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FORMULATION AND EVALUATION OF THE ORO-DISPERSIBLE TABLETS OF AMBROXOL HYDROCHLORIDE USING NATURAL DISINTEGRANTS BANANA POWDER

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Abstract

The tablet is the most broadly utilized dose frame on account of its accommodation regarding self-organization, conservativeness, and simple in assembling. The Aim of present work was to "Formulation and Evaluation of the Oro-Dispersible tablets of Ambroxol Hydrochloride using Natural Disintegrants Banana Powder". The release of formulation (F-8) was found to be 99.62 % in 18 minutes. The drug content of from the formulation (F-8) was good when compared with other with other formulations. The drug content of Ambroxol HCl was found to be 99.75 % by using UV-spectroscopy method. The in vitro disintegration of from the formulation (F-8) was good when compared with other with other formulations. The In vitro disintegration of Ambroxol HCl was found to be 47 seconds. According to the optimization of final formulation (F-8) is better than from the other formulations of Ambroxol HCl Oral dissolving tablets.

INTRODUCTION

ORO-DISPERSIBLE TABLETS(ODTs):

Oro-Dispersible tablets are increasing more unmistakable quality as a novel medication conveyance framework and rises as one of the mainstream and generally acknowledged dose shapes, particularly for pediatric patients as a result of inadequate improvement of strong and sensory system and if there should arise an occurrence of geriatric patients experiencing Parkinson's issue or hand tremors, from both pharmaceutical enterprises

and additionally patients since they are helpful to be produced and controlled, free of reactions, offering quick discharge and upgrade bioavailability , in order to accomplish better patient consistence.[1-3]

MATERIAL AND METHOD

Preparation of Oral Dissolving Tablets of Ambroxol HCl

The Oral dissolving tablets of Ambroxol HCl **(30mg)** was prepared by direct compression and wet granulation methods. Super disintegrants (Banana Powder, Sodium starch glycolate, cross povidone, cross carmellose sodium) were used in different concentration and ratio in eachformulations.9 formulations of Ambroxol HCl was prepared. Aspartame was used as main sweetener[4-7]. The preparation of Oral dissolving tablets as well as following. For formulation1and2,all ingredients were pass throw #60 mesh screen separately. The drug, super disintegrants and diluents were mixed in small proportion each time and blending it to form uniform mixture and set aside. The other ingredients were weighted and mixed in geometrical order. The 200 mg were formulated by direct compression technique using 10 station table t punching machine.[8-11] Similarily for other formulations all ingredients of granulation part were passed throw # 60andactive material passed throw # 100 mesh size and mixed well to each other. After well mixing add binder and done the granulation procedure. And keep the granulation part at 40^{o} c temperature in tray dryer. After well drying pass throw # 20 mesh size and now mixing the lubrication part in it. The lubrication part pass throw # 60 and then mixed in the granulation part. After well mixing all materials the tablets weighing 200 mg were formulate by using the 10 station punching machine, used the 7.5mmpunchforcompressed 200 mg tablet weight.[12-15]

TabletNo1:-Formula for Oral dissolves tablets of Ambroxol HCl with different concentration of super disintegrant.[16-19]

INGREDIENTs	FORMULATIONCODE								
	F-1	F-2	F-3	F-4	F-5	F-6	F-7	F-8	F-9
AmbroxolHCl	30.0	30.0	30.0	30.0	30.0	30.0	30.0	30.0	30.0
BananaPowder	2.0	3.0	2.0	4.0	8.0	8.0	10.0	12.0	14.0
DiCalciumPhosphate (DCP)	70.0	79.0	80.0	-	-	-	-	-	-
Croscarmellose Sodium	--	2.0	4.0	2.0	4.0	5.0	6.0	6.0	4.0
SodiumStarch Glycolate	-	-	1.0	2.0	-	1.0	-	-	-

LactoseMonohydrate	-	-	-	80.0	78.0	71.0	76.0	70.0	60.0
MCCPH-102	-	-	-	-	-	20.0	22.0	15.0	20.0
PVPK-30	-	0.5	1.0	1.0	2.0	1.0	2.0	2.0	2.0
IPA	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.
BananaFlavor	5.0	5.0	5.0	5.5	5.5	6.0	5.5	6.0	6.0
Colloidal Silicon DiOxide(Aerosil)	1.0	1.5	1.5	1.5	2.0	2.0	2.0	2.0	2.0
MagnesiumStearate	1.0	1.5	1.5	2.0	2.0	2.0	2.5	2.0	2.0
Mannitol(Plain)	88.5	74.0	66.5	64.5	60	43.5	34.5	45	50
CitricAcidanhydrous	-	-	4.0	3.5	4.0	5.0	4.5	4.0	4.0
Aspartame	2.0	2.5	2.5	3.0	3.5	4.0	3.0	4.0	4.0
Talcum	0.5	1.0	1.0	1.0	1.0	1.5	2.0	2.0	2.0
TOTAL(Mg)	200.0	200.0	200.0	200.0	200.0	200.0	200.0	200.0	200.0

RESULTS&DISCUSSION

Solubility Profile of Ambroxol HCl:

Solubility of Ambroxol HCl in distilled water was found to be 4.98mg/ml. The value comes under the description Slightly/Poorly soluble in water and confirm with monograph of drug.

Thickness:-(mm.)

The thickness was measured by placing tablet between two arms of theVerniercalipers.10 tablets were taken and their thickness was measured

% Friability:

The friability of the tablets was measured in a Friabilator (Harrison Pharma.). Tablets of a known weight (Wo) or a sample of 20 tablets are deducted in a drum for a fixed time (100 revolutions) and weighed (W) again. Percentage friability was calculated from the loss in weight as given in equation as below. The weight loss should not be more than 1 %. Determination was made in triplicate.

In-vitro Disintegration Study:-(Min/Sec)

The disintegration test will be implemented in USP disintegration apparatus. The set-up will be done by employing six tablets in each tube and the time necessary for the complete disintegration will be noted. It is expressed in Minutes.

Wetting Time:-

A circular tissue paper of 10cm diameter was placed in Petri dish with a 10cmdiameter; one in each after folding, 10 ml of simulated salivary solution

(Phosphate buffer pH 6.8) was poured into the tissue paper placed in the Petridis. A tablet placed carefully on the surface of the tissue paper. The time required for the solution to reach upper surface of the tablet was noted as wetting time.

%Drug-Content:-

20 tablets of various formulations will be weighed individually and powdered. The powder equivalent to average weight of tablets will weighed and drug will extracted in Phosphate Buffer Ph 6.8,the drug content will determine measuring the absorbance at 345 nm after suitable dilution using a UV/Visible Spectrophotometer according to the drug content or % drug assay study, take 50 mg standard and make the dilution of 10 ppm and similarly and take the power weight equivalent to the standard sample and make the dilution 10 ppm and determine the absorbance both of the mand calculated the% Drug-content of Ambroxol HCl(ODT).

SUMMARY AND CONCLUSION

All the formulations were subjected to physical stability testing program, under different stress condition to study the effect of temperature and humidity as per guidelines. The observation were made in respect of change in colour, size and shape, weight variation, hardness, thickness, % friability, disintegration time, % drug content. It is evident that the most of the Oral dissolving tablets of Ambroxol HCl were unaffected in respect of respect of colour, size and shape stability after storage for 3-months. No appreciable change in physical characteristic, weight variation, hardness, thickness, % friability, disintegration time, % drug content and in-vitro drug release amount was observed even after the evaluation for 3-months'storage.

Stability studies exhibited that the prepared tablets are quite stable at storage condition that is at 40°c± 2°C temperature(75 ± 5%RH).

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