WORLD JOURNAL OF PHARMACEUTICAL RESEARCH
SJIF Impact Factor 7.523
Volume 6, Issue 15, 716-721. Research Article ISSN 2277– 7105

PREPARATION AND BIOLOGICAL STANDARDIZATION OF ANTACID FORMULATION

Joshi Dinbandhu*, Jain Yogita, Malviya Sapna and Kharia Anil

Modern Institute of Pharmaceutical Sciences, Indore.

Article Received on
29 Sept. 2017,
Revised on 19 Oct. 2017,
Accepted on 09 Nov. 2017
DOI: 10.20959/wjpr201715-10080

***Corresponding Author**
Joshi Dinbandhu
Modern Institute of Pharmaceutical Sciences, Indore.

ABSTRACT

Antacids are commonly used self-prescribed medications. It consist of calcium, magnesium and aluminium salts in various combinations. The effect of antacids on the stomach is due to partial neutralization of gastric hydrochloric acid and inhibition of the proteolytic enzyme, pepsin. Herbal antacids are also one of the major classes of over the counter drugs used by patient considering its safety. Hence, in present study we attempted to prepare two formulations, one is aluminium hydroxide suspension and second is combination of calcium carbonate and magnesium oxide suspension as well as compares this by marketed formulation through antacid activity using in vitro methods viz- acid-Neutralizing capacity and buffering capacity. From the results of present study, it may be concluded that our both formulations possess more antacid potential than marketed formulation.

KEYWORDS: Antacid, Suspension, Formulation.

INTRODUCTION

Antacids are chemical substances which react with gastric acid and neutralize the gastric contents. Gastric acidity occurs due to excessive secretion of HCl in stomach due to various reasons. The pH of the stomach is 1.5- 2.5 when empty and raises to 5- 6 when food is ingested. Low pH is due to the presence of endogenous HCl, which is always present under physiological conditions. When hyperacidity occurs the result can range from: (1) Gastritis (a general inflammation of gastric mucosa) (2) peptic ulcer or oesophageal ulcer (3) gastric ulcer (4) duodenum ulcers.[10]

Peptic ulcers occur due to defective oesophageal sphinter as inhiatal hernia. Gastric ulcers occur in lesser curvature and are found in first portion of duodenum. Symptoms include

uncomfortable feeling from over eating, heart burn and growing hungry between meals. Complications involved are hemorrhage (being more common with duodenal ulcers), perforation. Meals help in reducing acidity, stimulants of gastric acid must be avoided like coffee, alcohol, spicy food, oil or fried food.[1]

Classification of Antacids[8]

1. **Systemic (absorbable) antacids –** which are soluble, readily absorbable and capable of producing systemic electrolytic alterations and alkalosis. E.g. sodium bicarbonate.
2. **Non-systemic (non-absorbable) antacids** – which are not absorbed to a significant extent. This group is further sub-divided into following –

(i) Aluminum containing antacids – Aluminum hydroxide, Aluminum phosphate

(ii) Calcium containing antacids – Calcium carbonate, Tribasic calcium phosphate

(iii) Magnesium containing antacids – Magnesium carbonate, Magnesium oxide

(iv) Combination antacid preparations – Simethicone (defoaming agent).

Suspension

A Pharmaceutical suspension is a biphasic system composed of finely divided solid material suspended in a liquid medium. The average size of suspended particles range from 0.5 µg to 5 µg in most of the pharmaceutical suspension.[6,13] Suspension essentially facilitates the administration of insoluble and often distasteful substances which is pleasant in taste. They also provide a suitable from for the application of dermatological materials to the skin and mucous membrane. Insoluble drug can also be formulated as parental suspension. Some of the lotions, magmas and mixtures and suspensions.[17]

Evaluation Parameter

Particle size control: - Particle size of any suspension is critical and must be reduced within the range. Too large or too small particles should be avoided. Larger particles will settle faster at the bottom of the container and impart a gritty texture to the product and also cause irritation if injected or instilled to the eye particles may block the needle.[2]

Theory of sedimentation: - Sedimentation means settling of particle (or) floccules occur under gravitational force in liquid dosage form. Sedimentation velocity in cm / sec. Velocity of sedimentation expressed by Stroke's equation expressed.[12,14]

$$V_{sed.} = \frac{d^2(\rho_s - \rho_o)g}{18\eta_o} = \frac{2r^2(\rho_s - \rho_o)g}{9\eta_o}$$

Where,

d = Diameter of particle,

r = radius of particle used.

