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Formulation and Evaluation of dispersible tablet (ampicillin and cloxacillin)

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Abstract

Present research work planned to develop a simple economical and effective technology which yield better product in termed of improved oral absorption, faster onset of action minimized first pass effect improved bioavailability, improved compliance, contains necessarily the generally regarded as safe excipients. The drug was ampicillin and cloxacillin used to the treatment of *Gonorrhea*. The drug ampicillin and cloxacillin were tested for the bacterial infections of staphylococcus. New formulation of dispersible tablet of new combination of ampicillin and cloxacillin and evaluated to various physical parameters of tablet. T

Key-Words: Dispersible tablets, Ampicillin, Cloxacillin

Introduction

The oral route of drug administration is the most common and convenient for patient use. Tablets and capsules have emerged as the most popular solid oral dosage forms used. Novel oral drug delivery systems that dissolve or disperse quickly in a few seconds after placement in the mouth without water can alleviate the problem of swallowing tablets. They enhance the potential for improved compliance in patients. dispersible systems are defined as systems that dissolve or disintegrate within seconds to a few minutes after placement. In these cases, the bioavailability of drugs from these formulations might be greater compared to the conventional oral dosage forms. The disintegrating property of the tablet is attributable to a quick ingress of water intothe tablet matrix, which creates porous structure and results in rapid disintegration. Hence, the basic approaches to develop dispersible tablet include maximizing the porous structure of the tablet matrix, incorporating the appropriate disintegrating agent and using highly water soluble excipients in the formulation, dispersible tablet can be achieved by various techniques like direct compression.[1-3]

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An antibiotic is a powerful medication designed to kill bacteria or stop them from growing, such as an illness caused by strep throat. They cannot cure illnesses caused by viruses, such as a cold or the flu. Different antibiotics may be used for different types of bacterial infections. There are many forms of antibiotics, each designed to work against a certain type bacteria. The Antibiotics either inhibits the growth of bacteria (bacteriostatic) or actually kill the bacteria (bactericidal). By stopping the growth of bacteria, it gives the body time to mount an immune response and allows the body to eliminate the bacteria. Drugs that kill the bacteria are the preferred choice when someone has a weakened immune system and whose body cannot destroy the bacteria on its own. Antibiotics are not effective against viruses on antibiotics opriate to treat it.[4-5]

Material and Methods[5-9]

Formula of tablet

Ampicillin Sodium (145mg)
Cloxicillin Sodium (145mg)
Blending
Disintegrants
Binder
Talc (6mg)
Compression

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Preparation of batches

Preparation of batches of dispersible tablet by varying the conc. of disintegrant (D-1)

Batch No.	Drug (ampicillin & cloxacillin)	Disintegrants (D-1)	Binder (B)	Glidant (G)
F.1	145mg+ 145mg	250mg	10mg	6mg
F.2	145mg+ 145mg	270mg	10mg	6mg
F.3	145mg+ 145mg	292mg	10mg	6mg

Preparation of batches of dispersible tablet by varying the conc. of binder (B)

Batch No.	Drug (ampicillin & cloxacillin)	Disintegrants (D-1)	Binder (B)	Glidant (G)
F.3	145mg+145 mg	292mg	10mg	6mg
F.4	145mg+145 mg	292mg	12mg	6mg
F.5	145mg+145 mg	292mg	13mg	6mg

Preparation of batches of dispersible tablet by varying the conc. of disintegrant(D-2)

Batch No	Drug (ampicillin & cloxacillin)	Disintegrants (D-2)	Binder (B)	Glidant (G)
F.6	145mg+145 mg	250mg	10mg	6mg
F.7	145mg+145 mg	292mg	10mg	6mg
F.8	145mg+145 mg	322mg	10mg	6mg

Preparation of batches of dispersible tablet by varying the conc. of binder (B)

Batch No.	Drug (ampicillin & cloxacillin)	Disintegrants (D-2)	Binder (B)	Glidant (G)
.F.7	145mg+145 mg	292mg	10mg	6mg
F.9.	145mg+145 mg	292mg	12mg	6mg
F.10	145mg+145 mg	292mg	14mg	6mg

Preparation of batches of dispersible tablet by varying the conc. of disintegrant (D-3)

Batch No.	Drug (ampicillin & cloxacillin)	Disintegrants (D-3)	Binder (B)	Glidant (G)
F.11	145mg+145 mg	272mg	10mg	6mg
F.12	145mg+145 mg	292mg	10mg	6mg
F.13	145mg+145 mg	312mg	10mg	6mg

Preparation of batches of dispersible tablet by varying the conc. of binder (B)

Batch No.	Drug (ampicillin & cloxacillin)	Disintegrants (D-3)	Binder (B)	Glidant (G)
F.12	145mg+145 mg	292mg	10mg	6mg
F.14	145mg+145 mg	292mg	12mg	6mg
F.15	145mg+145 mg	292mg	14mg	6mg

Preparation of batches of dispersible tablet by varying the conc. of disintegrant(D-4)

Batch No.	Drug (ampicillin & cloxacillin)	Disintegrants (D4)	Binder (B)	Glidant (G)
F.16	145mg+145 mg	240mg + 12mg	12mg	6mg
F.17	145mg+145 mg	260mg + 12mg	12mg	6mg
F.18	145mg+145 mg	280mg + 12mg	12mg	6mg

Preparation of batches of dispersible tablet by varying the conc. of binder (B)

Batch No.	Drug (ampicillin & cloxacillin)	Disintegrants (D-4)	Binder (B)	Glidant (G)
F.18	145mg+145 mg	280mg + 12mg	12mg	6mg
F.19	145mg+145 mg	280mg + 12mg	13mg	6mg
F.20	145mg+145 mg	280mg + 12mg	14mg	6mg

Results and Conclusion

The final batch are prepared by the direct compression method & then evaluated to the physical parameter of the dispersible tablet of ampicillin & cloxcillin & preformed to the wt. variation, hardness, friability & Disintegration time of the tablet accordingly to mentioned in I.P. standard.

