ISSN: 0974-2115
www.jchps.com Journal of Chemical and Pharmaceutical Sciences

Formulation and evalution of Levofloxacin hemihydrate immediate release tablets

Sugguna Ashok*, Harish Gopinath, Debjit Bhowmik, Praveen Khirwadkar, Ayushi Gupta
1. Nimra College Of Pharmacy, Nimranagar, Vijayawada
2. Institute of Pharmacy, Vikarm University, Ujjain, Madhya Pradesh
3. Deapartment of Pharmaceutical Chemistry, Bansthali University, Tonk Rajasthan
***Corresponding author: Email-harishgopinath4u@gmail.com**

ABSTRACT

The presentation deals with formulation of immediate release tablet of levofloxacin using super disintegrant such as Croscarmelose sodium and crospovidone. To enhance the rapid absorption rate to treat the case of bacterial infection. The study had been carried out by formulating 8 formulations by varying the concentration of disintegrating agent. The optimized batch F8 showed a disintegration time of about 55sec and released 99.08% of drug at the end of 30min in 0.1N HCL. The optimized batch F8 had been studied for the release in various dissolution mediums were it found to be about 90% in medium such as purified water, 0.1(N) HCl, Phosphate Buffer and acetate Buffer. Hence the formulated batch had the tendency to release the drug as rapid as possible irrespective of the medium. The stability studies had been carried out for a period of 1month in both accelerated and intermediate condition was no significant change had been observed.

Keywords: Immediate release tablet, disintegration time, levofloxacin.

INTRODUCTION

Immediate release drug delivery system is also conventional type of drug delivery system as it is defined as – Immediate release tablets are designed to disintegrate and release their medicaments with no special rate controlling features such as special coatings and other techniques. In the present study, the design of an oral immediate release dosage form by wet granulation technique has been carried out. The aim of the study was to develop fast disintegrating tablet with aesthetic, stable, acceptable physico-chemical properties, stability and ease of manufacture compared to innovator Levaquin tablets. The main motive is to develop and evaluate immediate release tablets with different compositions of excipients which will meet the standards to that of the innovator product with the subsequent achievement of in vitro correlation with the innovator product.

MATERIALS AND METHODS

Levofloxacin Hemihydrate procured from Hetero Drugs Pvt Ltd, Hyderabad. Micro crystalline cellulose USP-NF (Avicel PH 101), Micro crystalline cellulose USP-NF (Avicel PH 102) Procured from FMC biopolymer Croscarmellose Sodium USP-NF (Ac-Di-Sol) Povidone K-30 procured from BASF, Germany

Table.1.Formulation Table of Levofloxacin IM tablet

Ingredients	F1	F2	F3	F4	F5	F6	F7	F8
Levofloxacin	768.7	768.7	768.7	768.7	768.7	768.7	768.7	768.7
Microcrystalline cellulose USP-NF	18.5	13.13	10.43	15.1	13.5	14.5	15.5	13.5
Crosspovidone 5%	42.5	22	28	26	21	20	14.2	16.2
Croscamellose sodium USP-NF 2%	7.5	7.5	6	4.5	3.7	4	5	4
Povidone k-30 1-5%	-	-	11	11	11	10	8	10
Purified water	-	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S
Microcrystalline cellulose USP-NF	6	7.2	8	8.2	9	10.5	10.2	10.1
Magnesium stearate USP-NF	-	4.2	4.2	4	4	4.25	4	4.25
Croscamellose sodium USP-NF 2%	7.5	7.5	6	4.5	3.7	4	5	4
Total weight	850	850	850	850	850	850	850	850

Evaluation of Tablets: To design tablets and later monitor tablet production quality, quantitative evaluation and assessment of tablet chemical, physical and bioavailability properties must be made. The important parameters in the evaluation of tablets are physical appearance, hardness, thickness, weight variation, disintegration time, friability and dissolution.

RESULTS AND DISCUSSION

Table.2.Data of time for disintegration for all formulations of Levofloxacin Hemihydrate (n=6)

Formulation	Disintegration time(Minutes)
F1	3.20
F2	2.50
F3	2.25
F4	2.10
F5	2.0
F6	1.40
F7	1.10
F8	0.54

Table.3.In vitro dissolution profile of the innovator (levaquin 750mg) in various dissolution media

Medium	% drug release			
	10min	20 min	30 min	45 min
0.1 N HCl	46±0.56	98±0.78	99±0.45	101±0.87
pH 4.5 Acetate buffer	48±0.63	91±0.12	93±0.89	94±0.12
Purified water	53±1.25	85±0.24	92±0.12	97±0.78
pH 6.8 phosphate buffer	55±1.65	89±0.98	94±0.45	96±0.45

