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Formulation and Evaluation of Diclofenac Sodium Oral Dispersible Tablets

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A B S T R A C T

Diclofenac sodium oral disintegrating tablets were formulated using different concentrations of sodium starch glycolate (superdisintigrant) and other excipients. All the prepared tablets were evaluated for different evaluation parameters .Formulated tablets gave satisfactory results for various evaluation parameters like tablet dimensions, hardness and percent weight variation, percent friability, drug content percentage etc. Formulation containing high concentrations of sodium starch glycolate (super disintegrant) showed excellent drug release pattern. Formulation F1, showed better drug release pattern and released high amount of drug in comparison to the other formulations

Keywords: Diclofenac sodium, sodium starch glycolate, oral disintegrating tablets

A R T I C L E I N F O

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1. Introduction

An oral disintegrating tablet (ODT) is a solid-dosage form that disintegrates and dissolves in the mouth (either on or beneath the tongue or in the buccal cavity) without water within 60 seconds or less. Despite of tremendous advancements in drug delivery, the oral route remains the perfect route for the administration of therapeutic agents because the low cost of therapy and ease of administration lead to high levels of patient compliance. Many patients find it difficult to swallow tablets and hard gelatin capsules and do not take their medicines as prescribed. Diclofenac sodium Oral disintegrating tablets which comes under NSAID category were formulated as an approach to

disintegrate the tablets within the saliva of the mouth and thereby increasing its dissolution and absorption rate, thus improving its bioavailability to show rapid action.

2. Materials and Methods

Diclofenac Sodium, Sodium Starch Glycolate, Micro Crystalline Cellulose, Mannitol, Aspartane, Aerosil, Magnesium Stereate chemicals were Laboratory grade made of SD Fine chemicals Pvt Ltd

Preparation of Diclofenac sodium ODT's: All the tablets were prepared by direct compression method. In this method accurately weighed quantities of sodium starch glycolate (super disintigrant) and other excipients were taken in a geometrical fashion and to this mixture required quantity of drug was added and mixed slightly with pestle. This mixture was passed through sieve no.60 to get uniform particle size and collected in a polythene bag and further mixed for about 3 minutes to ensure a homogenous mass. To this Magnesium stearate was added and mixed for 5 minutes. This mixture was compressed into tablets with 6mm round punches at a hardness of 3.5 kg/cm^2.

Evaluation of prepared tablets

The designed formulation tablets were studied for their physicochemical properties like weight variation, hardness, thickness, friability, *In-vitro* release and drug content.

