EJPMR, 2026, 13(8), 384-387 **Research Article** **Impact Factor: 8.158**

EUROPEAN JOURNAL OF PHARMACEUTICAL AND MEDICAL RESEARCH

www.ejpmr.com

ISSN (O): 2394-3211
ISSN (P): 3051-2573
Coden USA: EJPMAG

FORMULATION AND EVALUATION OF IMMEDIATE-RELEASE OFLOXACIN TABLETS PREPARED BY WET GRANULATION METHOD

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DOI: https://doi.org/10.5281/zenodo.21703212

How to cite this Article: Sejal Madrecha*, Dr. R.P.S. Rathore. (2026). Formulation and Evaluation of Immediate-Release Ofloxacin Tablets Prepared By Wet Granulation Method. European Journal of Pharmaceutical and Medical Research, 13(8), 384–387.

Article Received on 07/07/2026 **Article Revised on 28/07/2026** **Article Published on 01/08/2026**

ABSTRACT

The present study was undertaken to formulate and evaluate immediate-release (IR) tablets of Ofloxacin using the wet granulation method. Six formulations (F1–F6) were prepared with different concentrations of pharmaceutical excipients to obtain tablets with satisfactory physicochemical properties and rapid drug release. The prepared granules were evaluated for pre-compression parameters, while the compressed tablets were assessed for post-compression characteristics, including weight variation, hardness, friability, disintegration time, drug content, and in vitro dissolution. All formulations complied with the prescribed pharmacopoeial limits. Among them, formulation F4 exhibited the best overall performance, showing excellent flow properties, adequate mechanical strength, rapid disintegration, and the highest drug release profile. The findings indicate that the wet granulation method is an effective approach for developing stable and immediate-release Ofloxacin tablets with desirable quality attributes.

KEYWORDS: Ofloxacin, Immediate-Release Tablets, Wet Granulation, Tablet Formulation, Pre-compression Evaluation, Post-compression Evaluation, In Vitro Dissolution, Drug Release.

INTRODUCTION

Ofloxacin is a broad-spectrum fluoroquinolone antibiotic widely used for the treatment of bacterial infections such as respiratory tract, urinary tract, gastrointestinal, and skin infections. It works by inhibiting bacterial DNA gyrase and topoisomerase IV, enzymes essential for bacterial DNA replication. Due to its broad antibacterial activity and good oral bioavailability, Ofloxacin is commonly formulated as an oral tablet.[1]

Immediate-release (IR) tablets are designed to disintegrate rapidly after administration, allowing the drug to dissolve quickly and produce a faster therapeutic effect. The quality of an immediate-release tablet depends on the appropriate selection of excipients and a suitable manufacturing method. Among the available techniques, the **wet granulation method** is widely used because it improves powder flow, compressibility, and tablet uniformity.[1,2]

The present study focuses on the formulation and evaluation of immediate-release Ofloxacin tablets prepared by the wet granulation method. Different formulations were developed and evaluated for pre-compression and post-compression parameters, along with in vitro dissolution studies. The objective was to identify an optimized formulation with good tablet characteristics and efficient drug release, ensuring effective and reliable oral drug delivery.[2]

MATERIAL AND METHODS

MATERIAL

Ofloxacin was obtained as the active pharmaceutical ingredient (API). Microcrystalline cellulose (MCC PH-102) and lactose monohydrate were used as diluents, while polyvinylpyrrolidone K-30 (PVP K-30) served as the binder. Sodium starch glycolate (SSG) was incorporated as a superdisintegrant to facilitate rapid tablet disintegration. Talc and magnesium stearate were

used as glidant and lubricant, respectively. All chemicals and reagents used in the study were of analytical grade.[4]

PREPARATION

Immediate-release tablets of Ofloxacin were prepared using the wet granulation method. The drug and excipients were accurately weighed and blended uniformly. A PVP K-30 binder solution was added to obtain wet granules, which were dried, lubricated with talc and magnesium stearate, and compressed into tablets using a tablet compression machine.[4]

FORMULATION TABLE

Ingredients (mg/tablet)	F1	F2	F3	F4	F5	F6
Ofloxacin	200	200	200	200	200	200
Microcrystalline Cellulose (MCC PH-102)	120	115	110	105	100	95
Lactose Monohydrate	45	45	45	45	45	45
Sodium Starch Glycolate	15	20	25	30	35	40
PVP K-30	10	10	10	10	10	10
Talc	5	5	5	5	5	5
Magnesium Stearate	5	5	5	5	5	5
Total Weight (mg)	400	400	400	400	400	400

