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Formulation and evaluation of Apalutamide immediate release tablets

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Abstract

The study aimed to formulate and evaluate Apalutamide immediate release tablets using various polymers, including Ac-Di-Sol, Sodium Starch Glycolate, and Crospovidone, in different ratios to optimize the drug release profile. Several formulations were prepared, and their pre-compression and post-compression parameters, such as flow properties, hardness, friability, drug content, and dissolution, were thoroughly evaluated to ensure they met the required standards. Among the formulations, Formulation A3 demonstrated the most promising results, achieving a 99.01% drug release within 30 minutes, significantly outperforming other formulations in terms of dissolution rate. All pre- and post-compression parameters of Formulation A3 were found to be within acceptable limits. This formulation proved to be the most optimized in terms of release characteristics and overall quality, suggesting its potential for further development in the treatment of conditions requiring rapid drug onset.

Keywords: Apalutamide immediate release tablets, Ac-Di-Sol, Sodium Starch Glycolate, and Crospovidone

Introduction

Prostate cancer remains one of the leading causes of cancer-related morbidity and mortality among men worldwide ^[1]. The treatment approach largely depends on androgen receptor inhibition, which plays a critical role in disease progression. Apalutamide, a second-generation non-steroidal anti-androgen, has demonstrated superior efficacy in blocking androgen receptor signaling compared to earlier agents such as bicalutamide and enzalutamide ^[2]. However, its poor aqueous solubility and variable oral bioavailability pose significant formulation challenges, limiting its therapeutic efficiency ^[3].

Immediate release (IR) formulations are designed to achieve rapid disintegration and dissolution, ensuring quick onset of action and consistent plasma concentrations [4]. Developing an IR tablet of Apalutamide can enhance dissolution rate, improve absorption, and provide faster therapeutic response, which is crucial in advanced prostate cancer management [5]. Selecting suitable excipients such as superdisintegrants, solubilizers, and diluents plays a key role in optimizing drug release and bioavailability.

The present study aims to formulate and evaluate Apalutamide immediate release tablets using various superdisintegrants to achieve enhanced dissolution and uniform drug content. Pre- and post-compression parameters, *in-vitro* disintegration, and dissolution characteristics were systematically assessed. The optimized formulation is expected to provide improved drug release performance, ensuring better patient compliance and therapeutic outcomes.

Materials and Methods Drug Profile

Apalutamide, also known by its brand name *Erleada*, is a nonsteroidal antiandrogen belonging to the class of androgen receptor inhibitors, primarily indicated for the treatment of non-metastatic castration-resistant prostate cancer (nmCRPC) ^[1]. Chemically designated as *N-[3-(4-{[3-(trifluoromethyl)phenyl]thio}phenyl]phenyl]methanesulfonamide*, it possesses a molecular formula of C₂₁H₁₆F₃NO₂S and a molecular weight of 521.44 g/mol. Apalutamide appears as a white to off-white crystalline powder, slightly soluble in water but freely soluble in organic solvents such as ethanol and DMSO ^[2]. It exhibits a high lipophilicity

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(Log P \approx 5.6) and a melting point of approximately 173-175°C, indicating good stability under normal storage conditions, though it is light- and moisture-sensitive [3]. Pharmacokinetically, Apalutamide demonstrates around 85% oral bioavailability, with a half-life of 3-4 days and peak plasma concentration attained within 2-6 hours post administration [4]. It shows extensive distribution (Vd \approx 1000 L) and is highly protein bound (>99%), undergoing hepatic metabolism mainly via CYP3A4 to inactive metabolites, which are excreted predominantly through feces (80%) [5]. The drug acts by competitively inhibiting androgen receptor signaling, thereby suppressing prostate cancer cell proliferation [6]. Common adverse effects include fatigue, rash, and hypertension, whereas severe events like seizures and liver enzyme abnormalities are rare but clinically significant [7]. Commercially, Apalutamide is marketed as Erleada (60 mg tablets) by Janssen Pharmaceuticals.

