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FORMULATION AND STABILIZATION OF ANTACID FORMULATION

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Abstract

The aim of present study was to develop Stabilized Antacid formulation without using different Suspending Agents. Sedimentation, Redispersibility and caking were the major problem in the stabilization of the antacid formulation. This challenge achieved by taking two different (F1& F2) trails batches using Sodium alginate, Sodium CMC and Xanthan Gum. Formulation (F2) obtained from the above trail batches were selected on the basis of three months accelerated stability data.

Keywords: - : Redispersibility, Sedimentation, Sodium alginate, Xanthan Gum, Sodium CMC.

Introduction

A Pharmaceutical suspension is a coarse dispersion in which internal phase is dispersed uniformly throughout the external phase. The internal phase consisting of insoluble solid particles having a specific range of size which is maintained uniformly throughout the suspending vehicle with aid of single or combination of suspending agent. The external phase (suspending medium) is generally aqueous in some instance, may be an organic or oily liquid for non oral use.[1] Sedimentation and suspension flows involve the mechanics, flow and transport properties of mixtures of fluids and solids, droplets or bubbles. Fundamental aspects of sedimentation and suspension flows include properties of suspensions and emulsions (rheology, particle size and shape, particle-particle interaction, surface characteristics, yield stress, concentration, viscosity), individual particles (orientation and surfactants). [2] Antacid are basic substances that neutralize gastric acid and raise ph of gastric contents. Antacid do not decrease acid production rather agents that raise the antral pH to > 4 evoke reflex gastrin release, more acid is secreted specially in patients with hyperacidity and duodenal ulcer "acid rebound" occurs and gastric motility is increased. The potency of antacid is generally expressed in terms of its acid neutralizing capacity. The antacids most widely used are Sodium bicarbonate, Sodium hydroxide, Magnesium hydroxide. Combinations of Mg2+ (rapidly reacting) and Al3+ (slowly reacting) hydroxides provide a relatively balanced and sustained neutralizing capacity and are preferred by most experts. Magaldrate is a hydroxymagnesium aluminate complex that is converted rapidly in gastric acid to Mg (OH) 2 and Al (OH) 3, which are absorbed poorly and thus provide a sustained antacid effect. [3]

Formulation of Antacid formulation:-

Two trials were planned in which different ratio of suspending agents were used in combination to formulate a stable formulation.

S. No.	INGREDIENTS	F1	F2
1.	Dried aluminium hydroxide gel	31.50	31.5
2.	Magnesium hydroxide	15.75	15.75
3.	Dimethicone oil	4.20	4.2
4.	Sodium methyl Paraben	1.00	1.00
5.	Sodium Propyl Paraben	0.10	0.10
6.	Sorbitol	30.00	30.00
7.	Sodium Alginate	3.00	-
8.	Xanthan Gum	3.00	2.00
9.	Sodium CMC	-	4.00
10.	Aerosil	2.00	2.00
11.	Polysorbate 80	0.50	0.50
12.	Sodium Saccharin	1.50	1.50
13.	Aspartame	1.00	1.00
14.	Potassium Citrate	4.00	4.00
15.	Menthol	0.20	0.20
16.	Propylene Glycol	10.00	10.00
17.	Colour Ponceau 4 R	0.03	0.03
18.	Flavour Peppermint	3.00	3.00

Use of Excipients: - Different excipients used in both formulations are explained on the basis of their use in the formulation.

S. No	Ingredients	Use
1.	Dried aluminium hydroxide gel	Active
2.	Magnesium hydroxide	Active
3.	Dimethicone oil	Active
4.	Sodium methyl Paraben	Preservative
5.	Sodium Propyl Paraben	Preservative
6.	Sorbitol	Base
7.	Sodium Alginate	Suspending Agent
8.	Xanthan Gum	Suspending Agent
9.	Sodium CMC	Suspending Agent
10.	Aerosil	Suspending Agent
11.	Polysorbate 80	Suspending Agent
12.	Sodium Saccharin	Sweetening Agent
13.	Aspartame	Sweetening Agent
14.	Potassium Citrate	Flocculating Agent
15.	Menthol	Soothing Effect
16.	Propylene Glycol	Stabilizer
17.	Colour Ponceau 4 R	Coloring Agent
18.	Flavour Peppermint	Flavoring Agent

Method of preparation:

1.Dissolve Sodium methyl paraben and Sodium propyl paraben in purified water with continuous stirring to get a clear solution.

2.Pass aluminum hydroxide through mess no #40 and soak into half quantity of Step no 1 for one hour with continuous stirring.

3.Pass Magnesium Hydroxide through mess no #40 and soak into half quantity of step no 1 for one hour with continuous stirring.

4.Soak Xanthan gum into hot purified water with continuous stirring to get smooth.