EVALUATION

1. **Angle of Repose** - The angle of repose was determined to evaluate the flow properties of the prepared granules. Good flowability is essential to ensure uniform die filling during tablet compression and to produce tablets with consistent weight.[5]
2. **Bulk Density** - Bulk density was measured to assess the packing characteristics of the granules before compression. It provides useful information about the initial volume occupied by the powder blend and its handling properties.[6]
3. **Tapped Density** - Tapped density was determined after mechanically tapping the measuring cylinder until a constant volume was achieved. This parameter helps in understanding the compressibility and packing behavior of the granules.[7]
4. **Carr's Index** -Carr's index was calculated using bulk and tapped density values to assess the compressibility of the granules. Lower values indicate better flow properties and improved suitability for tablet compression.[8]
5. **Hausner's Ratio** - Hausner's ratio was calculated as the ratio of tapped density to bulk density. It is a simple indicator of powder flowability, where lower values represent better flow characteristics.[9]
6. **Weight Variation**- The weight variation test was performed to ensure uniformity in the weight of the prepared tablets. The results were compared with pharmacopoeial limits to confirm consistency among individual tablets.[10]
7. **Thickness** - Tablet thickness was measured using a Vernier caliper to ensure uniform dimensions. Consistent thickness is important for maintaining tablet quality and appearance.[11]
8. **Hardness** - Tablet hardness was evaluated using a hardness tester to determine the mechanical strength of the tablets. Adequate hardness is necessary to withstand handling, packaging, and transportation.[12]
9. **Friability** - Friability testing was carried out to assess the resistance of tablets to abrasion during handling. Tablets with friability within the acceptable limit are considered mechanically stable.[13]
10. **Drug Content Uniformity** - Drug content was determined using UV spectrophotometric analysis to ensure uniform distribution of Ofloxacin in the tablets. Uniform drug content is essential for consistent therapeutic efficacy.[14]
11. **In Vitro Dissolution Study** - The in vitro dissolution study was performed to evaluate the drug release behavior of the prepared tablets. The optimized formulation was selected based on its ability to achieve rapid and satisfactory drug release within the specified time.[14]

RESULT AND DISCUSSION

Angle of Repose

Formulation	Angle of Repose ( )
F1	24.5 ± 0.12
F2	25.2 ± 0.14
F3	26.1 ± 0.11
F4	26.8 ± 0.15
F5	27.5 ± 0.13
F6	F628.1 ± 0.16

The angle of repose values indicated satisfactory flow properties for all formulations. Formulation F4 showed optimum flow behavior, supporting uniform die filling during tablet compression.[5]

Bulk Density

Formulation	Bulk Density (g/cm³)
F1	0.42 ± 0.02
F2	0.44 ± 0.01
F3	0.46 ± 0.02
F4	0.50 ± 0.01
F5	0.45 ± 0.02
F6	F60.43 ± 0.01

The bulk density values showed satisfactory packing characteristics of the prepared granules. F4 demonstrated

an optimum bulk density, indicating better compressibility.[6]

Tapped Density

Formulation	Tapped Density (g/cm³)
F1	0.49 ± 0.01
F2	0.50 ± 0.02
F3	0.52 ± 0.01
F4	0.56 ± 0.01
F5	0.53 ± 0.01
F6	F60.51 ± 0.01

The tapped density values indicated good packing characteristics of the prepared granules. Formulation F4 exhibited an optimum value, suggesting better compressibility during tablet manufacturing.[7]

Carr's Compressibility Index

Formulation	Carr's Index (%)
F1	14.29 ± 0.21
F2	12.00 ± 0.18
F3	11.54 ± 0.15
F4	10.71 ± 0.12
F5	15.09 ± 0.20
F6	15.69 ± 0.23

The Carr's index values were within the acceptable range, indicating satisfactory flowability and compressibility of all formulations. Formulation F4 showed the most suitable compressibility for tablet production.[8]

Hausner Ratio

Formulation	Hausner's Ratio
F1	1.17 ± 0.01
F2	1.14 ± 0.01
F3	1.13 ± 0.01
F4	1.12 ± 0.01
F5	1.18 ± 0.01
F6	1.19 ± 0.01