3. Results and Discussions

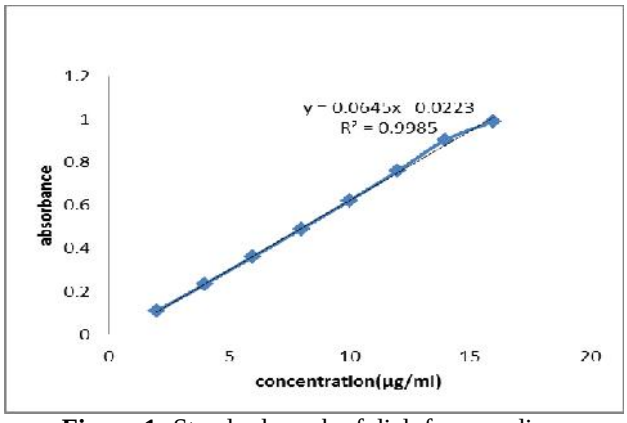

Figure 1: Standard graph of diclofenac sodium

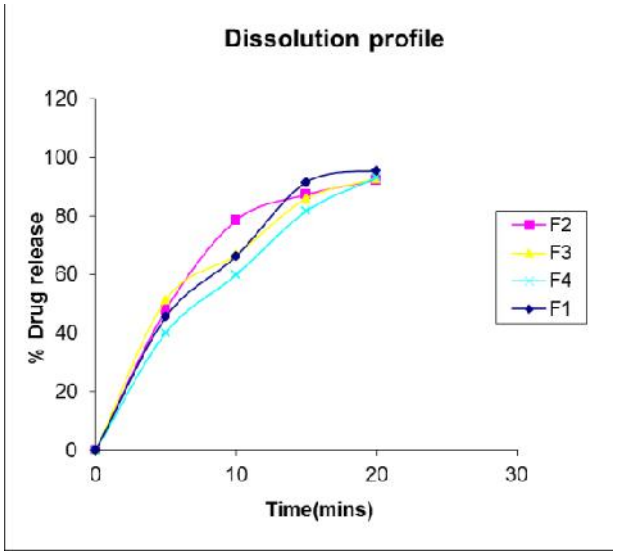

Figure 2: Percent drug release of 4 formulations Vs Time

To optimize the parameters which is related to the formulation of Diclofenac sodium ODT, using superdisintegrant sodium starch glycolate, Micro crystalline cellulose as diluent, and other expedients by direct compression technique. The hardness, thickness, friability percent , percent weight variation, percent drug content were within the specified official limits ,while the Disintegration time was in the range of 57 to 63 seconds. The drug release pattern was observed and compared among all the 4 formulations.

Discussion

Diclofenac sodium oral disintegrating tablets were formulated using different concentrations of sodium starch glycolate (superdisintigrant) and other excipients. All the prepared tablets were evaluated for different evaluation parameters .Formulated tablets gave satisfactory results for various evaluation parameters like tablet dimensions, hardness and percent weight variation, percent friability, drug content percentage etc.It was found that formulation with high concentration of sodium starch glycolate showed better drug release characteristics.

Table 1: Formulation composition of Diclofenac Sodium ODT

Ingredients	Formulation 1 (mg)	Formulation 2 (mg)	Formulation 3 (mg)	Formulation 4 (mg)
Diclofenac Sodium	50	50	50	50
Sodium Starch Glycolate	15	12	9	6
Micro Crystalline Cellulose	58	61	64	67
Mannitol	23	23	23	23
Aspartane	1	1	1	1

Aerosil	2	2	2	2
Magnesium Stereate	1	1	1	1

Total tablets weight – 150mg.

Table 2: Standard graph values of Diclofenac sodium

Concentration (µg/ml)	Absorbance
2	0.109
4	0.234
6	0.361
8	0.49
10	0.621
12	0.759
14	0.904
16	0.99

Table 3: Physicochemical evaluation Properties of Prepared Diclofenac Sodium ODT

	Thickness (mm)	Hardness (kg/cm^2)	Average % Weight Variation	% Friability	% Drug content
Formulation1	3.88	2.98	2.232	0.46	95.36
Formulation2	3.64	3.04	3.278	0.37	94.76
Formulation3	3.46	3.08	2.159	0.48	92.28
Formulation4	3.45	2.76	2.289	0.36	93.45

Table 4: In-vitro Disintegration time values

Formulations	Disintegration Time (sec)
Formulation1	57sec
Formulatin2	59sec
Formulation3	63sec
Formulation4	62sec

Table 5: Percentage Drug Release of Different Formulations.

Time (min)	% Drug Release of Formulation-1	% Drug Release of Formulation-2	% Drug Release of Formulation-3	% Drug Release of Formulation-4
0	0	0	0	0
5	44.14	45.3	47.88	40.14
10	60.84	76.78	74.78	59.4
15	85.62	81.94	80.94	75.62
20	92.64	91.8	90.68	91.47

4. Conclusion

Diclofenac sodium Oral disintegrating tablets which comes under NSAID category were formulated as an approach to disintegrate the tablets within the saliva of the mouth and thereby increasing its dissolution and absorption rate, thus improving its bioavailability to show rapid action. This ODT's were mainly targeted to use for the pediatric, geriatric and mentally unstable patients, who finds difficulty in swallowing conventional dosage forms and moreover to enhance the patient compliance. Formulation containing high concentrations of sodium starch glycolate (super disintegrant) showed excellent drug release pattern. Formulation F1, showed better drug release pattern and released high amount of drug in comparison to the other formulations.

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