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Preparation and Evaluation of Sustained Release Tablets of Aceclofenac: A Brief Review

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ABSTRACT

This study is mainly focused to produce a Sustained release dosage form of aceclofenac drug. The Sustained release tablet is an important need for the management of chronic diseases like pain, inflammation, and cardiac problems. This Sustained release dosage is prepared using different types of polymers like semi-synthetic, synthetic, and natural polymers used in different ratios. The tablet characteristics prepared with the official limits. The release of aceclofenac from tablets containing different polymer was completed within 12 hours and 8 hours using phosphate buffer 7.5 pH. Various evaluation studies are carried out like hardness, weight variation, friability, and drug content of prepared tablets. The prepared tablet was stable and no changes are shown in physical changes. Aceclofenac is the considerable NSAID utilized for the respite of pain and inflammation in ankylosing spondylitis and originated in various Sustained release dosage forms. Many research technologies have been developed for the propose and formulation of Sustained release tablets of Aceclofenac, which comprises different types of polymeric material and new methodologies were reviewed in this paper.

INTRODUCTION

The sustained release dosage forms are those dosage forms that provide medication over an extended period of time after administration of a single dose.

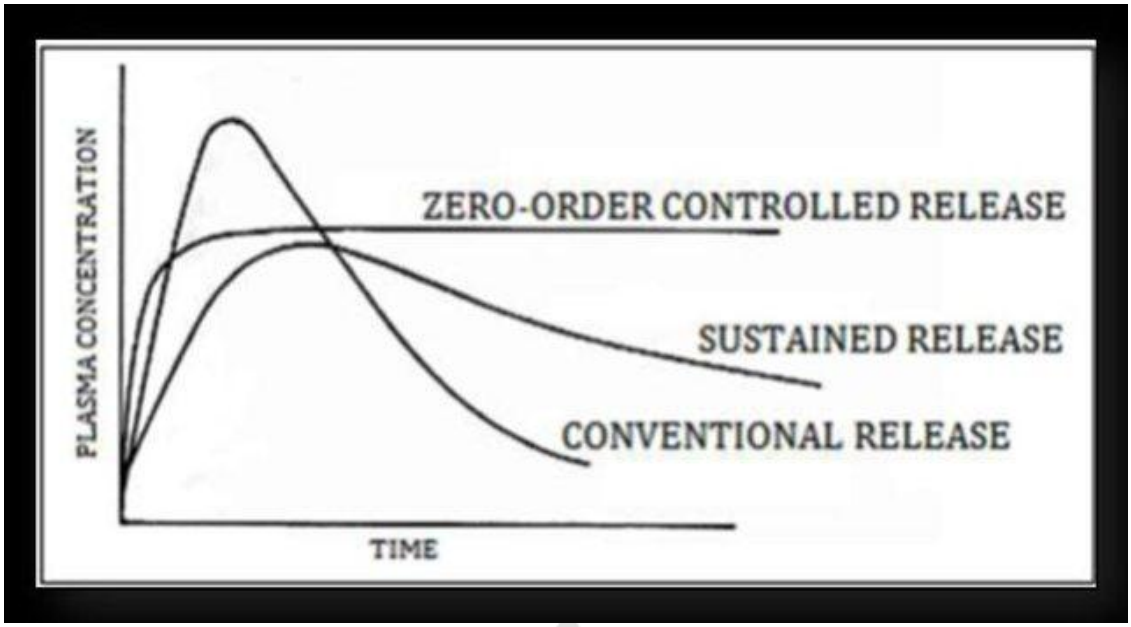

Figure No. 1: Plasma drug concentration profile for conventional tablet formation

Sustained release dosage form generally shows first order kinetics. There are so many advantages of Sustained release products like reduced dosing frequency, reduced adverse side effects, reduced toxicity due to overdose, the uniform release of a drug substance over time, and many more.

Some Rationale for Producing Sustained release Drug Delivery system

- To enhance the period of the deed of the drug.
- To weaken the frequency of dosing.
- To reduce the oscillations in the plasma level.