The Hausner ratio values below 1.25 confirmed good flow behavior of powder blends.[9]

Thickness and Diameter

Formulation	Thickness (mm)	Diameter (mm)
F1	3.12 ± 0.02	8.01 ± 0.01
F2	3.15 ± 0.03	8.02 ± 0.02
F3	3.18 ± 0.01	8.03 ± 0.01
F4	3.20 ± 0.02	8.04 ± 0.02
F5	3.19 ± 0.03	8.03 ± 0.01
F6	3.22 ± 0.02	8.05 ± 0.02

The results showed that all formulations possessed nearly uniform thickness and diameter, indicating proper die filling and uniform compression force during tablet punching.[10]

Weight Variation Test

Formulation	Average Tablet Weight (mg)	IP Limit
F1	398 ± 2.1	±5%
F2	400 ± 1.8	±5%
F3	401 ± 2.0	±5%
F4	399 ± 1.9	±5%
F5	402 ± 2.3	±5%
F6	400 ± 2.1	±5%

The percentage deviation of individual tablet weights was found within acceptable limits, indicating uniform die filling and proper mixing of powder blend.[11]

Hardness Test

Formulation	Hardness (kg/cm²)
F1	4.5 ± 0.1
F2	4.8 ± 0.2
F3	5.0 ± 0.1
F4	5.3 ± 0.2
F5	5.1 ± 0.1
F6	5.4 ± 0.2

The hardness values indicated adequate mechanical strength required for handling, packaging, and transportation.[12]

Friability Test

Formulation	Friability (%)	IP Limit
F1	0.78 ± 0.02	Not more than 1%
F2	0.72 ± 0.03	Not more than 1%
F3	0.66 ± 0.02	Not more than 1%
F4	0.58 ± 0.01	Not more than 1%
F5	0.61 ± 0.02	Not more than 1%
F6	0.56 ± 0.01	Not more than 1%

All formulations showed friability values below 1%, indicating sufficient mechanical resistance.[13]

Drug Content Uniformity

Formulation	Drug Content (%)	IP Limit
F1	97.42 ± 0.36	95–105%
F2	98.14 ± 0.41	95–105%
F3	99.05 ± 0.32	95–105%
F4	99.82 ± 0.28	95–105%
F5	98.94 ± 0.37	95–105%
F6	98.65 ± 0.40	95–105%

The drug content of all formulations was within the acceptable pharmacopoeial limits. Formulation F4 showed excellent content uniformity, indicating uniform distribution of Ofloxacin.[14]

Disintegration Time

Formulation	Disintegration Time (min)	IP Limit
F1	10.24 ± 0.18	Not more than 15 min
F2	8.95 ± 0.16	Not more than 15 min
F3	7.84 ± 0.15	Not more than 15 min
F4	6.42 ± 0.12	Not more than 15 min
F5	6.88 ± 0.14	Not more than 15 min
F6	7.12 ± 0.16	Not more than 15 min

All formulations passed the disintegration test according to IP standards[14]

In-Vitro Dissolution Study

Time (min)	F1	F2	F3	F4	F5	F6
5	18.4	22.1	25.3	30.4	98.8	26.2
10	32.5	38.8	45.2	52.4	50.1	47.5
15	48.6	56.4	45.2	72.5	70.2	67.3
20	62.4	71.2	80.6	88.4	85.7	82.2
30	78.6	86.5	92.4	98.8	96.4	94.5

The dissolution study demonstrated satisfactory drug release from all formulations. Formulation F4 exhibited the highest cumulative drug release, confirming it as the optimized formulation.[14]

CONCLUSION

The present study successfully formulated and evaluated immediate-release tablets of Ofloxacin using the wet granulation method. Among all formulations, **F4** exhibited the best pre-compression and post-compression characteristics along with the highest in vitro drug release. The findings demonstrate that the optimized formulation is suitable for the development of stable and effective immediate-release Ofloxacin tablets.[15]

ACKNOWLEDGEMENT

I sincerely express my heartfelt gratitude to **Dr.R.P.S Rathore**, my Research Guide, for valuable guidance, constant encouragement, and continuous support throughout this research work. I am also thankful to the **Principal** and the **Department of Pharmaceutics** for providing the necessary facilities to successfully complete this study.

Conflict of Interest

I declare that there is no conflict of interest regarding the publication of this research work.

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