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Research Article

FORMULATION AND EVALUATION OF LEVOFLOXACIN HEMIHYDRATE IMMEDIATE RELEASE TABLETS BY WET GRANULATION TECHNIQUE

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ABSTRACT

The present study was undertaken to formulate and evaluate immediate release tablets of Levofloxacin hemihydrate using the wet granulation method. The objective was to develop a formulation comparable to the innovator product (Levaquin®) with improved disintegration and dissolution characteristics. Pre-formulation studies including description, solubility, loss on drying, melting point, flow properties, sieve analysis, and compatibility studies were performed. Levofloxacin hemihydrate exhibited good physicochemical properties suitable for formulation development. Tablets were prepared using microcrystalline cellulose as diluent, croscarmellose sodium as superdisintegrant, crospovidone as binder, and magnesium stearate as lubricant. The prepared tablets were evaluated for hardness, thickness, friability, weight variation, disintegration time, and in vitro dissolution. Among eight formulations (F1–F8), formulation F8 showed optimized performance with acceptable mechanical strength, rapid disintegration, and dissolution profile comparable to the innovator product (f2 similarity factor ≈ 66.64). Stability and processing feasibility confirmed its suitability for large-s cale production. The study concludes that wet granulation is an effective and reproducible method for developing Levofloxacin immediate release tablets with equivalent performance to marketed products.

Keywords: Levofloxacin hemihydrate, Immediate release tablets, Wet granulation, Superdisintegrant.

INTRODUCTION

A drug delivery system (DDS) is designed to deliver therapeutic agents at the desired rate, time, and site to achieve optimal therapeutic response. Among all routes of administration, the oral route remains the most preferred due to convenience, patient compliance, stability, and cost-effectiveness. Tablets are solid unit dosage forms prepared by compression or molding methods. They offer advantages such as dose precision, stability, ease of packaging, and large-scale manufacturability. Immediate release tablets are designed to disintegrate rapidly after administration, allowing quick drug release and absorption. Superdisintegrants such as croscarmellose sodium and crospovidone facilitate rapid tablet breakup through swelling and wicking mechanisms.

Levofloxacin hemihydrate is a third-generation fluoroquinolone antibacterial agent that acts by inhibiting bacterial DNA gyrase. It is widely used in the treatment of respiratory tract infections, urinary tract infections, and skin infections. Although highly bioavailable, formulation optimization is essential to achieve rapid disintegration and dissolution comparable to innovator products. Hence, the present work ai med to design and evaluate Levofloxacin hemihydrate immediate release tablets using wet granulation technique.

MATERIALS AND METHODS

Materials

Levofloxacin hemihydrate was obtained as a gift sample from a reputed pharmaceutical manufacturer as described in the study. Microcrystalline cellulose (Avicel PH 101 and PH 102) was procured from approved pharmaceutical excipient suppliers. Croscarmellose sodium and crospovidone were obtained from certified commercial sources. Magnesium stearate was purchased from a pharmaceutical-grade chemical supplier. Opadry white used for film coating was obtained from a recognized

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coating material manufacturer. All chemicals and reagents used in the study were of analytical grade and used without further purification.

Preformulation Studies

Preformulation studies were conducted to determine the physicochemical characteristics of Levofloxacin hemihydrate prior to formulation development. The drug was evaluated for physical appearance, solubility in various media, melting point, loss on drying, and moisture content. Flow properties of the drug and powder blends were assessed by determining angle of repose, bulk density, tapped density, Carr's compressibility index, Hausner's ratio, and sieve analysis. Drug–excipient compatibility studies were performed under specified storage conditions to evaluate any potential interaction between Levofloxacin and selected excipients.

Preparation of Immediate Release Tablets

Immediate release tablets were prepared by the wet granulation technique. Accurately weighed quantities of Levofloxacin hemihydrate and excipients were passed through a suitable sieve and blended uniformly. A binder solution containing crospovidone was prepared and gradually added to the powder mixture to form a cohesive wet mass. The wet mass was passed through a sieve to obtain granules, which were dried in a hot air oven at controlled temperature until the desired moisture level was achieved. The dried granules were resized and lubricated with magnesium stearate. The lubricated blend was compressed into tablets using appropriate punches on a tablet compression machine. The compressed tablets were subsequently film-coated with Opadry white using a conventional coating process.

