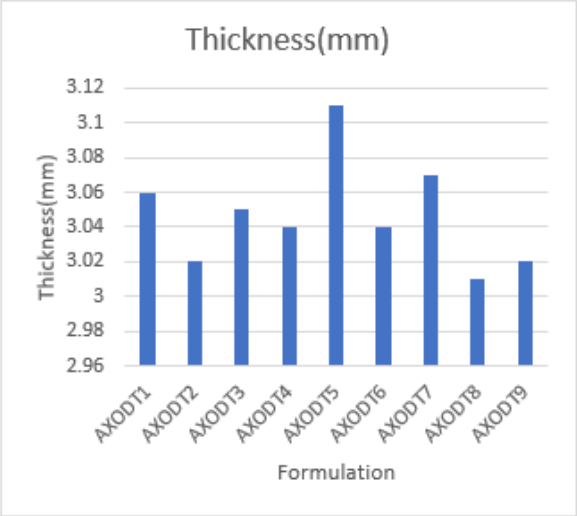


Figure no. 3(a) Thickness(mm)

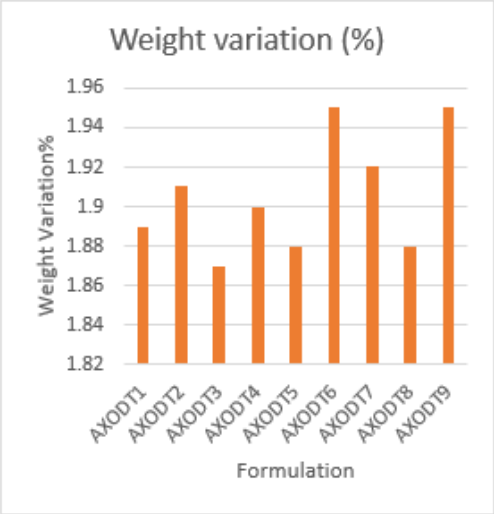


Figure no. 3(b) Weight Variation

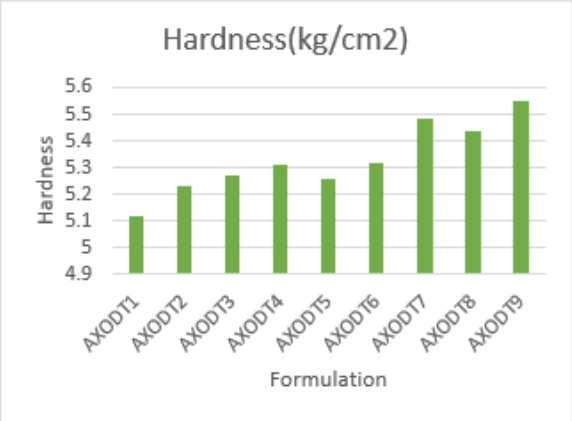


Figure no. 3(d) Friability

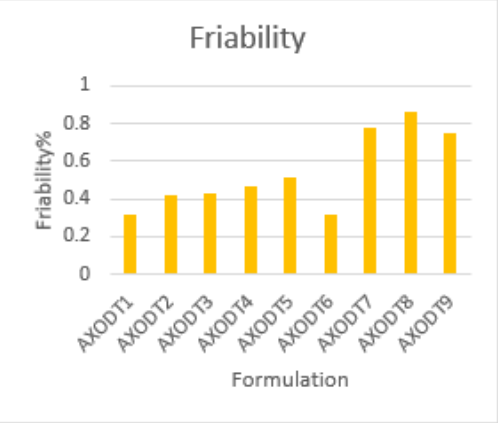


Figure no. 3(c) Hardness

The nine Atomoxetine fast dissolving tablet (AXODT1–AXODT9) formulations exhibit consistent physical attributes (**Table:2**) with notable differences in mechanical robustness. Thickness values(**Fig.3a**) are tightly clustered between 3.01–3.11 mm, indicating uniform die fill and compression across batches—suitable for scale-up and consistent mouthfeel. Weight variation(**Fig.3b**) remains controlled (1.87–1.95%), aligning with acceptable limits for uniform dosing in orodispersible formats. Mechanical strength shows a favourable profile: hardness ranges(**Fig.3c**) from 5.12–5.55 kg/cm², adequate to withstand handling while supporting rapid disintegration when paired with optimized excipient systems. However, friability(**Fig.3d**) reveals critical variability: while AXODT1 (0.321), AXODT2