5.Soak Sodium CMC into Hot purified water with continuous stirring to get smooth.

6.Add step no 5 into step no 4 with continuous stirring

7.Add Polysorbate 80 into hot purified water (30-35 degree), disperse aerosol into it and Simethicone separately one by one with continuous stirring.

8.Add step no 7 into step no 4 with continuous stirring.

9.Add half quantity of Step no 4 into step no 1 with continuous stirring.

10.Add half quantity of step no 4 into step no 2 with continuous stirring.

11.Add step no 2 into step no 1 with continuous stirring.

12.Dissolve Aspartame, Sodium saccharin and Potassium citrate in hot purified water one by one with continuous stirring to get a clear solution and add into step no 1

13.Dissolve Menthol into Propylene glycol with continuous stirring to get a clear solution.

14.Add Sorbitol into step no 1 with continuous stirring.

15.Add flavor into step no 1 with continuous stirring.

16.Dissolve Colour into purified water and add into step no 1 with continuous stirring.

17.Check the pH (7.5-8.5)

18.Volume was making with purified water up to the mark.

Evaluation of Antacid Suspension [4]

Colour, odour and taste

All the developed batches of suspension were evaluated for organoleptic properties such as colour, odour and taste.

pH

pH of the suspension was determined by the use of Metler Toledo pH meter.

Viscosity

The viscosity of suspension was determined at ambient condition using DV III+, Brookfield Programmable Rheometer. In adapter 15ml of suspension was taken and the adapter is set over the viscometer by a stand such a way that spindle is completely immersed in the suspension. Spindle no.S0 was used to measure the viscosity of suspension.

Sedimentation Volume

Fifty ml each of suspension was taken in 50 ml stoppered graduated measuring cylinder. The suspension was dispersed thoroughly by moving upside down for three times. Later, the suspension was allowed to settle for three minutes and the volume of sediment was noted. This is the original volume of sediment (H0).The cylinder was kept undisturbed for 7 days. The volume of sediment read at 7 hr and every 24 hr for 7 days was considered as final volume of sediment (Hu).

Sedimentation Volume (F) = Hu/ Ho

The ultimate height of the solid phase after settling depends on the concentration of solid.

Redispersibility

Fixed volume of each suspension (50 ml) was kept in stoppered cylinder which was stored at room temperature for 7 days. At regular interval, one stoppered cylinder was removed and moved upside down until there was no sediment at the bottom of the cylinder.

Assay of Oral Taste Masked Suspension

Suspension (5ml) was taken in 100 ml volumetric flask, 0.1 M HCl was added into it & sonicated it for 10 min. Volume was made up to 100 ml with 0.1 M HCl & filtered. Samples were prepared in Particle size. To obtain an acceptable suspension, F should be at least 0.9 for 1h but a longer period was preferred for our purpose.

Accelerated stability study:-

F2 suspension was packed in 200 ml Pet bottle. The packed bottles were placed in stability chamber maintained at 40 + 2 °C and 75 + 5% RH for 3 month. Samples were collected at days 0, 30, 60 and 90. The analyses comprised chemical testing of quantifiable parameters, which could possibly change during storage, such as viscosity, pH, drug contents, sedimentation volume, Redispersibility, colour, taste, odour and drug release.

Results :-

Evaluation of Antacid Suspension

Evaluation of Antacid was carried out for various parameters like confirmation of formation of complex, pH, odour, and taste, Viscosity, Sedimentation Volume, Redispersibility and assay.

S. No.	Parameters	F1	F2
1.	Colour	Light Pink	Light Pink
2.	Odour	Peppermint	Peppermint
3.	Taste	Sweet	Sweet
4.	pH	8.0	7.6
5.	Viscosity	8225	8231
6.	Sedimentation on volume	1.50	0.70
7.	Redispersibility	+++	+++
8.	Assay of Aluminum hydroxide	99.4%	99.8%
9.	Assay of Magnesium hydroxide	98.9%	99.2%
10.	Assay of Dimethicone	99.0%	99.3%

Accelerated Stability Studies

S. No.	Parameters	Initials	time periods		
			1 month	2 month	3 month
1.	Colour	Light Pink	Light Pink	Light Pink	Light Pink
2.	Odour	Peppermint	Peppermint	Peppermint	Peppermint
3.	Taste	Sweet	Sweet	Sweet	Sweet
4.	pH	7.6	7.8	7.8	8.0
5.	Viscosity	8231	8200	8180	8169
6.	Sedimentation Volume	+++	+++	+++	+++
7.	Redispersibility	0.70	0.77	0.80	0.81

Conclusion

The Antacid final Batch (F2) prepared with Xanthan Gum and Sodium CMC showed the satisfactory result in every aspect of evaluation parameters and stability criteria in comparison with other formulation.

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