Evaluation of Tablets

The prepared tablets were evaluated for physical appearance, weight variation, hardness, thickness, friability, disintegration time, moisture content, and drug content uniformity. Hardness was measured using a hardness tester, and friability was determined using a Roche friabilator. Disintegration testing was carried out using a USP disintegration apparatus. In vitro dissolution studies were performed using USP type II (paddle) apparatus in the specified dissolution medium maintained at 37 ± 0.5°C. Samples were withdrawn at predetermined intervals and analyzed using UV spectrophotometry to determine cumulative percentage drug release.

Stability Studies

The optimized formulation was subjected to stability studies under accelerated and long-term storage conditions as per standard guidelines. Tablets were periodically evaluated for physical appearance, hardness, drug content, and dissolution profile to ensure stability and reproducibility of the formulation.

RESULTS AND DISCUSSION

Pre-formulation studies

Table 1. Table showing the description of Levofloxacin hemihydrates.

Test	Description
Color	A pale yellow to yellow colored powder
Odor	Odorless
Morphology	Crystalline

Table 2. Drug-excipient compatibility studies.

SNO	Composition details	Ratio	Observations		
			Storage conditions		
			Initial	40°C/ 75% RH	60o C
1.	Levofloxacin emihydrate + Microcrystalline cellulose (Avicel pH 101)	1:1	Pale yellow Powder	Complies	Complies
2.	Levofloxacin hemihydrate + Croscaramellose Sodium	1:0.25	Pale yellow Powder	Complies	Complies
3.	Levofloxacin hemihydrate + Microcrystalline cellulose (Avicel pH 102)	1:1	Pale yellow Powder	Complies	Complies
4.	Levofloxacin hemihydtate + Povidone (kollidon-30)	1:0.1	Pale yellow Powder	Complies	Complies

5.	Levofloxacin hemihydrate + Magnesium Stearate	1:0.5	Pale yellow Powder	Complies	Complies
6.	Levofloxacin hemihydrate + Opadry white	1:0.1	White powder	Complies	Complies
7.	Levofloxacin hemihydrate	_	Pale yellow to yellow Powder	Complies	Complies

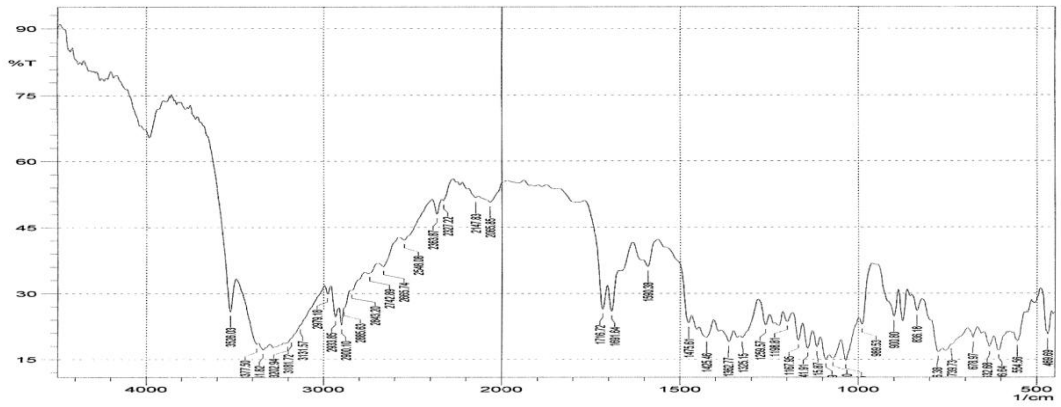

Figure. FTIR Spectrum of Levofloxacin hemihydrate.

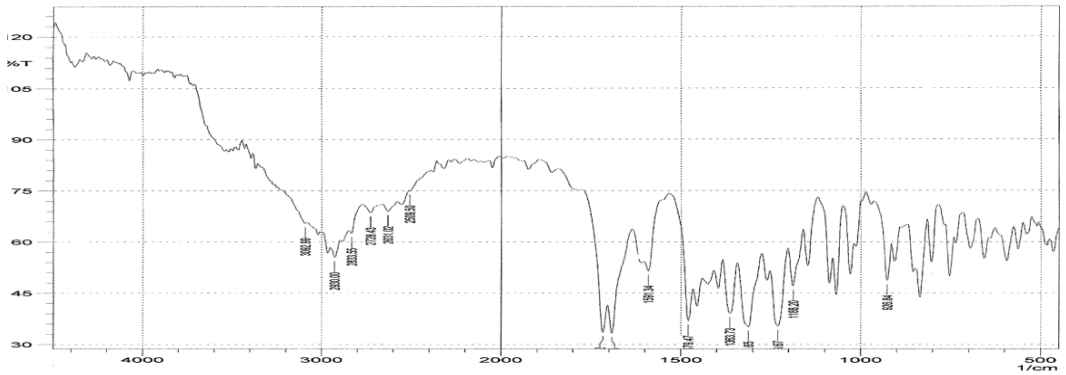

Figure 2. FTIR Spectrum of Levofloxacin hemihydrate + Microcrystalline Cellulose.