(0.421), AXODT3 (0.432), AXODT4 (0.471), AXODT5 (0.512), and AXODT6 (0.312) fall within or near the typical acceptance threshold (≤0.5–1.0%), AXODT7 (0.782), AXODT8 (0.861), and AXODT9 (0.751) show elevated friability, suggesting insufficient binding or excessive porosity risking chipping and powdering during packaging and transport. Overall, AXODT6 presents the most balanced profile—consistent thickness (3.04 mm), controlled weight variation (1.95%), robust hardness (5.32 kg/cm²), and low friability (0.312)—making it the strongest candidate for fast-dissolving performance with acceptable mechanical integrity. Batches with higher friability (AXODT7–AXODT9) likely require binder optimization (e.g., microcrystalline cellulose or low-viscosity HPMC), modest compression force adjustment, and fine-tuning of superdisintegrant levels to maintain rapid disintegration without compromising tablet strength. Collectively, the dataset supports manufacturability, with targeted improvements enabling reliable, patient-friendly fast dissolving tablets.

Table no. 3 Characterization of Atomoxetine Fast dissolving tablets

Formulation	Wetting time(sec)	Dispersion Time(sec)	Disintegration Time(sec)	Drug Content (%)
AXODT1	220	182	200	92
AXODT2	110	98	110	91
AXODT3	100	84	121	94
AXODT4	112	80	114	93
AXODT5	**103**	**82**	**125**	**94**
AXODT6	81	52	100	99
AXODT7	99	74	132	94
AXODT8	103	78	123	92
AXODT9	105	62	118	91

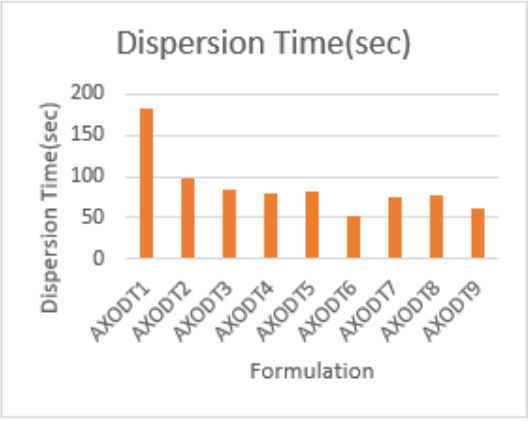


Figure no. 4(a) Dispersion Time(sec)

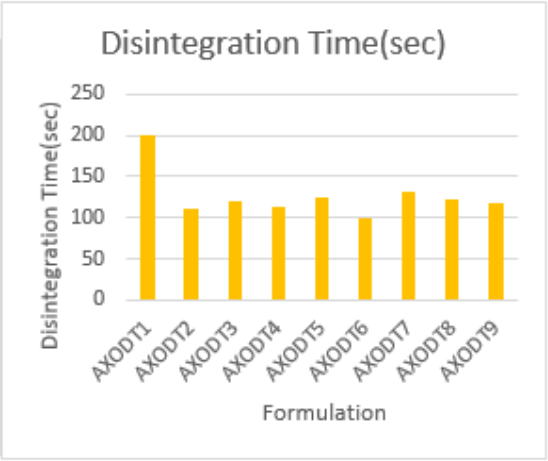


Figure no. 4(b) Disintegration Time

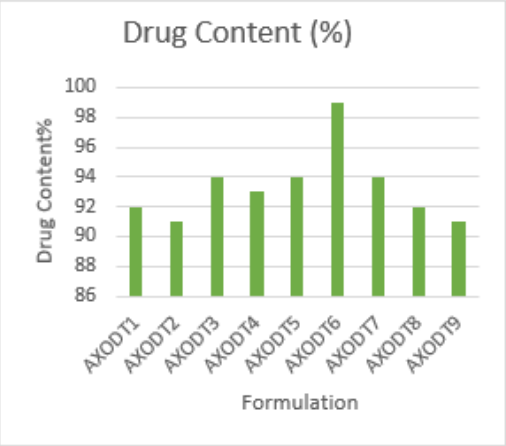


Figure no. 4(c) Drug Content (%)

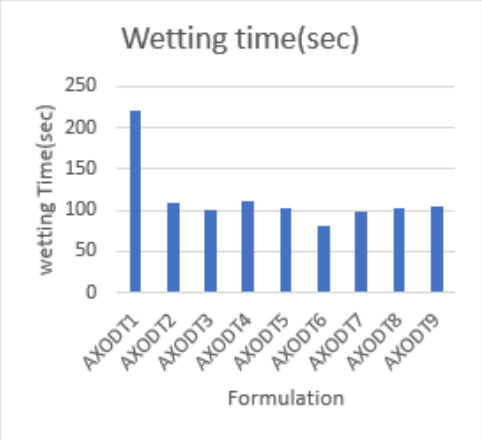
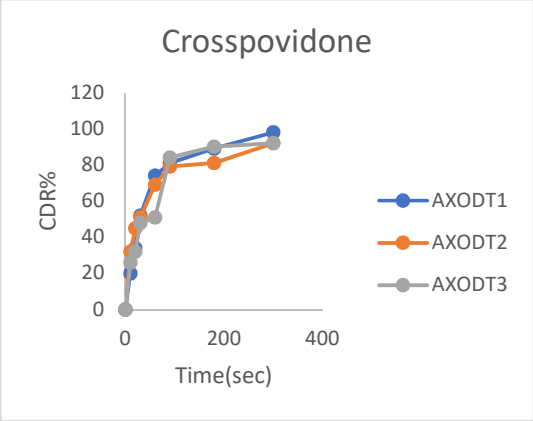


