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Formulation and Evaluation of Immediate Release tablets of Bedaquiline

P. Samba Siva Rao[1*], Dr.G. Nagaraju[1], L. Sanjeev[2], MD. Sana[3], T. Shivani[4], V. Sahithya[5].

[1]Associated professor Dhanvanthari institute of pharmaceutical sciences,[1]Principal of Dhanvanthari institute of pharmaceutical sciences, Sujatha Nagar, Kothagudem.*

2,3,4,5. 4thYear 2 semester Pharmacy Students of Dhanvanthari institute of pharmaceutical sciences, Sujatha Nagar, Kothagudem, Telangana, India, 507120.

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ABSTRACT:
The development of immediate-release tablets of Bedaquiline aims to enhance its therapeuticefficacy in the treatment of multidrug-resistant tuberculosis (MDR-TB). This study focuses on theformulation and evaluation of immediate-release tablets using wet granulation technique. Variousexcipients were employed to achieve rapid disintegration and improved bioavailability. Pre-formulation studies were conducted to assess the physicochemical properties of Bedaquiline,including solubility, compatibility excipients, and flow properties. Tablets were formulated usinga combination of superdisintegrants like croscarmellose sodium and sodium starch glycolate to ensureimmediate drug release. The formulations were evaluated for key parameters, including weightuniformity, hardness, friability, disintegration time, and dissolution profile. The optimized formulationexhibited rapid disintegration within 30 seconds and demonstrated more than 85% drug release withinthe first 30 minutes, complying with the pharmacopeial standards. Stability studies conducted underaccelerated conditions indicated no significant changes in the physicochemical properties or drugrelease profile. The study concludes that immediate-release tablets of Bedaquiline can provide apromising approach to improve patient compliance and therapeutic outcomes in MDR-TB treatmentby ensuring rapid onset of action and optimal drug delivery

KEY WORDS: Multi drug resistant tuberculosis (MDR-TB), Fourier transform infra-redspectroscopy (FTIR), Mycobacterium tuberculosis.

I. INTRODUCTION:

Oral route is most popular for systemic effect due to its easy of ingestion, pain, avoidance,versatility and most importantly, patient compliance. Solid oral delivery systems (especially tablets) issystem of choice among all drug delivery system and they do not require special treatment and aretherefore, less expensive to manufacture, likewise immediate release tablets are more acceptableamong all the tablets. [1]

An ideal dosage regimen in the drug therapy of any disease or the goal of any drug delivery system is

the one, which immediately attains the desired therapeutic concentration of drug in plasma (or at thesite of action) and maintains it constant for the entire duration treatment. [2]

Immediate release drug delivery systems are designed to provide immediate drug levels in short periodof time. In recent decades, a variety of pharmaceutical research has been conducted to develop new dosage forms considering quality of life, most of these efforts have been focused on ease ofmedication. [3]

An immediate release dosage form allows a manufacturer to extend market exclusivity, while offeringpatients a convenient dosage form or dosage regimen. Recently immediate release tablets havestarted gaining popularity and acceptance as a drug delivery system, mainly because they are easy toadminister, has quick onset of action is economical and lead to better patient compliance. [4]

Bacteria:

Bacteria are ubiquitous, mostly free-living organisms often consisting of one biological cell.

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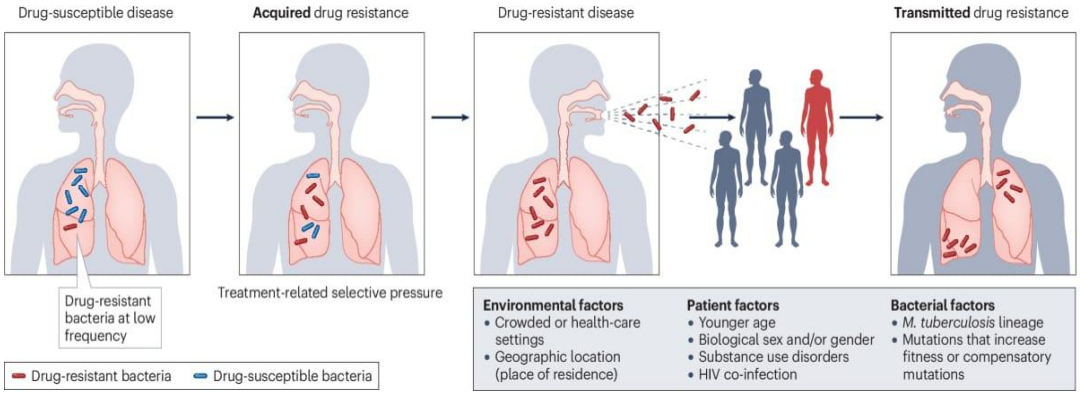
Theyconstitute a large domain of prokaryotic microorganisms.