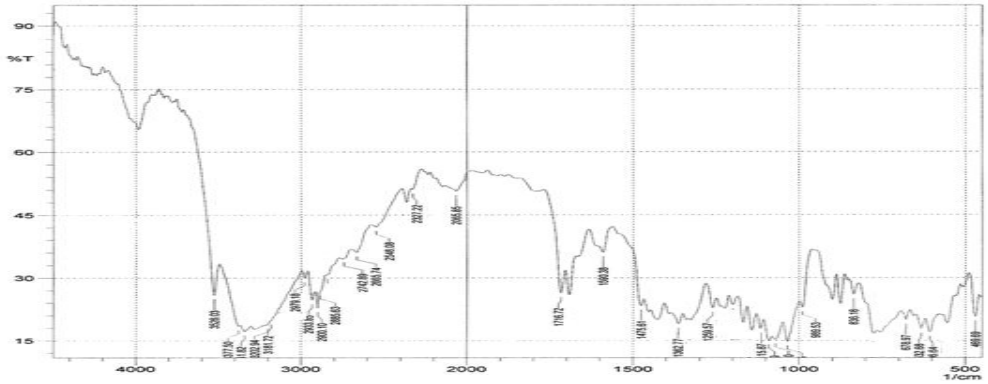

Figure 3. FTIR Spectrum of Levofloxacin hemihydrate + Crosscarmellose Sodium.

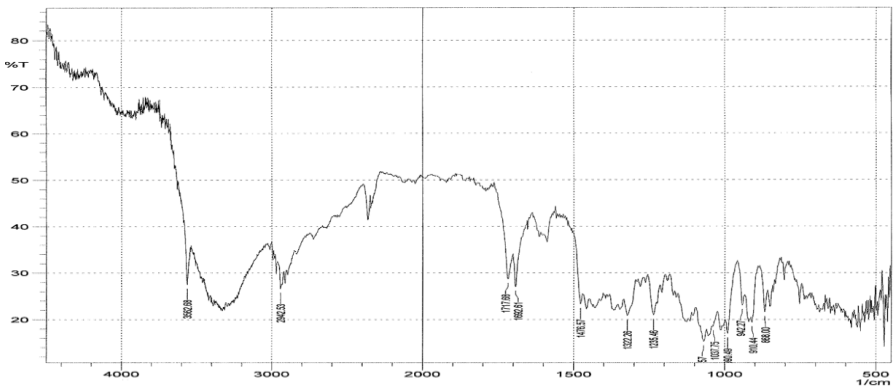

Figure 4. FTIR Spectrum of Levofloxacin hemihydrate +Povidone.

Table 2 . Data showing the result of blend uniformity during dry mixing.

S.No	Trials	Assay%.(w/w) of Levofloxacin
Time (min)		Dry mixing time 15Min
1	F1	102.3
2	F2	105.4
3	F3	104.6
4	F4	105.2
5	F5	106.8
6	F6	103.4
7	F7	109.6
8	F8	110.0

Minimum: 102.3% w/w: Maximum: 110.0% w/w

Table 3. Data showing the result of blend uniformity during Pre-lubrication.

S.No	Trials	Assay%(w/w) of Levofloxacin
Time (min)		Prelubrication time' 10Min
1	F1	96.5
2	F2	98.5
3	F3	98.4
4	F4	100.1
5	F5	97.0
6	F6	95.4
7	F7	98.4
8	F8	97.0

Minimum: 95.4% w/w: Maximum: 100.1 % w/w

Table 4. Data showing the result of blend uniformity during lubrication.

S.No	Trials	Assay%. (w/w) of Levofloxacin
Time (min)		Lubrication time 5Min
1	F3	95.3
2	F4	97.8

3	F5	96.2
4	F6	95.2
5	F7	97.8
6	F8	100.1

Minimum: 95.1 % w/w: Maximum: 100.9% w/w

Table 5. Compression parameters of Levofloxacin750mg.