Figure no. 4(d) Wetting time(sec)

The evaluation of Atomoxetine fast dissolving tablets revealed notable differences in wetting time, dispersion time, disintegration time, and drug content across formulations AXODT1–AXODT9. (**Table:3**)Figure No: 4a, 4b, 4c Wetting time ranged widely from 81 sec (AXODT6) to 220 sec (AXODT1),(**Fig4d**) indicating that formulation variables strongly influenced hydration and onset of disintegration. AXODT6 demonstrated the shortest wetting time (81 sec), suggesting superior surface wettability and rapid initiation of tablet breakdown. Dispersion time values(**Fig4a**) followed a similar trend, with AXODT6 showing the fastest dispersion (52 sec) compared to AXODT1 (182 sec), confirming its optimized excipient balance for rapid particle disintegration. Disintegration times varied between 100–200 sec,(**Fig4b**) with AXODT6 again performing best (100 sec) and AXODT1 showing the longest (200 sec), highlighting AXODT6 as the most efficient formulation for fast oral delivery. Drug content across all formulations remained consistent(**Fig4c**) within acceptable limits (91–99%), ensuring dose uniformity. Notably, AXODT6 achieved the highest drug content (99%), reinforcing its suitability as the optimized batch. Overall, the data indicate that while all formulations met basic performance criteria, AXODT6 emerged as the most promising candidate, combining rapid wetting, fast dispersion, shortest disintegration time, and highest drug content. This formulation is therefore best suited for patient compliance and effective therapeutic delivery in fast dissolving tablet systems.

Table no. 4 In Vitro Drug Release Study

Time (sec)	CROSS POVIDONE	AXODT1	AXODT2	AXODT3	SSG	AXODT4	AXODT5	AXODT6	AcDiSOL	AXODT7	AXODT8	AXODT9
0		0	0	0		0	0	0		0	0	0
10		20	32	26		19	25	31		20	28	21
20		34	45	32		28	33	48		34	40	36
30		52	51	48		46	51	55		52	59	52
60		74	69	51		69	68	78		74	72	71
90		81	79	84		78	81	99.33		81	85	84
180		89	81	90		87	92	99.33		89	94	94
300		98	92	92		90.14	94	99.33		98	98	95