Excipients Profile

The formulation of Apalutamide immediate-release tablets employed pharmaceutically acceptable excipients selected for their functionality, compatibility, and safety. Ac-Di-Sol (Croscarmellose Sodium) served as a superdisintegrant that enhances tablet disintegration through rapid wicking and swelling, ensuring prompt drug release. Sodium Starch Glycolate, another potent disintegrant, was incorporated to facilitate water uptake and tablet breakup without being affected by compression pressure or hydrophobic excipients. Crospovidone functioned as a crosslinked polymeric disintegrant and solubility enhancer, improving wetting and dissolution of the poorly soluble drug. Polyvinylpyrrolidone (PVP K-30) was employed as a binder and solubilizer, imparting mechanical strength and uniform drug dispersion in granules. Aspartame was used as a non-caloric sweetener to enhance palatability, while Magnesium Stearate acted as a lubricant, reducing friction during compression and ejection. Talc was incorporated as a glidant and antiadherent to improve powder flow and prevent sticking to punches and dies. Microcrystalline Cellulose (MCC) functioned as a diluent, binder, and disintegrant, contributing to tablet compressibility and uniformity. All excipients were pharmaceutically inert, compatible with Apalutamide, and complied with pharmacopeial standards. Their synergistic functionality ensured rapid disintegration, uniform content, and optimal mechanical properties essential for immediate-release formulation performance.

Methodology

a) Buffer Preparation

Preparation of 0.2 M Potassium Dihydrogen Orthophosphate Solution: Accurately weighed 27.218 g of monobasic potassium dihydrogen orthophosphate was dissolved in 1000 mL of distilled water with continuous stirring until a clear solution was obtained.

Preparation of 0.2 M Sodium Hydroxide Solution: Accurately weighed 8 g of sodium hydroxide pellets was dissolved in 1000 mL of distilled water and mixed thoroughly.

Preparation of pH 6.8 Phosphate Buffer: A volume of 250 mL of 0.2 M potassium dihydrogen orthophosphate and 112.5 mL of 0.2 M sodium hydroxide were transferred into a 1000 mL volumetric flask, and the volume was adjusted to the mark with distilled water. The prepared buffer was used

as the dissolution medium and analytical solvent throughout the study.

b) Preformulation Studies

Preformulation studies were carried out to evaluate the physicochemical and compatibility characteristics of Apalutamide. These studies help in identifying suitable excipients and optimizing formulation parameters to achieve desirable tablet properties.

c) Analytical Method Development for Apalutamide

Determination of Absorption Maxima (λ max): A UV spectrum of Apalutamide was recorded between 200-400 nm using pH 6.8 phosphate buffer as the solvent and blank. The absorption maximum was found at 270 nm, which was selected for all subsequent spectrophotometric evaluations. Preparation of Standard Calibration Curve in pH 6.8 Buffer: A stock solution of Apalutamide (1 mg/mL) was prepared by dissolving 100 mg of the drug in 100 mL of pH 6.8 phosphate buffer. From this, 1 mL was further diluted to 100 mL to obtain a 10 µg/mL solution. Aliquots of 0.2, 0.4, 0.6, 0.8, and 1.0 mL were transferred into 10 mL volumetric flasks and diluted to volume with pH 6.8 buffer to yield concentrations of 2, 4, 6, 8, and 10 µg/mL, respectively. The absorbance of each solution was measured at 270 nm to establish a calibration curve.

d) Formulation Development of Immediate Release Tablets

Apalutamide and other excipients were accurately weighed and sieved through a 40-mesh screen to obtain a uniform particle size. The ingredients were mixed thoroughly in a glass mortar for 15 minutes to ensure homogeneity. The blend was then lubricated with magnesium stearate and talc, followed by mixing for an additional 5 minutes. The resulting powder blend was compressed into tablets using a rotary tablet compression machine with a constant compression force.

e) Evaluation Parameters Pre-Compression Studies

- 1. Angle of Repose: The flow property of the powder blend was determined by the funnel method. The height (h) and radius (r) of the formed powder cone were measured, and the angle of repose (θ) was calculated using the formula: $\tan \theta = h/r$.
- **2. Bulk Density:** A pre-weighed 25 g powder sample was poured into a 100 mL graduated cylinder, and the unsettled volume (V_0) was recorded.
- **3. Tapped Density:** The same sample was subjected to mechanical tapping for 500-1250 taps using a tapped density tester until a constant volume (Vf) was obtained.
- **4.** Carr's Compressibility Index: Carr's Index = $((\rho t \rho b)/\rho t) \times 100$.
- 5. Hausner's Ratio: Hausner's Ratio = $\rho t/\rho b$.

