FORMULATION AND DEVELOPMENT OF HERBAL FAST DISINTEGRATING TABLET OF ACHYRANTHES ASPERA LINN ROOT EXTRACT.

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Abstract:
Fast dissolving Tablets are disintegrating and/or dissolve rapidly in the saliva without the need for water. FDTs can be prepared by different methods as direct compression, freeze-drying, spray drying, sublimation and wet granulation method. Herbal drugs comprise of a major share of all the officially recognised systems of health in India. The herbal extract of Achyranthes aspera Linn was used in this formulation. The aim of this study was to formulate FDTs with sufficient mechanical integrity and to achieve faster disintegration in the oral cavity without water. To achieve this goal, MCC is used as diluent and sodium saccharin as sweetening agent for the formulation of tablets. Attempts were made to enhance dissolution rate along with faster disintegration using super disintegrants like Crospovidone, Sodium starch glycolate (SSG)and mixture of crospovidone and sodium starch glycolatein the formulation of tablets. The tablets were subjected to weight variation, drug content uniformity, hardness, friability, wetting time, In vitro dispersion time and In vitro drug release studies.

Keywords: Fast dissolving tablets (FDTs), Sodium starch glycolate, Microcrystalline cellulose (MCC), Crospovidone.

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Introduction :

Fast dissolving Tablets are disintegrating and/or dissolve rapidly in the saliva without the need for water. Some tablets are designed to dissolve in saliva extremely fast, within a few seconds, and are true fastdissolving tablets. Others contain agents to increase the rate of tablet disintegration in the oral cavity, and are more appropriately termed fast-disintegrating tablets. Fast or mouth dissolving tablets have been formulated for pediatric, geriatric, patients and for active patients who are busy and traveling and may not have access to water. Swallowing problems also are common in young individuals because of their underdeveloped muscular and nervous systems. Other groups that may experience problems using conventional oral dosage forms include the mentally ill, mentally disabled, and patients who are uncooperative, or are nauseated.[1] FDTs can be prepared by different methods as direct compression, freeze-drying, spray drying, sublimation and wet granulation method.[2] In the present era, market of all commodities has become global. Market of health-related products has been active and these products are manufactured at different parts of the world and sold all over. Standardization is necessary to make sure the availability of a uniform product in all parts of the world. Herbal medicines are effective in all types of disease. WHO collaborates and assists health ministries in establishing mechanisms for the introduction of traditional plant medicines into primary healthcare programs, in assessing safety and efficacy, in ensuring adequate supplies, and in the quality control of raw and processed materials. Herbal formulations in general can be standardized schematically as to formulate the medicament using raw materials collected from different localities and a comparative chemical efficacy of different batches of formulation is to be observed. A preparation with better clinical efficacy has to be selected. In India, diabetes is a serious disease due to irrational food habits.[3]

The aim of this study was to formulate FDTs with sufficient mechanical integrity and to achieve faster disintegration in the oral cavity without water. To achieve this goal, MCC is used as diluent and sodium saccharin as sweetening agent for the formulation of tablets. Attempts were made to enhance dissolution rate along with faster disintegration using super disintegrants like Crospovidone, Sodium starch glycolate (SSG)and mixture of crospovidone and sodium starch glycolatein the formulation of tablets[4].

The herbal extracts of Achyranthes aspera was used in this formulation. It is a herbal formulation prepared for Asthama. Asthama is diseases characterized by shortness of breath contraction in blood vessel. The synthetic antiashthamatic agents have serious side effects like haematological effects, disease of liver, kidney and coma etc. Plant derived drugs are mostly considered to be less toxic and with fewer side effects. Therefore, search for more effective and safer herbal antiasthamatic agent has become an area of active research.[5]

Materials and Methods:

Material:

Collection of root part of Achyranthes aspera is done from Rahata, District Ahmednagar (Maharashtra). Crospovidone, Sodium starch glycolate and microcrystalline cellulose were obtained as gift sample from Loba Chemie Pvt Ltd Mumbai 40002.All other chemicals and reagent was of analytical grade.

Method:

Extraction:

The roots of plant Achyranthes aspera Linn are collected. Dried under roof & then powdered. This Powder is then placed in the soxhlet Apparatus for extraction process. 250gm of powder is placed in packing column & extraction is carried out by Petroleum ether .The extraction process is continued upto 8 cycles for 24hrs. Then the extract is dried at room temperature. This powdered extract is used for preparation of the tablet .[2]

Preparation of tablet:

Preparation of fast dissolving tablet: Herbal Fast dissolving tablets were prepared by direct compression method using various formulation additives in varying concentrations. All the ingredients were powdered separately in a clean and dry porcelain mortar and then they were passed through 60 mesh sieve. The extract and β-cyclodextrin were complexed (kneading method) and then all the additives were mixed thoroughly in an inflated polyethylene pouch in a geometric ratio of their weight. Then the powder mixture was compressed in to the tablets of 500 mg weight.

Tablet 1: Formulation table of fast disintegrating tablets of Achyranthes aspera root extract

Ingredients (mg/tablet)	F1	F2	F3	F4	F5	F6	F7	F8	F9
Extract of DI	200	200	200	200	200	200	200	200	200
B-cyclodextrin	200	200	200	200	200	200	200	200	200
Crospovidone	40	35	30	40	35	30	40	35	30
Sodium Starch glycolate	5	10	15	5	10	15	5	10	15
Microcrystalline cellulose	40	45	50	40	45	50	40	45	50
Sodium saccharin	10	10	10	10	10	10	10	10	10
Magnesium stearate	5	5	5	5	5	5	5	5	5
Talc	5	5	5	5	5	5	5	5	5

Evaluation of tablets

The tablets from all the batches were evaluated for different parameters as follows:

Weight Variation [6]

Ten tablets were selected and average weight was determined. Then individual tablets were weighed and the individual weight was compared with an average weight

Friability[7]

Pre-weighed sample of tablets was placed in the Roche Friabilator tester, which was then operated for 100 revolutions. Tablets were deducted and reweighed; tablets should not lose more than 1% of their initial weight.

