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RESEARCH ARTICLE

FORMULATION, DEVELOPMENT AND EVALUATION OF SUSTAINED RELEASE TABLET OF ACECLOFENAC

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Abstract

In this study, sustained-release (SR) tablets of Aceclofenac were developed using acrypol 971Pas polymers. The tablets were prepared by mixing the active drug (Aceclofenac) with the polymer and other excipients, and then compressing the mixture into tablets using a tablet press.The release profile of the SR tablets was optimized by adjusting the ratios of the polymers and other excipients. The optimized formulation showed sustained release of the drug up to 16 hours, and the release kinetics followed first-order models. The tablets were stored under various conditions (e.g., at different temperatures and humidity levels) for a set period of time. The results showed that there were no significant changes in the drug content, physiochemical parameters. This suggests that the optimized SR tablets of Aceclofenac are stable and may be suitable for use as a sustained-release formulation of the drug.

Introduction:-

A tablet is a solid dosage form that contains a medicine and is intended to be taken orally (by mouth). It is usually taken with water and is designed to be swallowed whole. Tablets can come in various shapes and sizes and can be made using a variety of manufacturing methods. Some tablets are coated with a protective layer to make them easier to swallow or to help them work better in the body. The active ingredient in a tablet may be a single chemical compound or a combination of several different compounds. The amount of active ingredient in a tablet is usually measured in milligrams (mg) or micrograms (mcg).

Tablets can be formulated to release the active ingredient quickly (immediate-release tablets) or slowly over time (extended-release tablets). Some tablets also contain additional ingredients, such as binders, fillers, and disintegrants, which help the tablet hold its shape, improve its stability, and aid in the release of the active ingredient.

Tablets are a convenient and widely-used form of medicine, as they are easy to manufacture, store, and transport. They are also relatively inexpensive compared to other dosage forms, such as injectables or inhalers. However, not all medications are suitable for formulation as tablets, and some patients may have difficulty swallowing tablets due to physical or medical conditions. In these cases, alternative dosage forms, such as liquids or capsules, may be used.

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SustainedRelease Dosage form
Sustained release dosage forms are a type of medication that is designed to release the active ingredient over an extended period of time. This can be achieved through a variety of different mechanisms, such as using a polymer matrix or controlled release coatings. Sustained release formulations are often used for drugs that have a narrow therapeutic window and require precise dosing. They can also be useful for patients who have difficulty complying with a regular dosing schedule.

Sustained release tablets are designed to release medication over an extended period of time. The active ingredient in the tablet is released slowly, which allows for a more even distribution of the drug throughout the body. This type of tablet is often used for medications that need to be taken over a long period of time, such as those used to treat chronic conditions. The sustained release mechanism can also help to reduce side effects by allowing the body to adjust to the medication more slowly.

Advantages of Tablets
There are several advantages of using tablets in the pharmaceutical industry:

Ease of use:
Tablets are easy to swallow and do not require any preparation, such as cutting or crushing, before they can be taken. This makes them a convenient and simple option for patients who may have difficulty swallowing pills or capsules.

Accuracy of dosage:
Tablets can be manufactured to very precise dosage specifications, ensuring that patients receive the correct amount of medication.

Customization:
Tablets can be customized with different coatings, colors, and shapes to help distinguish different medications and make them easier for patients to identify.

Stability:
Tablets are stable and do not degrade over time, making them an ideal choice for long-term storage and use.

Cost effectiveness:
Tablets are often more cost effective to produce than other dosage forms, such as liquids or injectables, which can make them more affordable for patients.

Disadvantage of Tablet
Tablets are a type of pharmaceutical drug that are designed to be taken orally. They are typically round and flat, and come in a variety of sizes. While tablets offer a number of advantages, there are also some disadvantages associated with them.

1. One of the biggest disadvantages of tablets is that they can be difficult to swallow. This is especially true for larger tablets, or those that are not coated with a film that makes them easier to swallow.
2. Some people may also have difficulty digesting tablets, which can lead to gastrointestinal issues. Another disadvantage of tablets is that they can be ineffective if not taken as directed. For example, if a tablet is meant to be taken with water, it may not work as intended if the person takes it without water.
3. Additionally, some people may forget to take their tablet at the correct time, or may not take it regularly enough to see the desired effect.
4. Finally, while tablets offer a number of benefits, they also come with a risk of side effects. These can range from mild side effects such as headaches or stomach upset, to more serious ones such as liver damage or heart problems.

Methodology:-

Sifting
Sift Aceclofenac, Acrypol 971P , Lactose and Microcrystalline cellulose -PH101 through mechanical sifter fitted with 60 # sieve and Collect the sifted materials in double polythene.

Preparation Of Binder
Take Isopropyl Alcohol in a suitable SS container and dissolve PVP-K30 in it.