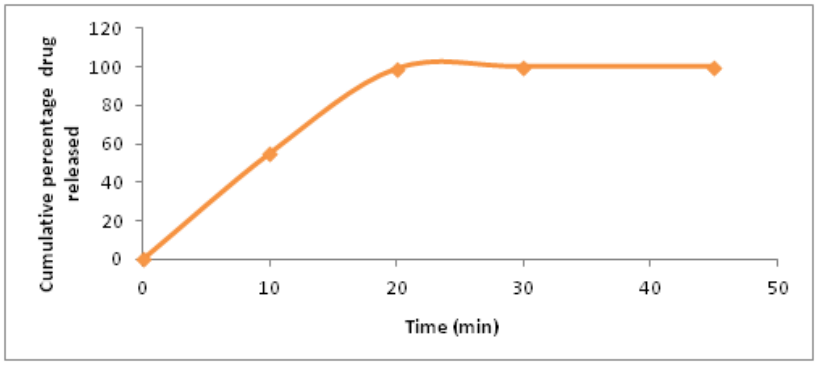

Figure.1.In-vitro dissolution profile of innovator in Purified water

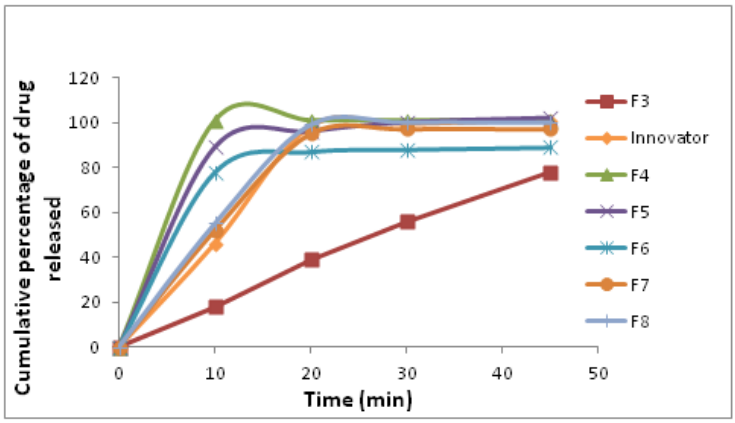

Figure.2.Comparison of *in-vitro* dissolution profiles of all formulations (f3 to f8) to the innovator in 0.01n hydrochloric acid medium

Table.4.Data showing various physico- chemical parameters after stability study.

Conditions	Parameter	Initial data	Data after one month
Room temperature	Hardness (kp)	12	12± 1
Room temperature	Assay (%)	101.2	99.82±2
Accelerated	Hardness (kp)	12	11.8±0.4
Accelerated	Friability (%)	0.052	0.054±.02
Accelerated	Assay (%)	101.2	99.16±2

CONCLUSION

Levofloxacin Hemihydrate is a class of Fluoroquinolone derivative which is used in the treatment of bacterial infections. In the present study, Levofloxacin tablets were prepared by wet granulation technique by using croscarmellose as a superdisintegrant. Out of eight formulations, F8 formulation was found to be the best formulation showing the disintegration time was found to be within a minute and drug release matched with that of the innovator. The percentage cumulative amount of drug release at the end of 30min was found to be 101±0.12 as matches with the innovator product.

REFERENCES

Ansel H, Allen L & Jr. popovich N, Ansel's Pharmaceutical Dosage Forms and Drug Delivery Systems, 8th edition, published by Lippincott Williams & Wilkins, 2004, 227-259.

Aulton M, PHarmaceutics, The Science of Dosage Form Design, International student edition, published by Churchill Livingstone, 2002, 304-321.

Banker GS, Modern pharmaceutics, 3rd edition, Marcel Dekker Inc, Newyork, 2002, 576 – 820.

Bi YX, Sunada H, 25th edition, Evaluation of rapidly disintegrating tablets prepared by Direct compression method, Drug DevInd PHarm, 1999, 571-581.

Chaudhari, PD., 42nd edition, Formulation and evaluation of fast dissolving tablets of Famotidine, Indian Drugs, 2005, 641-649.

Chen, GL., Kuo MK., 52nd edition, Formulation Design for Pioglitazone Rapid Release Tablet, Chinese pharmaceutical Journal, 2000, 295-300.

Herbert A, Lieberman, Leon lachman and JosepH B.Schwartz, Pharmaceutical Dosage Forms Tablets, 2003, 3rd edition, 201-238.

Herbert A, Lieberman, Leonlachman and JosepH B.Schwartz, Pharmaceutical Dosage Forms Tablets, 2003, 3rd edition, 1-11.

Hinz, B., Hug, AM, Bioequivalence study of low-dose diclofenac potassium tablet formulations, Int J ClinPHamacolTher, 2009, 47th edition, 643-648.

Jantratid E, Reported the bio wavier Monographs for immediately release solid dosage forms cimetidine, Journal of pharmaceutical Research, 17, 2006, 381.

Lachman L, Lieberman H & Kanig J, The Theory of practice of Industrial pharmacy, 3rd Edition, Published by Lea & Febiger, 1986, 346-373.

Larry Augsburger L, Huijeoing Hahm A, Albert Brezeczko W, Umang shah Super disintegrants: Characterization and function, 2nd edition, 2002, 2623-2638.