Dispersion time[8]

Two tablets were placed in 100 ml of water and stirred gently until completely dispersed. A smooth dispersion was obtained which passes through a sieve screen with a nominal mesh aperture of 710 μm.

Wetting Time[9]

A piece of tissue paper (12cmx10.75cm) folded twice was placed in a Petri dish containing 10 ml of water. Containing Eosin, a water soluble dye, was added to Petri dish. A tablet was carefully placed on the surface of the tissue paper and allowed to wet completely. The time required for water to reach upper surface of the tablet was noted as a wetting time.

Disintegration Time[9]

The disintegration time of tablet was measured in water (37^0C) according to USP Disintegration test apparatus. Hardness 16 Tablets were selected at random from each formulation and Hardness was checked using Monsanto Hardness Tester.

Drug content[10]

Drug content of all the batches was determined. Six tablets were weighed and crushed with pestle in a small glass mortar. The fine powder was weighed to get 500 mg, and transferred to 250 ml conical flask containing 100 ml of Distilled water stirred for 45 min in ultra sonicator. Solution was filtered and the filtrates obtained were analyzed UV spectrophotometrically and drug content was determined.

In-vitro Dissolution[10]

The in vitro dissolution study was performed in the USP apparatus type II Aliquot equal to 5 ml of dissolution medium was withdrawn at specific interval and replaced with fresh medium for maintaining sink condition. Sample was filtered and absorbance of filtered solutions determined by UV spectroscopy. Dissolution rate was studied for all formulations.

Table 2 : Evaluation of fast disintegrating herbal tablet of Achyranthes aspera root extract

Batch	Friability (%)	Weight Variation (%)	Disintegration Time (sec)	Wetting time (sec)	Content uniformity (%)	Water absorption ratio
F1	0.558±0.016	9.467±0.024	1.246±0.030	69.8±1.04	93.438±0.020	26 ± 1.12
F2	0.338±0.017	3.447±0.096	1.789±0.067	39.0±0.95	97.527±0.094	28 ± 1.34
F3	0.548±0.240	3.396±0.022	1.811±0.098	42.4±1.15	97.875±0.097	29 ± 1.40
F4	0.911±0.019	3.41±0.098	1.791±0.065	89.0±0.85	97.489±0.098	30 ± 1.20
F5	0.954±0.026	3.499±0.064	1.78±0.239	66.0±1.35	97.451±0.065	32 ± 1.09
F6	1.58±0.098	3.319±0.067	1.805±0.027	36.4±1.48	97.587±0.027	36 ± 1.59
F7	1.3±0.022	0.974±0.243	2.072±0.101	67.8±0.35	99.353±0.019	43 ± 2.01
F8	0.55±0.066	2.431±0.023	1.909±0.249	41.7±1.45	97.905±0.249	45 ± 2.06
F9	1.5±0.242	10.001±0.236	1.123±0.096	29.1±1.05	96.394±0.032	48 ± 2.46

Table 3: In vitro drug release data of Fast Disintegrating herbal tablet

Time (min)	F1	F2	F3	F4	F5	F6	F7	F8	F9
0	0	0	0	0	0	0	0	0	0
2	10.52	15.89	9.79	8.24	12.57	15.89	12.04	10.52	8.02
4	22.85	33.21	21.38	18.18	26.91	33.21	25.88	22.85	17.73
6	30.96	43.82	29.08	24.92	36.10	43.82	34.80	30.96	24.32
8	52.34	68.44	49.70	43.64	59.17	68.44	57.50	52.34	42.73
10	67.10	82.27	64.32	57.68	73.91	82.27	72.29	67.10	56.66
12	81.29	90.04	78.70	86.23	93.33	98.04	94.93	79.29	91.20

Result and Discussion:

Physicochemical evaluation of tablets

The results of physicochemical evaluation of tablets are given in Table 2. As the material was free flowing, tablets were obtained of uniform weight due to uniform die filling. Friability was found in between 0.52-1.5%. The friability value below 2 % was an indication of good mechanical resistance of the tablet. The drug content was found to be 98.18- 102.50% which was within the acceptable limits. The disintegration time is shorter with quick wetting properties at the core of the tablets. The wetting time/dispersion time decreases with increase in the concentration of super disintegrants. The batch F6 Shows all evaluation parameter in permissible limit..

In vitro release study

Formulations F1, F4 and F7 which contains 3% super disintegrants releases 81.29%, 86.23% and 94.93% drug respectively at the end of 12 min . An increase in the drug release was observed when 3% super disintegrants used in formulations. The rapid drug dissolution might be due to easy breakdown of particles and rapid absorption of drug into the dissolution medium. The batch F6 Shows 98.04 % release shows maximum drug release among all prepared batches.

Conclusion

The prepared herbal fast dissolving tablets shows good disintegration property and dissolution rate. The comparative study of several super disintegrants yielded a conclusion that Crospovidone at 3% concentration are suitable for the preparation of Herbal fast dissolving tablets which will satisfy all the criteria and official limits.

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