Bacteria can have a variety of shapes, including spherical, rod-shape, spiral, and comma shape.However, several species of bacteria are pathogenic and cause infectious diseases, including cholera,syphilis, leprosy, tuberculosis and tetanus.[5]

Multi-Drug-Resistant Tuberculosis (MDR-TB)

Multidrug-resistant tuberculosis (MDR-TB) is a form of tuberculosis (TB) infection caused bybacteria that are resistant to treatment with at least two of the most powerful first-line anti-TBmedications (drugs): isoniazid and rifampicin Mycobacterium tuberculosis drug resistance typicallyarises through sequential mutations in the bacterial genome. In biological terms, the occurrenceof drug resistance is almost inevitable, and the development and spread of drug-resistant bacterialstrains are exacerbated by numerous logistical and social factors.3 This situation threatens theability to effectively treat individuals and the preservation of tuberculosis as a curable disease,particularly considering the paucity of new drugs.[6]

Bedaquiline has been a game changer. In 2012, it became the first new class of drugs fortuberculosis to be approved by the US Food and Drug Administration (FDA). This approval occurred inparallel with the development of other new drugs (pretomanid and delamanid) and the use of linezolidand clofazimine, which altered the tuberculosis-treatment landscape and resulted in the firstmultidrug combination that differed completely from the standard regimen and could override pre-existing resistance to first-line drugs. Programmatic and trial data prompted WHO to revise its guidancefor treating drug-resistant tuberculosis in 2022 to include bedaquiline-containing regimens.[7]



Multidrug-resistant-tuberculosis medications:

World Health Organization released a new treatment for multidrug-resistant/rifampicin-resistant tuberculosis (MDR/RR-TB) guideline. The main novelty of this update is two newrecommendations (i) a 6-month treatment regimen composed of bedaquiline, pteromalid, linezolid(600 mg), and moxifloxacin (BPaLM) is recommended in place of the 9-month or longer(18-month)regimens in MDR/RR-TB patients, now including extensive pulmonary TB andextrapulmonary TB(except TB involving central nervous system, miliary TB and osteoarticular TB); (ii) the use of the 9-month all-oral regimen rather than longer (18-months) regimen is suggested in patients with MDR/RR-TB. The new guidelines represent a milestone in MDR/RR-TB treatment landscape, setting the basisfor a shorter, all-oral, more acceptable, equitable, and patient-centered model for MDR/RR-TBmanagement. [8]

NEWER DRUGS:
Bedaquiline
Delamanid
Linezolid
Pteromalid

FLUOROQUINOLONES
Levofloxacin
Moxifloxacin

DRUG EXCIPIENT PROFILE
BEDAQUILINE:

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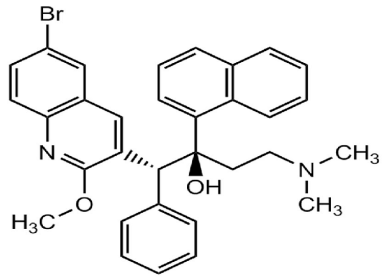

Chemical Formula: $C_{32}H_{31}BrN_2O_2$
Molecular Weight: 555.52

SUMMARY:
BEDAQUILINE is a diarylquinoline antimycobacterial used in combination with other antibacterials to treatpulmonary multi drug resistant tuberculosis

BRAND NAME: Sirturo
GENERIC NAME: BEDAQUILINE
DRUG BANK ACCESSION NUMBER: DB08903
HALF LIFE:164 days.