Dry Mixing
Mix the sifted materials of step no. 1 in manually.

Kneading
Add the binder of step no.2 slowly in small lots to the Dry Mix of step inmanually to get proper dough mass. Additional Isopropyl Alcohol may be added (if needed) to achieve desired mass towards the granulation point.

Wet Passing
Pass the Granules of step no.4 through mechanical sifter fitted with 24 # sieve.

Drying
Drythewetgranulesof StepNo.5with temperature set at 55ºC under Trey Dryer (with raking for 10 Minutes). Total Drying Time :

Dry Screening
Pass the dried granules of step no. 6 through mechanical sifter fitted with 30 # sieve.
Check the moisture content of the granules…….%.(Not More Than 2.50% at 80°C)

Lubrication
a) SiftAerosil through mechanical sifter fitted with 60 # sieve. Collect the sifted materials Separately in double polythene.
b) Sift Magnesium Stearate and Purified Talc through mechanical sifter fitted with 60 # sieve. Collect thesifted materials separately in double polythene.
c) Blend the rasped granules of step no. 7 with the sifted mix of Step No. 8 (i) in Double cone blender for 5minutes and then mix the Step No. 8 (ii) in Double cone blender for 5minutes.

Bulk For Testing
After Receiving the bulk Report, then the bulk ready to compression.

Formulation Table

S.No	INGREDIENTS (mg)	F1 (mg/tabs)	F2 (mg/tabs)	F3 (mg/tabs)	F4 (mg/tabs)	F5 (mg/tabs)	F6 (mg/tabs)
1	Aceclofenac	200	200	200	200	200	200
2	MCCP PH 101	50	52	53	53.50	54	54.5
3	Acrypol 971 P	10	8	7	6.50	6	5.5
4	Lactose monohydrate	37	37	37	37	37	37
5	PVP K-30	20	20	20	20	20	20
6	Isopropyl Alcohal	100	100	100	100	100	100
7	Aerosile 200	3	3	3	3	3	3
8	Magnesium Stearate	4	4	4	4	4	4
9	Purified Talc	6	6	6	6	6	6
10	**TOTAL WEIGHT**	330	330	330	330	330	330

Preformulation Characteristics of All Formulations:

S.No	Formulations	Angle of Repose (º)	Bulk Density (gm/ml)	Tapped Density (gm/ml)	Compressibility Index (%)	Moisture Content (%)	Assay%
1	F1	29.05	0.53	0.62	14.51	2.10	98.06
2	F2	30.05	0.56	0.65	13.84	2.30	101.04

3	F3	31.00	0.54	0.64	15.62	2.15	103.31
4	F4	31.05	0.56	0.69	18.84	2.00	100.88
5	F5	31.50	0.58	0.71	18.30	1.95	102.50
6	F6	32.08	0.55	0.66	16.66	2.25	98.68

Physical Evaluation:

Postcompressionalparameters:

Physical parameters of tables of each batches are shown in given table.

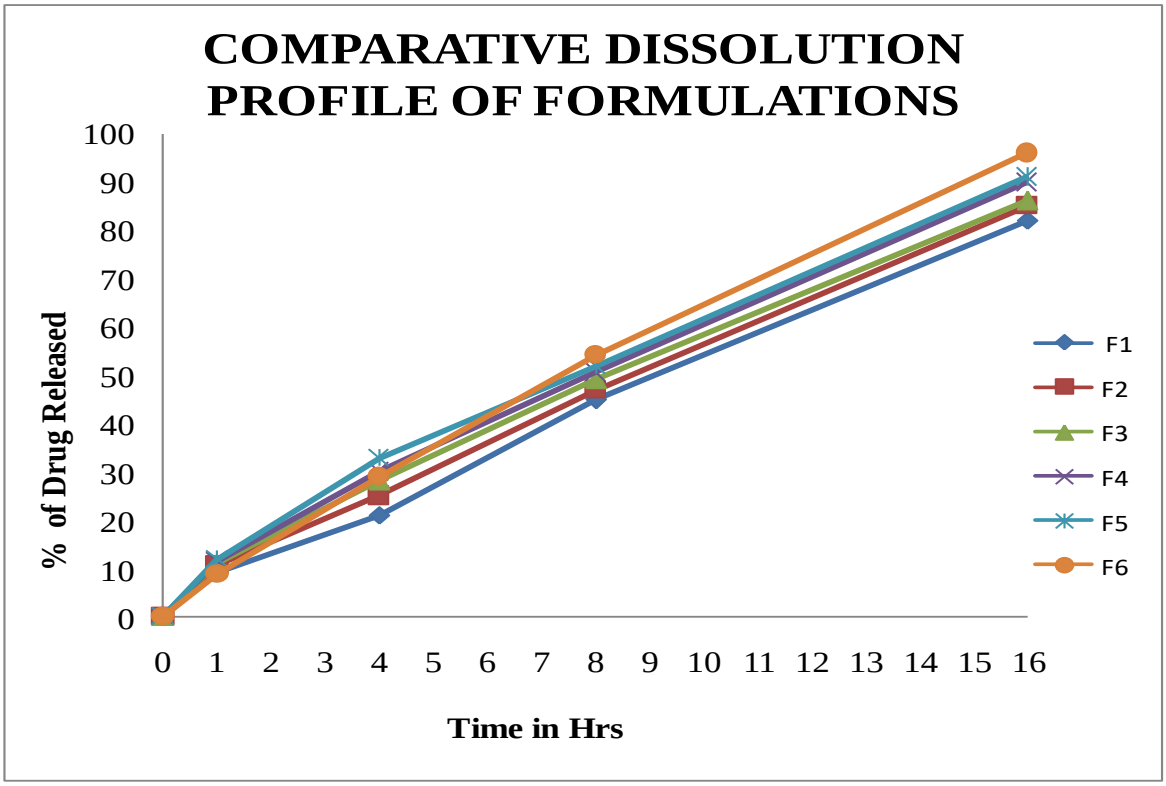
S.No.	Physical Parameters	F1	F2	F3	F4	F5	F6
1	Weight variation (mg)	330±4	330± 3	330± 3	330± 2	330± 3	330± 2
2	Hardness (kg/cm^2)	5.0	5.25	5.35	5.50	5.75	5.95
3	Thickness (mm)	4.20±0.02	4.21±0.02	4.18±0.02	4.15±0.02	4.10±0.02	4.06±0.02
4	Friability (%)	0.40	0.32	0.20	0.20	0.15	0.11