S.No	Parameters	Results
1.	Tooling	21.6x6.8 mm capsule shaped punches embossed 18 on upper punch and 1 on lower punch.
2.	Average weight	1.049 - 1.058 g
3.	Thickness (mm)	6-7mm
4.	Hardness (kp)	12-14kp
5.	Disintegration time (min)	NMT 15min

Table 6. Data of average Hardness for all the formulations of Levofloxacin hemihydrate (n=5).

Formulation	Average Hardness (Kp)
F1	14±0.09
F2	7 ± 0.05
F3	13 ± 0.32
F4	14 ± 0.12
F5	14 ± 0.08
F6	13 ± 0.33
F7	14 ± 0.25
F8	12 ± 0.12

Table 7. Data showing the thickness for all formulations of Levofloxacin hemihydrate (n=5).

Formulation	Thickness (mm)
F1	6.3-6.4
F2	6.3-6.4
F3	6.4-6.5
F4	6.4-6.5
F5	6.38-6.49
F6	6.43-6.53
F7	6.48-6.65
F8	6.35-6.67

Table 8. Data showing the results of Friability for all the formulations of Levofloxacin hemihydrate (n=10).

Formulation	Percentage of weight loss (%)
F1	0.04-0.042
F2	0.04-0.042
F3	0.042-0.044
F4	0.042-0.044
F5	0.044-0.046
F6	0.044-0.046

F7	0.046-0.048
F8	0.048-0.05

Table 9. Data of average weight of tablets for all the formulation of Levofloxacin hemihydrate (n=30).

Formulation	Average weight (gms)
F1	1.050-1.056
F2	1.048-1.052
F3	1.049-1.052
F4	1.049-1.0552
F5	1.049-1.051
F6	1.049-1.050
F7	1.049-1.051
F8	1.049-1.052

Table 10. Data of time for disintegration for all formulations of Levofloxacin hemihydrate (n=6).

Formulation	Disintegration time(minutes)
F1	43-45
F2	4-5
F3	11-12
F4	10-11
F5	10min 55sec
F6	9min 53 sec
F7	9min 50 sec
F8	8min 58sec

Table 11. Data for standard curve of Levofloxacin in pH 1.2 acidic buffer at t_{max} 249 nm.

Concentration (µg/ml)	Absorbance
0	0
1.0	0.102
2.0	0.167
3.0	0.250
4.0	0.348
5.0	0.433
6.0	0.544

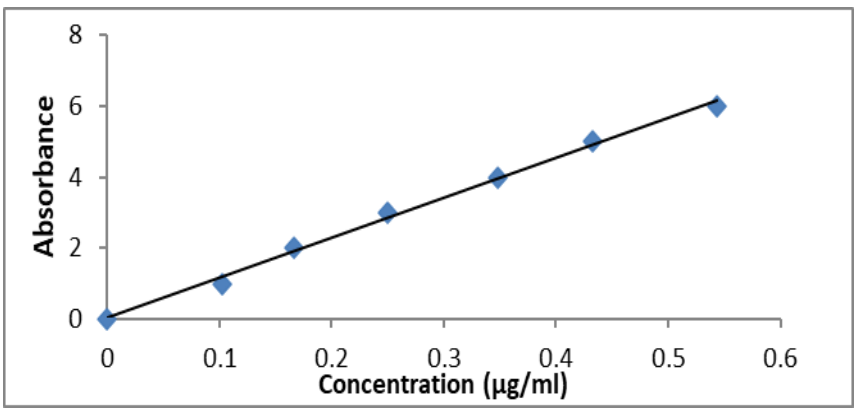

Figure 5. Standard Curve of Levofloxacin hemihydrte in pH 1.2acidic buffer.

Table 12. *In vitro* dissolution profile of the innovator (levaquin 750mg) in various medium.