ACECLOFENAC

Aceclofenac is the newest derivative of diclofenac having low gastrointestinal complications. It is a nonsteroidal anti-inflammatory drug. The chemical formula of aceclofenac drug is $C_{16}H_{13}Cl_2NO_4$. The chemical structure is shown in Figure No. 2.

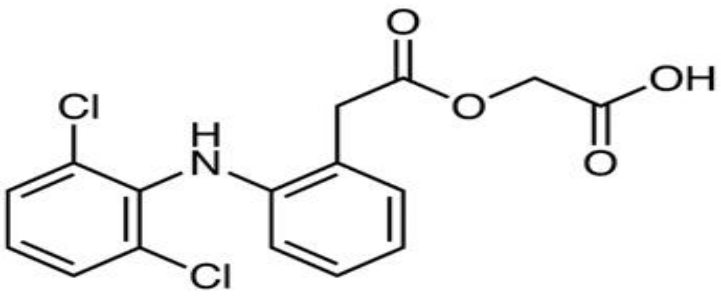

Figure No. 2: The chemical structure of aceclofenac

Aceclofenac is an ideal drug for Sustained release formulation because it has a short biological half life of about 4 hours and a dosing frequency of more than 1 per day. So for reducing the frequency of administration and minimizing gastrointestinal disturbance like peptic ulceration with bleeding and also to improve patient compliance we designed aceclofenac as a Sustained release. So a patient can take only one tablet daily for their treatment. For designing the Sustained release system a simple approach was followed that tablets composed of polymer and drug as release retard material. Matrix tablets were prepared by direct compression method or wet granulation method. The study of this experiment is to design a Sustained release matrix tablet of aceclofenac using carboxymethylcellulose, xanthan gum, and hydroxypropyl methylcellulose as polymers with the drug in different proportion[1][2].

On the other hand, xanthan gum was used in the formulation as a natural polymer which is mainly produced by the gram negative bacteria of the genus bacterium *Xanthomonas campestris*. Xanthan gum was discovered in 1950 by Allen Rosalind Jeans at the United States Department of Agriculture USA. The xanthan gum was approved by the FDA in 1969 as a nontoxic and safe polymer. And on the other hand, HPMC (Hydroxypropyl Methylcellulose) was used in this formulation as a semisynthetic polymer, which is also known as Hypromellose which is the best known cellulosic polymer used in the designing Sustained release drug delivery system.[3] It is available in various grades because of its high water absorption capacity, it is used as an excellent hydrophilic gel formed polymer[4].

LITERATURE SURVEY

This study is mainly concern with the design, formulation, and evaluation of aceclofenac drug for the Sustained release form of tablets. I have studied the following research paper

whose summary is shown below one by one with their methodology and dissolution profile and type of polymer utilized in their paper. This literature survey comprises of research paper up to Dec 2019. so I will discuss one by with their paper.

Uzair Nagra1 et al.,[2] have formulated & evaluated SR matrix tablet of aceclofenac. The tablets were prepared by wet granulation technique using various propagation of Carbopol 934P, kollidon SR, and Eudragit L-100 and also their combination. The study of *in-vitro* drug release was carried out for the first 2 hours in pH1.2 and pH 6.8 buffer for a total of 12hours (2019).

Ramachandra M. Koli et al.,[3] have developed & evaluated SR matrix tablet of Aceclofenac in this they have used HPMC polymer & eggshell powder. The technique used was direct compression. The study of *in-vitro* release showed that the SR matrix tablets having a higher concentration of eggshell powder & HPMC indicated slower release. These tablets followed the zero order model (2018).

Kamlesh J. Wadher et al.,[4] have investigated and evaluated the SR matrix table of aceclofenac. In this investigation two polymer combination was used one was hydrophilic polymer HPMC and other was Eudragit S100 which was a synthetic polymer. This tablet was investigated for colonic delivery. The study of the *in-vitro* evaluation was the drug release up to 12 hours with 67.78%(2017).

T Bisht et al.,[5] Formulated matrix & triple layer matrix of aceclofenac sodium tablets. They used natural polymer gum acacia which was acting as a forming agent for matrix and cross povidone acting as an immediate layer. In the comparison of the plain matrix tablet, the triple layer matrix tablet gave better results (2016).