BACKGROUND:

Bedaquiline is a bactericidal antimycobacterial drug belonging to the class of diarylquinoline. The quinolinic central heterocyclic nucleus with alcohol and amine side chains is responsible for bedaquiline-mediated antimycobacterial activity. Bedaquiline to treat pulmonary MDR-TB, following favourable results in multiple pre-clinical and clinical studies. It is the first drug that was approved in the last 40 years by the FDA for TB unresponsive to current treatments on the market Currently, bedaquiline is the anti-TB drug and must only be used in an appropriate combination regimen. [9&10]

MECHANISM OF ACTION

Bedaquilinepossesses antimycobacterial activity that is both distinct and specific. It inhibits mycobacterialadenosine triphosphate (ATP) synthase's proton pump. Prokaryotic as well as eukaryotic cells require the productionof ATP for cell life. It is done with the help of ATP synthase. Bedaquiline inhibits the generation of ATP. It binds tomycobacterial ATP synthase at subunit c which is oligomeric and proteolipid. As a result, it causes bacterial death.

Bedaquiline binds to mycobacterial ATP synthase with more than 20,000 times more affinity than it binds to humanmitochondrial ATP synthase. It is the reason for specific action in mycobacterium only and minimum host cell damage[11,12,13].

Bedaquiline
↓
Binds to c subunit of ATP synthase (enzyme complex)
↓
Inhibits proton pump function of ATP synthase
↓
Disruption of ATP production
↓
Energy depletion in Mycobacterium tuberculosis
↓
Cell death

Antimicrobial spectrum

By blocking mycobacterial ATP synthase, bedaquiline kills dormant as well as actively reproducingmycobacteria. It inhibits drug-resistant mycobacterium along with drug-sensitive mycobacterium. Bedaquiline has a substantial inhibitory impact on a wide range of nontuberculous mycobacteria (NTM), including Mycobacterium avium, Mycobacterium ulcers, Mycobacterium abscesses, and Mycobacterium intracellular**.** Bedaquiline has a mild inhibitory effect on Gram-positive bacteria and Gram-negative bacteria[14].

IMMEDIATE RELEASE OF BEDAQUILINE

The multi-source product is a white to off -white, round uncoated tablet, they are biconvex (rounded on top and
bottom). The objective was to develop stable, robust, Immediate release dosage form. Wet granulation wasselected as method of product manufacture to achieve the desire powder flowability, powder containment, andsatisfactory product performance [15,16].

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Composition
Each immediate-release tablet typically contains Bedaquiline fumarate equivalent to 100 mg of bedaquiline [17].

Indication
Bedaquiline is indicated for the treatmentof:
Pulmonary multidrug-resistant tuberculosis (MDR-TB) as part of combination therapy with otherantitubercular agents.

Dosage and Administration
Adults and Adolescents (≥12 years and ≥30 kg)
First 2 weeks: 400 mg once daily.
Weeks 3 to 24: 200 mg three times per week (at least 48 hours between doses). Must be taken with food to enhance
absorption [18].

Common Side Effects
Nausea
Arthralgia
Headache
Increased liver enzymes
QT prolongation [19]

Contraindications
•Clinically significant ventricular arrhythmia.
•A QTcB interval of >500 Ms
•Severe liver disease.
•Use with other QT prolonging drugs
•A history of torsade de pointes
•A history of congenital long QT syndrome
•A history of hypothyroidism
•A history of uncompensated heart failure
•Serum calcium, magnesium or potassium levels below t [20,21].

Important Considerations:
ECG should be obtained before initiation of treatment, and at least two, 12 and 24 weeks after startingtreatment with bedaquiline. ECGs should be done at least monthly, The QT interval must always be corrected forheart rate [22].

Hepatic Effects:
Liver test abnormalities occur in 8% to 12% of patients treated with multiple drug regimens that includebedaquiline Elevations in liver enzymes have been observed. Regular monitoring of liver function tests is advised [23].

Drug Interactions:
Caution is advised when co-administering bedaquiline with other QT-prolonging drugs or strong CYP3A4 inhibitors/inducers [24].

II. MATERIALS AND METHODS:

Bedaquiline, sodium starch glycolate, crosspovidone, microcrystalline cellulose, Magnesium stearate.sodium was sieved through mesh 40 (#40). Bedaquiline was first mixed geometrically withmannitol and then with all other excipients manually in a polybag for 5 minutes.

Magnesium Stearate and Aerosol were sieved through mesh 60 (#60) and lubrication was done with the abovemixed powder manually in a polybag for 45 seconds. The moisture content of the lubricated powder was observedin Denever digital moisture analyzer at 105°C. The pre-compression parameters of the bulk lubricated powder wereperformed using Electrolab Tapped Density Tester USP.