Dissolution Studies of All Formulations:

By comparing the all formulations F6 formulation showed better percentage drug release.

S. No.	Dissolution time (Hrs)	F1	F2	F3	F4	F5	F6
1	0	0.00	0.00	0.00	0.00	0.00	**0.00**
2	1^{st}Hr	8.95	10.63	11.00	11.44	11.91	**8.85**
3	4^{th}Hrs	21.00	25.00	28.00	30.00	32.72	**28.99**
4	8^{th}Hrs	44.83	47.00	49.00	50.50	52.00	**54.07**
5	16^{th}Hrs	82.00	85.00	86.00	89.90	91.00	**95.92**

Comparitive Dissolution Profile Of Formulations:



Conclusion:-

This Study Was Showed Acrypol971 P Act As Suitable Excipient For Development Of Sustained Release Of Drug Aceclofenac On Direct Compression Without Coating Other Excipients.

Reference:-

1. Liberman, lachman and Joseph, Tablet in pharmaceutical dosage form, 2nd edn 2005, 2, 201-339.
2. M.E.Aulton, Tablet in the science of dosage form design, 2nd edn, 397-460.
3. Remington, The science and practice of pharmacy, 20th edition, 1, B.I publications Pvt.Ltd, Noida, 2000, 903-929.
4. Aulton ME, pharmaceutics- The sciences of dosages form design, 3rd edition, international student Edition, Churchill Living stone, 2007, 419-421.
5. Manish maheshwari, Development of tetracycline serratiopeptidase-containing gel: Formulation and preliminary clinical studies. AAPS pharm sci Tech, 2006, 76.
6. T.H. Al khateeb, Effect of the proteolytic enzyme serrapeptase on swelling pain and trismus after surgical extraction of mandibular third molar, International journal of oral and maxillofacial surgery, 2008, 37, 264-265.
7. Deependrasingha, serratiopeptidase-loaded PLA microspheres using selected variables, Journal PDA (pharmaceutical science and technology), 2009.
8. K.V.Sandya, liposomal formulation of Serratiopeptidase – in vitro studies using PAMPA and CACO – to model, Molecular pharmaceutics book, 2008, 92-97.
9. Sumitchakraborty, Formulation development and evaluation of Pantoprazole enteric coated tablet, International Journal of chem tech Research, 2009, 1, 663-2666.
10. Murat – turkoglu, Tableting and stability evaluation of enteric coated omeprazole pellets, European Journal of pharmaceutics and Biopharmaceutics, 2004, 279-286.
11. J. Michael, Enteric coated pellets: theoretical analysis of effect of dispersion in the stomach on blood level profiles, 1976
12. J,G.Hardy, Evaluation of an enteric coated naproxen pellets formulation, 1990.
13. Gonzales,

14. Gilbert) An enteric-coated caffeine delivery system(Application Number: 10/154629) et al (2003)
15. im, Sang Min et al an enteric, sustained-release tablet comprising paroxetine or a hydrates United States Patent Application 20080292696.