S.No	Medium	% drug release			
		10 min	20 min	30 min	45 min
1.	0.1 N HCI	46±0.56	98±0.78	99±0.45	101±0.87
2.	pH 4.5 Acetate buffer	48±0.63	91±0.12	93±0.89	94±0.12
3.	Purified water	53±1.25	85±0.24	92±0.12	97±0.78
4.	pH 6.8 phosphate buffer	55±1.65	89±0.98	94±0.45	96±0.45

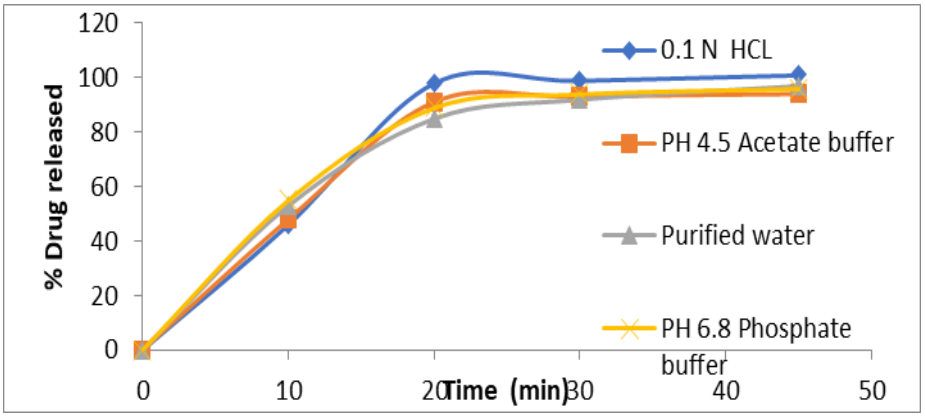

Figure 6. *In vitro* dissolution profile of the innovator (levaquin 750mg) in various medium.

Table 13. *In vitro* dissolution studies of the formulations in 0.1 N HCl.

S.No	Time (min)	% Drug release					
		F3	F4	F5	F6	F7	F8
1	**10**	18±0.0I2	101±0.0I6	89±0.068	78±0.59	52±0.712	55±0.568
2	**20**	39±0.026	101±0.056	96±0.018	87±0.456	95±0.568	99±0.869
3	**30**	56±0.456	101±0.123	100±0.564	88±0.246	97±0.689	100±0.564
4	**45**	78±0.589	101±0.231	102±0.564	89±0.231	97±0.123	100±0.231

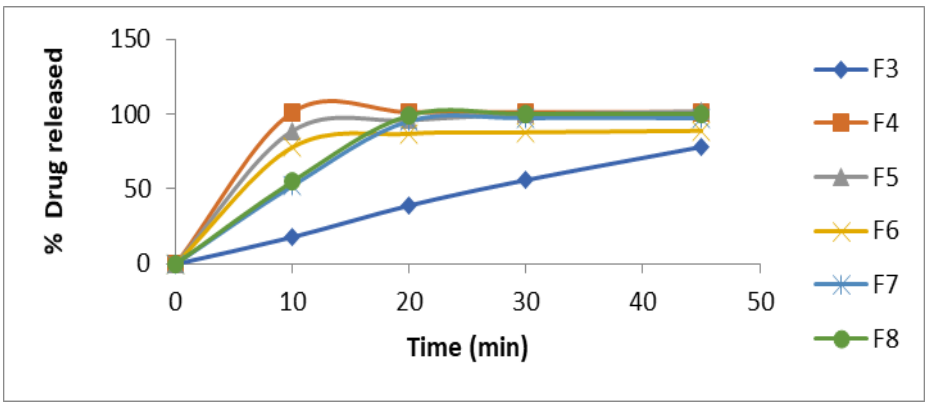

Figure 7. *In vitro* dissolution studies of the formulation F3 - F8 in 0.1 N HCI.

Table 14. Values of f1 and f2.

Formulations			
Factors			
Similar **(f2)**	Disimilar **(f1)**	**F7**	**F8**
5.98	3.64	62.72	**66.44**