Md A Habib et al.,[6] formulated Sustained release matrix tablets of aceclofenac involving newly investigated pharmaceutical excipient which is eggshell in powder form. In this paper, two separate eggshells have experimented with chloroform & ethanol are tested. So Dissolution testing of formulations in pH 6.8 phosphate buffer was evaluated with USP Dissolution equipment II which showed that chloroform tested eggshell powder illustrated most adaptable sustain release within 24 hours than other methods (2015).

A Gandhi et al.,[7] have formulated Aceclofenac matrix tablet and the method used in the formulation was melt granulation. They prepared tablets by using hydrophobic waves. The dissolution studies were carried out for drug release(2015).

MV Laxmi et al.,[8] Established a Sustained release matrix tablets of Aceclofenac. They used two polymers for their establishment, one was calcium acetate phthalate, and the other was ethylcellulose which was a SR polymer & Calcium acetate phthalate was pH dependent polymer(2014).

Khan et al.,[9] Designed Sustained release of Aceclofenac Bilayer matrix tablet containing HPMC polymer. Evaluation of *in-vitro* release was carried out in pH 1.2 (0.1N) with SLS 1% w/v. The study of drug release was investigated for twelve hours(2014).

H Panikkarakayil et al.,[10] have designed a Sustained release aceclofenac matrix tablet constituting KSR (Kollidon Sustained release). The Sustained release of aceclofenac was designed by the direct compression method and by dry blending. For characterization, the drug release behavior from polymeric systems exponential model was used. With the help of *in-vivo* as well as *in-vitro* evaluation the release rate of tablets was determined(2013).

B Rasogi et al.,[11] have designed aceclofenac loaded chitosan microspheres which showed promising results for a Sustained release during an enhanced time duration. Ionotropic gelation method was used for designing Sustained release microspheres using chitosan which acts as a mucoadhesive and biodegradable polymer. This designed formulation was submitted for its *in-vitro* release profile and also evaluated for *in-vivo* anti-inflammatory activity(2012).

A Mohsen et al.,[12] prepared a Sustained release matrix tablet of aceclofenac by using three techniques solid dispersion, wet granulation with Eudragit RLPO, and Eudragit PSPO. Prepared tablets were estimated regarding their physical property and *in-vitro* release over 24 hours. The *in-vitro* release study of the prepared formulation reveals that Eudragit RSPO retards the release more than Eudragit RLPO and the most suitable preparation technique was solid dispersion. For optimization, they used albino rabbits for pharmacokinetics studies(2012).

BV basavaraj et al .,[13] have prepared a modified release tablet of Aceclofenac. They used Plantago ovate powder and compared it with HPMC K4M for their efficiency. The dissolution studies were carried out up to twelve hours(2012).

D Gaikwad et al.,[14] have prepared & evaluated Sustained release tablets of film coated aceclofenac. In this, the Sustained release tablet of aceclofenac was prepared by using (HPMC) Hydroxypropyl methylcellulose polymer. For its physiochemical properties and *in-vitro* release studies the prepared tablet was evaluated(2011).

Basavaraj et al.,[15] have formulated & evaluated of Sustained release tablet of aceclofenac using monolithic matrix technology. The tablet is formulated by using tamarind seed polysaccharide which acts as a hydrophilic and rate controlling polymer and a wet granulation technique was used for the preparation of the tablet. The result of the *in-vitro* drug release study showed 98.062% release up to 12 hours by using phosphate buffer pH 7.4 media(2011).

KPR Chowdhary et al.,[16] have advanced the designing of aceclofenac tablets by using a new modified starch (Starch Phosphate). This starch phosphate is used for increasing the dissolution rate of tablet aceclofenac. By reacting starch with disodium hydrogen orthophosphate anhydrous at elevated temperature, starch phosphate was prepared solvent evaporation method was used for preparing solid dispersion of aceclofenac in starch phosphate(2011).