Evaluation of batches by varying the conc. of disintegrant (D-1)

Batch No.	Friability Test (%)n=3	Hardness Test (kg/cm2)	Disintegration Test
F.1	0.28	3.00	3.20min
F.2	0.40	2.46	3.10min
F.3	0.43	3.33	2.30min

Evaluation of batches by varying the conc. of binder (B)

Batch No.	Friability Test (%)n=3	Hardness Test (kg/cm2)	Disintegration Test
F.3	0.46	3.32	4.10min
F.4	0.34	3.44	2.38min
F.5	0.45	3.23	4.05min

Evaluation of batches by varying the conc. of disintegrant (D-2)

Batch No.	Friability Test (%)n=3	Hardness Test (kg/cm2)	Disintegration Test
F.6	0.44	3.22	20.10min
F.7	0.50	2.34	8.10min
F.8	0.48	2.54	10.00min

Evaluation of batches by varying the conc. of binder (B)

Batch No.	Friability Test (%)n=3	Hardness Test (kg/cm2)	Disintegration Test
F.7	0.33	2.89	10.10min
F.9	0.32	2.63	6.12min
F.10	0.42	2.33	15.20min

Evaluation of batches by varying the conc. of disintegrant (D-3)

Batch No.	Friability Test(%) n=3	Hardness Test (kg/cm2)	Disintegration Test
F.11	0.33	3.65	3.45min
F.12	0.53	3.54	3.15min
F.13	0.22	3.22	2.40min

Evaluation of batches by varying the conc. of binder (B)

Batch No.	Friability Test (%)n=3	Hardness Test (kg/cm2)	Disintegration Test
F.12	0.32	3.29	2.55min
F.14	0.22	2.33	3.48min
F.15	0.32	2.98	4.12min

Evaluation of batches by varying the conc. of disintegrant (D-4)

Batch No.	Friability Test (%)n=3	Hardness Test (kg/cm2)	Disintegration Test
F.16	0.36	4.32	3.05min
F.17	0.41	3.45	2.55min
F.18	0.26	4.00	2.30min

Evaluation of batches by varying the conc. Of binder **(B)**

Batch No.	Friability Test (%)n=3	Hardness Test (kg/cm2)	Disintegration Test
F.18	0.43	3.43	2.15min
F.19	0.44	3.22	3.30min
F.20	0.32	3.56	3.47min

Table 17: Comparision of batches

Batch No.	Hardness (kg/cm2)	Friability (%)n=3	Disintegration time (min)
F.4	3.44	0.34	2.38 min
F.9	2.63	0.86	6.12 min
F.14	2.33	0.22	3.48 min
F.18	3.43	o.43	2.15.min.

Table 18: Final formula are selected as F.18 because this batch pass to all parameter.

S/No.	Ingredients	Quantity taken (In each tablet)
1.	Ampicillin Sodium	(145mg)
2.	Cloxicillin Sodium	(145mg)
3.	Disintegrant (D-4)	(280mg+12mg)
4.	Binder (B)	(12mg)
5.	Glidant (G)	(6mg)

Preparation, Optimization & Evaluation

The prepatation of ampicillin & cloxacilline tablet was prepared to the varying the conc. Of the disintegrants & binder to shown in table no. 1,2,3,4,5,6,7,8. And their evaluation are shown in table no.9,10,11,12,13,14,15,16.comparision of batches are shown in table no.17 and selection of batch are shown In table no.18.

Formulation of optimize Dispersible tablet

Accordingly to optimization I was select to the final batch into the production of the dispersible and the quantity of excipients to taken are shown in table no (18)

Evaluation of Optimize batch:-

The final batch are prepared by the direct compression method & then evaluated to the physical parameter of the dispersible tablet of ampicilline & cloxcilline & preformed to the wt. variation, hardness, friability & Disintegration time of the tablet accordingly to mentioned in I.P. slandered & the tablet was successfully perform & pass the test. Optimized batch of dispersible tablet prepared to successfully and there hardness, friability of tablet were performed to I.P. & GMP limits and the batch was fulfillment of the official test for weight variation, according to I.P.& final batch of tablets was prepared to found to be disintegrate in to the water in minimum time.and their result shown in table.

The experiment was initiated with on objective of formulation & evaluation of dispersible tablet (ampicillin and cloxacillin) to the preparation of the batch of dispersible tablet are used to the direct compression method then optimized the varying the concentration of the disintegrant & binder after evaluation of bat And the batch was successfully done in to the physical parameter of the tablets i.e. the formulation & evaluation of dispersible tablet (ampicillin & closacilin) which is shown in this project work has been successfully done & its evaluation will be carried out by using optimize batch of dispersible tablet and the optimize batch was fast disintegration to the water.

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