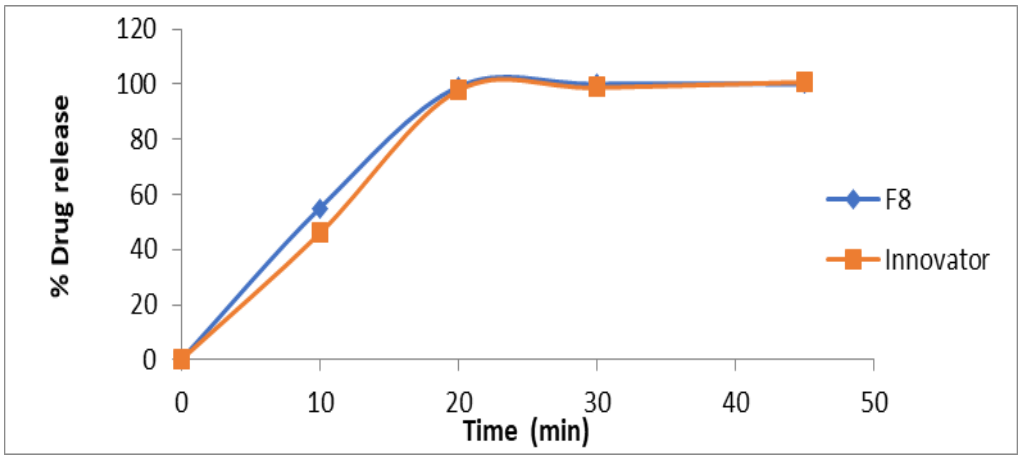

Figure 8. Comparison of in-vitro dissolution profile of formulation (F8) and innovator in 0.01 N Hydrochloric acid medium.

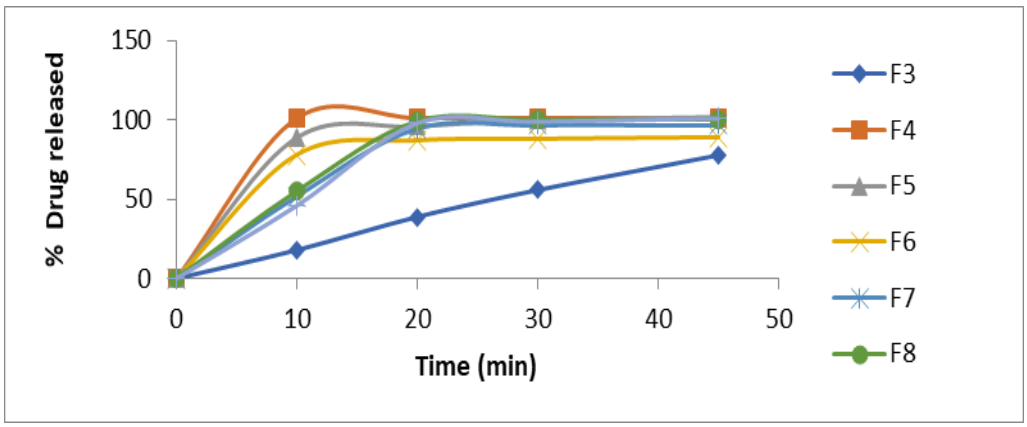

Figure 9. Comparison of *in-vitro* dissolution profiles of all formulations (F3 to F8) to the innovator in 0.0l N hydrochloric acid medium.

Table 15. Data showing various physico-chemical parameters after stability study.

Conditions	Parameter	Initial data	Data after one month
Room temperature	Hardness (kp)	12	12
Room temperature	Friability (%)	0.04	0.05
Room temperature	Assay (%)	101.2	99.82
Intermediate	Hardness (kp)	12	12

Intermediate	Friability (%)	0.04	0.052
Intermediate	Assay (%)	101.2	99.37
Accelerated	Hardness (kp)	12	11.8
Accelerated	Friability (%)	0.04	0.054
Accelerated	Assay (%)	101.2	99.16

Preformulation studies confirmed acceptable physicochemical properties. Loss on drying (2.57%), melting point (226°C), and moisture content (2.8%) were within limits. Flow properties showed good angle of repose (22°), but high compressibility index (42%) indicated need for granulation. Drug-excipient compatibility studies showed no interaction under accelerated conditions. Among eight formulations, F7 and F8 exhibited improved disintegration time and dissolution profile. Mechanical evaluation showed: Hardness: 12–14 kp, Friability: <0.05%, Thickness: 6–7 mm, Weight variation: Within IP limits, Formulation F8 demonstrated dissolution profile equivalent to innovator product (f2 = 66.64), indicating similarity.

CONCLUSION

Levofloxacin hemihydrate immediate release tablets were successfully formulated using wet granulation technique. All formulations met pharmacopeial specifications. Among them, F8 was identified as the optimized formulation due to: Rapid disintegration, Comparable dissolution to innovator, Good mechanical strength, Ease of scalability, Reproducibility in manufacturing. The study confirms that wet granulation is a suitable and cost-effective method for large-scale production of Levofloxacin immediate release tablets.

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CONFLICT OF INTERESTS

The authors declare no conflict of interest

ETHICS APPROVAL

Not applicable

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AI TOOL DECLARATION

The authors declares that no AI and related tools are used to write the scientific content of this manuscript.

DATA AVAILABILITY

Data will be available on request

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