Post-Compression Studies

- 1. Thickness: Tablet thickness was determined using a digital micrometer, and results were expressed as mean ± SD for ten tablets.
- **2. Weight Variation:** Twenty tablets were weighed individually, and the percentage deviation from the

mean was calculated. The formulation complied with pharmacopeial limits.

- **3. Friability:** Six tablets were placed in a Roche friabilator and rotated at 25 rpm for 4 minutes.
- **4. Assay:** Five tablets were powdered, and an accurately weighed quantity equivalent to one tablet was dissolved in pH 6.8 buffer, sonicated for 30 minutes, filtered, and analyzed at 270 nm using a UV spectrophotometer.
- **5. Disintegration Time:** Six tablets were tested using a USP disintegration apparatus in pH 6.8 buffer at 37 ± 0.5°C. The time required for complete disintegration was recorded.
- **6.** *In vitro* **Dissolution Study:** Dissolution testing was performed using USP Type II (paddle) apparatus at 50 rpm in 500 mL of pH 6.8 phosphate buffer maintained at 37 ± 0.5°C. Samples (5 mL) were withdrawn at 5, 10, 15, 20, 25, and 30 minutes, filtered, and analyzed spectrophotometrically at 270 nm. An equal volume of fresh medium was replaced each time.

f) Drug-Excipient Compatibility Studies

Drug-excipient compatibility was assessed by mixing Apalutamide with selected excipients in a 1:1 ratio and storing the mixtures in closed glass vials at ambient conditions. The samples were periodically examined for physical changes such as color, odor, and texture. Spectroscopic or thermal analyses were conducted to confirm compatibility

Results and Discussion

• Determination of λ_{max}

The prepared stock solution was scanned between 200-400 nm to determine the absorption maxima. It was found to be 270nm.

• Calibration curve of Apalutamide

The standard curve of Apalutamide was obtained, and a good correlation was obtained with an R^2 value of 0.999. The medium selected was pH 6.8 phosphate buffer.

Table 1: Standard graph values of Apalutamide at 270nm in pH 6.8 phosphate buffer

Concentration (µg/ml)	Absorbance
0	0
2	0.121
4	0.234
6	0.343
8	0.457
10	0.573

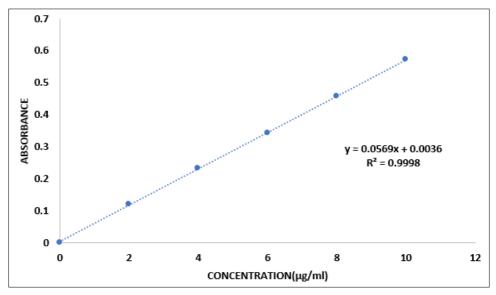


Fig 1: Standard curve of Apalutamide

Table 2: Formulation of Apalutamide Immediate Release Tablets

Ingredients (MG)	Formulations								
nigredients (MG)	A1	A2	A3	A4	A5	A6	A7	A8	A9
Apalutamide	60	60	60	60	60	60	60	60	60
Ac-Di-Sol	20	40	60	-	-	1	-	-	-
Sodium Starch Glycolate	-	-	-	20	40	60	-	-	-
Crospovidone	-	-	-	-	-	1	20	40	60
PVP K30	15	15	15	15	15	15	15	15	15
Aspartame	10	10	10	10	10	10	10	10	10
Mg stearate	10	10	10	10	10	10	10	10	10
Talc	8	8	8	8	8	8	8	8	8
MCC	127	107	87	127	107	87	127	107	87
Total weight	250	250	250	250	250	250	250	250	250

Evaluation: Characterization of precompression blend The precompression blend of Apalutamide showed an angle of repose below 29.9° and Carr's index under 27.75,

indicating good to fair flow and compressibility. Hausner's ratio was below 1.43 for all batches, confirming satisfactory flow properties.