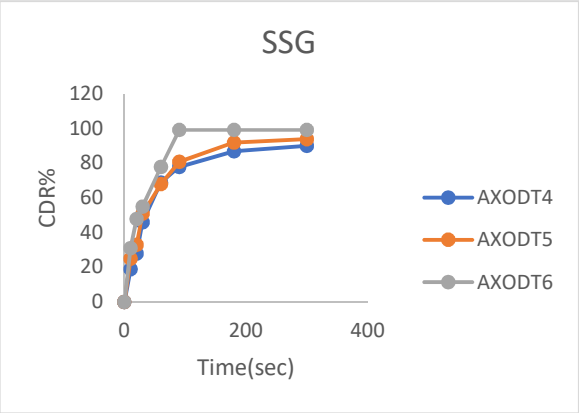


Figure no. 5(a) Crosspovidone **Figure no. 5(b) SSG**

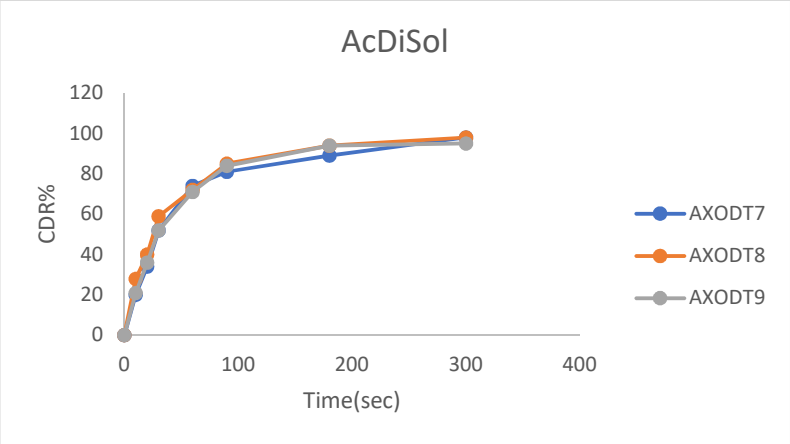


Figure no. 5(c) AcDiDSol

The in vitro release profiles of Atomoxetine fast dissolving tablets prepared (Fig:5a, 5b, 5c) with different superdisintegrants (Crospovidone, SSG, and AcDiSol) demonstrated rapid and efficient drug release within 300 seconds. Initial release at 10 seconds was modest (19–32%), reflecting the onset of disintegration and hydration. By 30 seconds, release values increased significantly (46–59%), confirming the role of superdisintegrants in accelerating tablet breakdown and drug diffusion. At 60–90 seconds, formulations showed marked differences: AXODT6 (SSG-based) achieved nearly complete release (99.33% at 90 seconds), while Crospovidone and AcDiSol batches exhibited moderate release (≈79–85%). By 180 seconds, most formulations exceeded 90% release, with AXODT6 maintaining complete release and AXODT5 (SSG-based) showing strong performance (92%). At 300 seconds, nearly all formulations reached >90% release, with AXODT6 consistently delivering 99.33% release, highlighting its superiority in ensuring rapid and complete drug availability. Crospovidone and AcDiSol formulations also demonstrated efficient release but with slightly lower values compared to SSG-based tablets. Overall, the study confirms that SSG, particularly in AXODT6, is the most effective superdisintegrant, producing the fastest and most complete drug release. This indicates that formulation optimization with SSG enhances the performance of Atomoxetine fast dissolving tablets, ensuring rapid onset of therapeutic action and improved patient compliance.

Table no. 5 Release Kinetic Data for Atomoxetine oral dissolving tablets

Formulation code	Zero order	First order	Higuchi	Peppas	Drug release mechanism
	R^2	R^2	R^2	N	
AXODT1	0.977	0.978	0.970	0.681	Non-fickian
AXODT2	0.948	0.992	0.974	0.681	Non-fickian
AXODT3	0.905	0.992	0.989	0.552	Non-fickian
AXODT4	0.966	0.985	0.984	0.653	Non-fickian
AXODT5	0.928	0.985	0.992	0.550	Non-fickian
AXODT6	0.999	0.994	0.992	0.485	Non-fickian
AXODT7	0.918	0.991	0.989	0.569	Non-fickian
AXODT8	0.912	0.986	0.987	0.521	Non-fickian
AXODT9	0.873	0.985	0.987	0.446	Fickian

The kinetic modeling of Atomoxetine fast dissolving tablets (Table No: 5) revealed that most formulations exhibited strong correlation with First-order (r^2 = 0.978–0.994) and Higuchi models (r^2 = 0.970–0.992), indicating that drug release was primarily governed by diffusion-controlled mechanisms with concentration dependence. The Korsmeyer–Peppas model (n values between 0.485–0.681) further confirmed that the majority of formulations followed a non-Fickian (anomalous) transport, where both diffusion and erosion contributed to drug release. Among all formulations, AXODT6 demonstrated the highest Zero-order fit (r^2 = 0.999), suggesting nearly constant release independent of concentration, which is highly desirable for maintaining predictable therapeutic levels. Other formulations such as AXODT3, AXODT5, and AXODT7 showed strong Higuchi correlations, reinforcing the role of diffusion through the matrix. Interestingly, AXODT9 exhibited a Fickian release mechanism (n = 0.446), indicating that drug release was predominantly controlled by simple diffusion rather than matrix relaxation. This distinguishes AXODT9 from the other batches, which showed non-Fickian behavior. Overall, the data confirm that Atomoxetine fast dissolving tablets predominantly follow non-Fickian release kinetics, with AXODT6 emerging as the most optimized formulation due to its near-perfect Zero-order release profile, ensuring sustained and reliable drug delivery.

Conclusion

The study successfully developed and evaluated Atomoxetine oral disintegrating tablets (ODTs) using direct compression with Crospovidone, Sodium Starch Glycolate (SSG), and Croscarmellose Sodium as superdisintegrants. Compatibility studies (DSC and FTIR) confirmed no drug–excipient interactions. All formulations showed acceptable physicochemical properties within pharmacopoeial limits. Among them, AXODT6 (containing optimized SSG) demonstrated the shortest wetting, dispersion, and disintegration times, along with nearly complete drug release (≈99.33% within 300 seconds). Release kinetics mainly followed First-order and Higuchi models, with non-Fickian transport, while AXODT6 showed an excellent Zero-order profile (R^2 = 0.999). Overall, AXODT6 was identified as the optimized formulation, offering rapid disintegration, efficient drug release, and improved potential for patient compliance in ADHD treatment.

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