K S Prabha et al.,[17] have detailed formulation and evaluation of Sustained release microspheres of aceclofenac. The emulsion cross-linking method and solvent evaporation technique both were used for the preparation of the microsphere of aceclofenac by using different grades of gelatin with varying concentrations & Eudragit (S-100, L-100) polymers respectively. The developed formulation showed good *in-vitro* Sustained release of aceclofenac(2011).

S K Umadevi et al.,[18] formulated novel colon specific drug delivery. Aceclofenac an NSAID was successfully encapsulated into the chitosan microsphere. For coating the formulation, pH dependent polymeric coating solution was used containing Eudragit L-100 and S-100 (1:4)(2010).

S Ghosh et al.,[19] have stated the design and evaluation of aceclofenac tablets of Sustained release and differentiated with marketed products. Aceclofenac matrix tablets of Sustained release was designed by using hydrophilic polymer HPMC with various viscosity in two separate proportion with a hydrophobic polymer, guar gum and ethylcellulose for designing

matrix tablet by wet granulation technique was used and the *in-vitro* method was used to the study the drug release(2009).

S Basak et al.,[20] have prepared and evaluated Aceclofenac enteric-coated tablets. HPMC was used in the preparation of the tablet. These tablets were prepared by the technique of wet granulation. 1:0.47 was the ratio of drug and polymer showing extended release up to twelve hours(2009).

Santanu Gosh et al.,[21] have developed a matrix tablet for oral Sustained release of the drug Aceclofenac. They used Guar gum, ethylcellulose, and a different proportion of cellulose polymer(2009).

Different methods used for the preparation of the Sustained release formulation of Aceclofenac along with polymers used were briefly outlined in Table No.1.

Table No. 1: Different methods used for the preparation of Sustained release formulation of Aceclofenac along with polymers used

Sr. No.	Name of Author	Publication Year	Type of Dosage Forms	Methods/ Technique	Polymers
2	Uzair Nagra1 et al.,	2019	Matrix Tablet	Wet Granulation & Compression	Kollidon SR Carbapal 934P, Eudragit L-100
3	Ramachandra M. Koli et al.,	2018	Matrix Tablet	Direct Compression	Eggshell Powder, HPMC
4	Kamlesh J. Wadher et al.,	2017	Matrix Tablet	Wet Granulation Technique	HPMC, Eudragit S-100
5	T Bisht et al .,	2016	Matrix Tablet	Direct Compression	Gum Acacia, Guar Gum
6	Md A Habib et al.,	2015	Matrix Tablet	Wet Granulation & Direct Compression	Eggshell Powder
7	A Gandhi et al .,	2015	Matrix Tablet	Melt Granulation method	Hydrophobic Waves
8	MV Laxmi et al	2014	Matrix Tablet	Direct Compression	Calciumacetatephthalate, Ethylcellulose
9	Khan et al .,	2014	Matrix Tablet	Direct Compression	HPMC

10	H Panikkarakayil et al.,	2013	Matrix Tablet	Direct Compression Dry blend	KSR
11	B Rasogi et al.,	2012	Matrix, Microsphere Tablet	Ionotropic Gelatin method	Chitosan
12	A Mohsen et al.,	2012	Matrix Tablet	Wet Granulation, Solid dispersion	Eudragit RSPO, RLPO
13	BV basavaraj et al	2012	Matrix Tablet	Wet Granulation, Solid dispersion	Plantago ovate powder, HPMC K4M
14	D Gaikwad et al.,	2011	Matrix Tablet	Direct Compression	HPMC
15	Basavaraj et al.,	2011	Matrix Tablet	Wet Granulation	Tamarind Seed
16	KPR Chowdhary et al.,	2011	Matrix, Solid dispersion of starch phosphate Tablet	Solvent Evaporation, Direct & wet compression	Starchphosphate
17	K S Prabha et al.	2011	Microsphere	Solvent Evaporation, Emulsion crosslinking	Eudragit S-100, L-100, Gelatin
18	S K Umadevi et al.,	2010	Microsphere	Wet Granulation & Direct Compression	Eudragit S-100, L-100
19	S Ghosh et al.,	2009	Matrix Tablet	Wet Granulation	Guar gum, Ethylcellulose
20	S Basak et al.,	2009	Enteric Tablet	Wet Granulation	HPMC
21	Santanu Gosh et al	2009	Matrix Tablet	Wet Granulation	Methocel K4M, Guar gum, K15M, Ethylcellulose

CONCLUSION

This study/work illustrates different methods for the formulation and testing of the Sustained release of Aceclofenac. Dissimilar types of methods, polymers, and many more excipients utilized to make Aceclofenac Sustained released formulation were illustrated along with its release profile and it was originated that the use of synthetic and natural polymers makes a vital role in formulation. The use of Natural polymer was found to be more as a polymeric matrix in most of the formulation.