Table 3: Physical properties of precompression blend

Formulation code	Angle of repose (Θ)	Bulk density (gm/cm ³)	Tapped density(gm/cm ³)	Carr's index (%)	Hausner's ratio
A1	24.514±0.336	0.5159 ± 0.0114	0.6772±0.0053	23.80±1.6335	1.3128±0.0284
A2	26.763±0.314	0.5104±0.0069	0.6152±0.0121	17.01±0.8365	1.2051±0.0122
A3	26.463±0.358	0.4923±0.0070	0.6052±0.0013	18.63±1.0889	1.2292±0.0165
A4	28.763±0.765	0.5039±0.0076	0.6380±0.0146	21.01±0.2798	1.2660±0.0045
A5	29.654±0.436	0.3852±0.0026	0.4991±0.0042	22.82±0.6827	1.2956±0.0114
A6	27.748±0.301	0.3661±0.0044	0.4805±0.0041	23.81±0.7456	1.3126±0.0128
A7	27.413±0.330	0.4355 ± 0.0025	0.5782±0.0032	24.67±0.7104	1.3277±0.0125
A8	30.631±0.213	0.3279±0.0008	0.4709±0.0048	20.80±0.6574	1.2628±0.0105
A9	30.763±0.324	0.3525±0.0019	0.4840±0.0043	27.16±1.0438	1.3731±0.0196

All the values represent n=3

Evaluation of tablets: Physical evaluation of Apalutamide Immediate release tablets: All tablet batches complied with weight variation limits, showing hardness of

246.66-253.39 kg/cm², friability <0.69 %, and thickness of 2.42-2.63 mm. Drug content ranged from 97.08-99.83 %, indicating uniformity and acceptable physical attributes.

Table 4: Evaluation of Apalutamide Immediate Release Tablets

Formulation code	Weight variation (mg)	Thickness (mm)	Hardness (Kg/cm²)	Friability (%)	Content uniformity (%)	In vitro Disintegration time (seconds)
A1	248.35	2.57	3.95	0.28	97.12	38
A2	249.12	2.48	3.92	0.39	98.36	45
A3	250.26	2.42	3.87	0.24	99.48	33
A4	251.77	2.63	4.12	0.42	98.61	42
A5	247.86	2.52	3.96	0.31	99.83	58
A6	249.41	2.49	4.01	0.37	98.73	37
A7	246.66	2.56	4.09	0.44	98.22	49
A8	253.39	2.61	3.89	0.51	97.08	51
A9	248.17	2.55	3.93	0.49	99.61	55

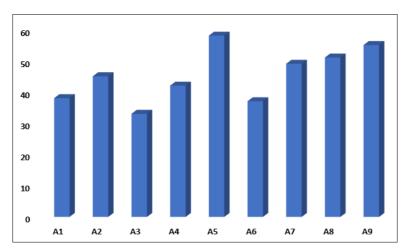


Fig 2: In vitro disintegration time graph

In vitro **Dissolution:** *In vitro* dissolution of Apalutamide tablets was performed using USP type II apparatus in 500 mL pH 6.8 phosphate buffer at 37 ± 0.5 °C and 50 rpm.

Samples were withdrawn up to 30 min and analyzed at 270 nm using a UV spectrophotometer.

Table 5: In vitro data for formulation A1 - A9

Time (Minutes)	In vitro drug release								
	A1	A2	A3	A4	A5	A6	A7	A8	A9
0	0	0	0	0	0	0	0	0	0
5	56.57	61.02	64.69	53.24	59.17	62.85	58.99	65.41	68.37
10	63.81	74.17	78.41	61.59	64.69	66.47	62.57	73.61	78.29
15	71.26	79.18	82.72	68.51	73.53	75.39	66.25	78.93	83.07
20	84.01	89.29	91.85	77.05	79.28	87.46	72.87	83.72	88.12
25	88.37	91.08	97.61	82.98	86.69	91.33	77.44	89.89	92.46
30	94.41	96.24	99.01	87.23	92.82	95.29	88.21	96.17	94.38