The pre compression parameters revealed good flow property of powder for both 0.2 and 0.3 mg of Bedaquiline tablets.

FORMULATION OF IMMEDIATE RELEASE TABLET OF BEDAQUILINE

The formulation of bedaquiline tablets using the wet granulation process involves several key steps,including material selection, weighing and sifting, wetgranulation, granulation, drying, milling, blending,compression, and coating. Below is a general outline of the process:

Ingredients
Active Ingredient: Bedaquiline
Excipients:
Fillers (e.g., lactose, microcrystalline cellulose)
Binders (e.g., polyvinylpyrrolidone, starch paste)
Disintegrants (e.g., croscarmellose sodium, sodium starch glycolate)
Lubricants (e.g., magnesium stearate)
Glidants (e.g., colloidal silicon dioxide)
Optional coating materials (e.g., hydroxypropyl methylcellulose)

PROCEDURE
1. Weighing and Sifting
Weigh the required quantities of bedaquiline and excipients. Sift all ingredients through an appropriate sieve to ensure uniform particle size distribution.

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2. Wet Granulation

Mix the active ingredient (bedaquiline) with fillers and disintegrants in a blender or planetary mixer.

Prepare a binder solution using a binder (e.g., polyvinylpyrrolidone dissolved in water or hydroalcoholic solvent).

Gradually add the binder solution to the dry mix while stirring until a wet mass with sufficient cohesiveness isformed.

3. Granulation

Pass the wet mass through a granulator or sieve to form uniform granules.

4. Drying

Dry the wet granules in a fluid bed dryer or tray dryer at a controlled temperature (e.g., 40-60°C) to reduce the moisture content to an acceptable level.

5. Milling

Pass the dried granules through a mill to achieve uniform particle size if necessary.

6. Blending

Blend the dried granules with lubricants (e.g., magnesium stearate) and glidants (e.g., colloidal silicondioxide) in a blender to improve flow properties and prevent sticking during compression.

7. Compression

Compress the granules into tablets using a tablet compression machine. Adjust the compression force to achieve the desired hardness and friability.

SL NO	INGRIDENTS	F1	F2	F3	F4	F5	F6
01	BEDAQUILINE	250	250	250	250	250	250
02	FDLC	1	1	1	1	1	1
03	SODIUM STARCH GLYCOLATE	-	-	-	10	20	30
04	CROSS POVIONE.	10	20	20	-	-	-
05	POVIDONE K30	30	30	10	30	20	20
06	PURIFIED WATER	QS	QS	QS	QS	QS	QS

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07	MAGNESIUM STERATE	9	9	9	9	9	9
08	TOTAL	400	400	400	400	400	400

TABLE 1: FORMULATION OF IMMIDIATE REALESE BEDAQUILINE TABLET

EVALUATION OF IMMEDIATE RELEASE OF BEDAQUILINE TABLETS:

1. **Uniformity of weight:**

Twenty tablets were selected at random from the lot, weighed individually and the average weight was determined. The percent deviation of each tablets weight against the average weight was calculated.

Hardness test:

The prepared tablets were subjected to hardness test28,38. It was carried out by using hardness tester
and expressed in kg/cm2.

Friability test:

400 The friability was determined using friabilator and expressed in percentage (%). 20 tablets from each batch were weighed separately (Winitial) and placed in the friabilator, whichwas then operated for 100revolutions at 25 rpm. The tablets were reweighed (Wfinal) and the percentage friability (F) was calculated.

In-vitro disintegration test:

6 tablets each formulation was employed for the test in distilled water at 370c using tablet disintegrating tablet tester. The time required for disintegrating to tablet and to broke down from large particles to small particleswere recorded.
The release rate of bedaquiline immediate release tablet was determined using united state pharmacopeia (USP) XXIV dissolution test apparatus II (PADLE METHOD).