REFERENCES

[1] Shailendra Suryawanshi Sanjay, Shruthi B, Sarvesh, P Rama Smriti and Zaranappa Journal of Chemical and Pharmaceutical Research, 2017, 9(3):302-307.
[2] Uzair Nagra, Sherjeel Adnan, Sana Shafqat, Maryam Shabbir, Sajid Ali, Anum Zafar, Syed Saeed ul Hassan, Javed Iqbal Indian Journal of Pharmaceutical Education and Research | Vol 53 | Issue 2 (Suppl) | Apr-Jun, 2019
[3] Kamlesh J. Wadher*, Pallavi Kalambe, Milind J. Umekar, International Journal of Medi Pharm Research ISSN:2395-423X www.medipharmsai.com Vol.03, No.01, pp 229-236, 2017
[4] Ramachandra M. Koli*1, Nitin N. Mali1, Sagar S. Kale, Ritesh S. Bathe1 and Birappa A. Satpute1 WORLD JOURNAL OF PHARMACY AND PHARMACEUTICAL SCIENCES SJIF Impact Factor 7.421 Volume 7, Issue 3, 681-701 Research Article ISSN 2278 – 4357
[5] T Bisht; P Rishishwar. *WJPPS*, 2016, 5(11), 1687-1696.
[6] Md A Habib; Md F Mahmud; Md T Islam; M Hasan; *SK* Ahamed; Md M Billah; PMU Arefin. *J Pharm Sci*, 2015, 42(2), 93-100.
[7] A Gandhi; S Harikumar, *Indian J Drugs*, 2015, 3(3), 49-56.
[8] MV Laxmi; VJ Krishna, *JGTPS*, 2014, 5(3), 1804-1810.
[9] H Khan; A Javed. *Drug Deliv Lett*, 2014, 4(3), 221-226.
[10] H Panikkarakayil; M Nampoothiri; G Kachappilly; M Shameem; R Pariyani; Y Anith A. *Asian J Pharm*, 2013, 7, 8-14.
[11] B Rastogi; A Chaudhary; U Nagaich. *J Adv Pharm Edu Res*, 2012, 2(4), 215-220.
[12] A Mohsen; OM Khoweysa; RA Shoukri. *J Pharm Res Opinion*, 2012, 2(1), 12 - 22.
[13] BV Basavaraj; P Anusha; S Bharath; R Deveswaran; V Madhavan. *Am J PharmTech Res*, 2012, 2(2), 519-527.
[14] D Gaikwad; RT Jadhav; A Limkar; S Sangeetha; B Kisan; M Patil. *Int J Res Pharm Biomed Sci*, 2011, 2(1), 310-318.
[15] Basavaraj; B Rao; Someswara; SV Kulkarni; P Patil; S Chetan. *Asian J Pharm and Technol*, 2011, 1(1), 17-21.
[16] KPR Chowdary; V Enturi; S Rani. *Int J Pharm Sci Res*, 2011, 2(3), 124-129.
[17] KS Prabha; VSR Chandrasekhar; PM Prasanna; M Thadanki. *Int J Pharm Life Sci*, 2011, 2(10), 1142-1146.
[18] SK Uma Devi; R Thiruganesh; S Suresh. *JPRHC*, 2010, 2(1), 46-65.
[19]S Gosh; BB Barik. *Int J Med Med Sci*, 2009, 1(9), 375-382.
[20] S Basak; KJB Bhusan. *Internet J Pharmacol*, 2009, 8(2).
[21] S Ghosh; BB Barik, *Int J Med Med Sci*, 2009, 1(9), 375-382