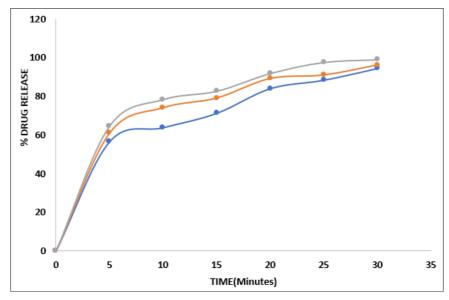


Fig 3: In vitro dissolution data for formulation A1-A3

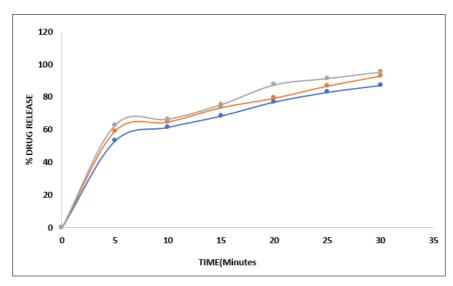


Fig 4: In vitro dissolution data for formulations A4 - A6

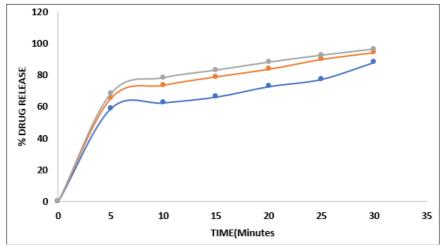


Fig 5: In vitro dissolution data for formulations A7-A9

The A3 formulation with $60\,\mathrm{mg}$ of Ac-Di-Sol showed the highest drug release (99.01%) at $30\,\mathrm{min}$, making it the optimized batch. Other formulations with Sodium Starch

Glycolate and Crospovidone showed slightly lower release, confirming A3 as the best-performing formulation.

Drug-Excipient compatibility studies by FTIR

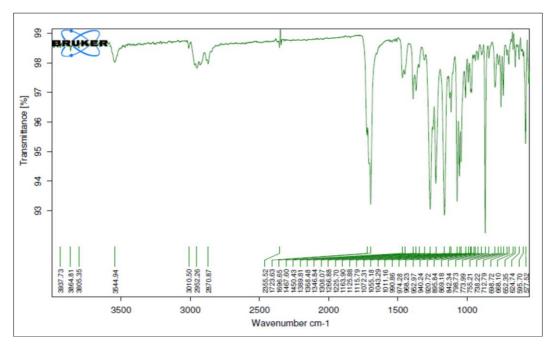


Fig 6: FTIR spectra of pure drug

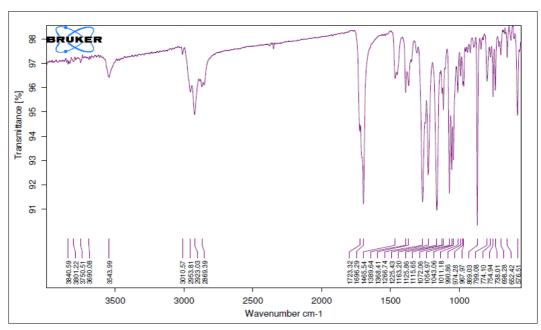


Fig 7: FTIR spectra of optimized formulation

Apalutamide, when mixed with different excipients, showed no color change after two months, indicating the absence of drug-excipient interactions.

Discussion: The study demonstrated that all precompression blends had good flow properties and the tablets met pharmacopeial standards for weight, hardness, friability, and drug content. Dissolution studies showed that formulation A3 with 60 mg Ac-Di-Sol exhibited the highest drug release (99.01% in 30 min), highlighting the efficiency of the selected superdisintegrant. Drug-excipient compatibility studies confirmed stability, indicating A3 as the optimized formulation for immediate release Apalutamide tablets.

Conclusion: In conclusion, Apalutamide immediate release tablets were successfully formulated using polymers like Ac-Di-Sol, Sodium Starch Glycolate, and Crospovidone in various ratios. Formulation A3 was identified as the optimized batch, showing 99.01% drug release within 30 minutes, demonstrating its superior dissolution profile and potential for enhanced therapeutic efficacy.

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