SNO	BAT CHC ODE	WEIGHT VARIATION TEST	HARDNESS	THICKNESS	FRIABILITY	DISINTEGR ATION	ASSAY
1	F1	400.2+0.1	4.33+-0.64	4.16+-0.12	0.43+-0.64	0.45+-0.32	98.01+-0.32
2	F2	400.6+0.2	4.36+-0.67	4.10+-0.24	0.56+-0.31	0.56+-0.32	96.54+-0.52
3	F3	400.7+0.3	4.55+-0.75	4.09+-0.32	4.08+-0.13	0.55+-0.82	97.02+-0.64
4	F4	400.3+0.8	4.86+-0.89	4.05+-0.12	4.07+-0.08	0.52+-0.32	95.09+-0.76

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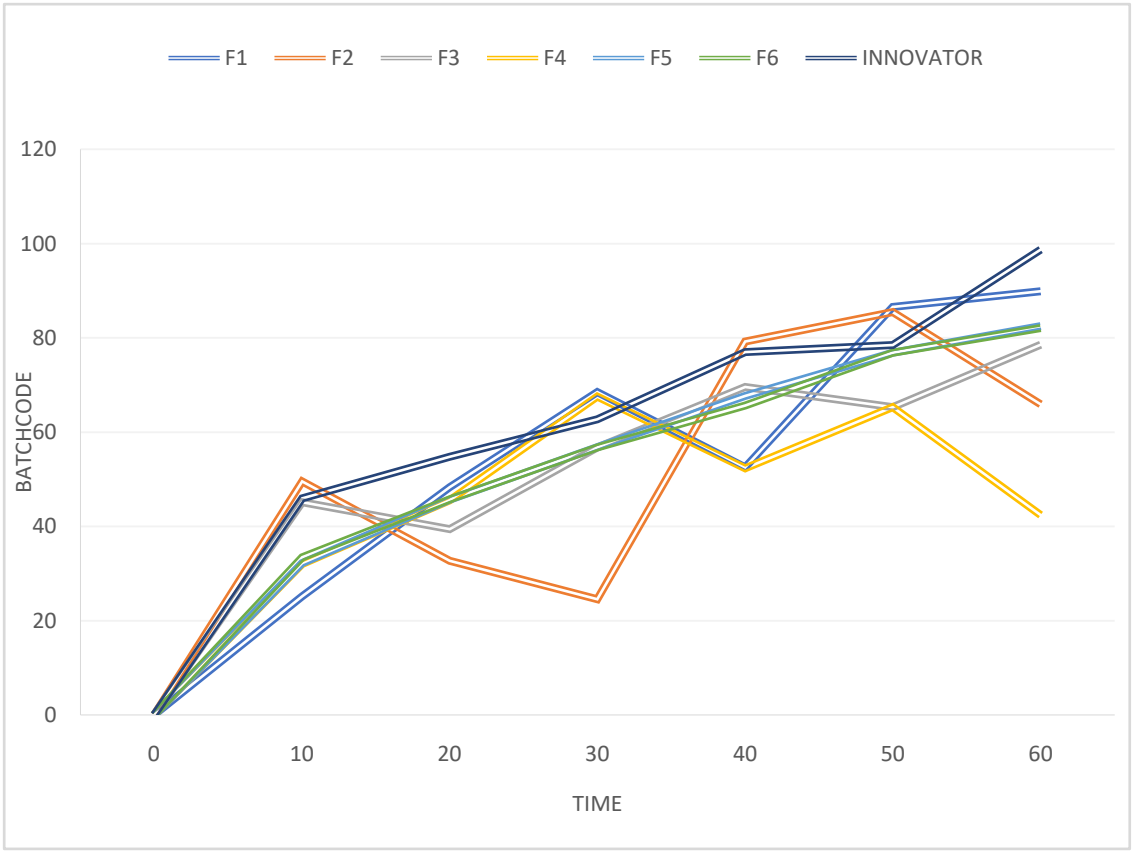
5	F5	400.4+0.6	4.72+-0.45	4.07+-0.08	4.07+-0.01	0.56+-0.32	98.97+-0.78
6	F6	400.8+0.56	4.22+-0.54	4.19+-0.34	4.18+-0.32	0.68+-0.32	98.49+-0.85

TABLE 2: EVALUATION OF POST COMPRESSION PARAMETERS

TABLE 3: DISSOLUTION PROFILE OF FORMULATION COMPARED WITH INNOVATOR

SNO	TIME	F1	F2	F3	F4	F5	F6	INNOVATOR
1	0	0	0	0	0	0	0	0
2	10	25.14	49.51	45.51	32.02	33.22	33.46	45.96
3	20	48.34	32.67	39.44	45.56	45.65	45.76	54.77
4	30	68.53	24.51	56.77	67.55	56.78	56.75	66.72
5	40	52.54	79.23	69.56	52.31	67.65	65.66	76.98
6	50	86.62	85.47	65.31	65.31	76.84	76.86	75.52
7	60	89.97	65.91	78.55	42.41	82.48	88.11	98.76



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III. RESULT AND DISCUSSION:

Present study was done on immediate release tablets of bedaquiline with different formulations F1 F6. Bedaquilinewas prepared by wet granulation method using different concentration of microcrystalline cellulose, mannitol, croscarmellose sodium, magnesium sterate.

FTIR spectral study FT-IR spectroscopy study was carried out separately to find out the compatibility between the drug bedaquiline and microcrystalline cellulose, mannitol, croscarmellose sodium. The FT-IR was performed for the drug, the physical mixture of drug polymer. The spectra obtained from FT-IR spectroscopy study shows in and the peaks obtained in the spectra of drug mixtures. This indicates that the drug was compatible with the formulation components IR studies indicated no interaction between drug and polymers.

The formulation and evaluation of immediate-release tablets of bedaquiline yielded promising results. The developed tablets exhibited desirable physical characteristics, including acceptable hardness (5.2 ± 0.3 kg) within the target range of 4.72–0.3 kg, low friability (0.5 ± 0.1%) indicating good resistance to breakage, and a disintegration time Dissolution profile of the batches f5 and f6passed the disintegration test. These findings suggest that the tablets possess good mechanical strength and readily disintegrate in the gastrointestinal tract, facilitating rapid drug release.

The drug content analysis revealed an average drug content of falling within the acceptable range. indicating accurate drug loading and consistent tablet formulation. Stability studies conducted and demonstrated the stability of the developed tablets. No significant changes were observed in key parameters like drug content, dissolution rate, and appearance, confirming the robustness of the formulation. The successful development of immediate-release bedaquiline tablets with desirable physical properties, rapid dissolution, and good stability represents a significant step towards improving the therapeutic efficacy of this important drug. The rapid release profile of the developed tablets is expected to enhance patient compliance and potentially improve clinical outcomes. Theresults of this study suggest that the developed formulation of immediate-release bedaquiline tabletshold great promise for effective treatment of drug-resistant tuberculosis. The formulation offers several advantages, including rapid drug release, accurate drug loading, and good stability, which are essential for achieving optimal therapeutic outcomes.

IV. CONCLUSION:

The formulation and evaluation of immediate-release tablets of bedaquiline represent a significant advancement in the treatment of multidrug-resistant tuberculosis (MDR-TB), aiming to improve therapeutic efficacy, patient compliance, and drug bioavailability. Immediate-release formulations are designed to release the active pharmaceutical ingredient promptly after administration, ensuring rapid onset of action, which is particularly crucial for treating life-threatening infections such as MDR-TB. The development process involves a meticulous selection of excipients, optimization of tablet composition, and manufacturing techniques to achieve the desired pharmacokinetic profile. Critical parameters such as drug solubility, stability, compressibility, and dissolution rate is carefully evaluated to ensure the formulation meets regulatory and clinical standards. The evaluation process typically includes pre-formulation studies, in-vitro dissolution testing, and stability studies to ensure the tablets provide consistent and reliable drug release.

Moreover, pharmacodynamic and pharmacokinetic assessments are performed to confirm the formulation's therapeutic efficiency. The use of advanced technique such as wet granulation incorporation of disintegrants like croscarmellose sodium or sodium starch glycolate can enhance the tablet's disintegration and drug release profile. This formulation approach not only ensures optimal bioavailability but also reduces the dosing frequency, thereby enhancing patient adherence to treatment regimens. The evaluation data demonstrate that immediate-release tablets of bedaquiline exhibit favourable dissolution profiles, consistent drug content, and adequate mechanical strength, meeting the requirements for effective clinical application. Overall, the successful development of immediate-release tablets of bedaquiline underscores its potential to play a pivotal role in improving treatment outcomes for patients with MDR-TB, addressing a critical public health challenge globally.

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CONFLICT OF INTREST:
The author declares no conflict of interest.

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