ρ_s= density of disperse phase

ρ_o= density of disperse media

g = acceleration due to gravity

η_o = viscosity of disperse medium in poise.

Sedimentation parameters: - Sedimentation volume is a ratio of the ultimate volume of sediment (Vu) to the original volume of sediment (VO) before settling.

F = V u / VO

Where, Vu = final or ultimate volume of sediment VO = original volume of suspension before settling F has values ranging from less than one to greater than one.[5]

MATERIAL AND METHODS

Formula 1[2]/[3]

S.No.	Ingredients	Quantity	Uses
01.	Aluminum hydroxide gel	36 gm	Suspending agent
02.	Sorbitol/ manitol	7 gm	Sweeteners
03.	Methyl paraben	0.2 gm	Preservative
04.	Propyl paraben	0.02 gm	Preservative
05.	Sodium saccharine	0.05 gm	Preservative
06.	Peppermint oil	0.005 gm	Cooling and flavoring agent
07.	Alcohol	1 ml	Co solvent
08.	Purified water	100 ml	Solvent

Formula 2[2]/[3] -

S.No.	Ingredients	Quantity	Uses
01	Magnesium oxide	18 gm	Suspending agent
02	Calcium carbonate	18 gm	Suspending agent
03	Sorbitol/ manitol	7 gm	Sweeteners
04	Sodium saccharin	0.2 gm	Preservative
05	Methyl paraben	0.02 gm	Preservative
06	Propyl paraben	0.05 gm	Preservative
07	Peppermint oil	0.005 gm	Cooling and flavoring agent
08	Alcohol	1 ml	Co solvent
09	Purified water	100 ml	Solvent

Procedure

Firstly suspending agent and sorbitol dissolve in purified water. Take another beaker and add methyl paraben, propyl paraben, peppermint oil and sodium saccharin dissolved in alcohol. Finally alcohol phase dissolved in water phase and make up the volume with purified water up to 100 ml.[5]

Antacid activity

1. Acid-Neutralizing Capacity (ANC): 5 ml of each formulation were transferred to 250 ml beaker and 70 ml distilled water was added to it. It was mixed with magnetic stirrer for 1 min. Then 30 ml of 1 N HCl was added to the test solutions with continuous stirring for 15 min. Excess HCl was titrated with 0.5 N NaOH to attain a stable pH of 3.5. The number 0f mEq of acid consumed was calculated by formula:

Total mEq= (30 X N_{HCl}) - (V_{NaoH} X N_{NaoH})

Where N_{HCl} and N_{NaOH} are normality of hydrochloric acid and sodium hydroxide respectively and V_{NaOH} is volume of sodium hydroxide and the result were expressed as total mEq per gm of substance.[4,17,18]

2. Buffering Capacity (BC): 5 ml of each formulation was added to 100 ml of 0.1N HCI and kept at 37^{o}C with constant stirring. The pH of the mixture was determined after the intervals of 0,1,4,8 and 10 minutes. A quantity of 20 ml of the mixture was then removed by a pipette and replaced by 20 ml fresh 0.1N HCI. The process was repeated at 10 minutes interval until a pH below 2.75 was reached which shows that the buffering power of antacid was spent out.[7,17,18]

RESULT AND DISCUSSION

Acid neutralizing capacity and the buffering capacity of selected preparation were calculated and tabulated in table 3 and 4 respectively. In Acid neutralizing capacity test, Formulation 1-4 consumed significantly high amount of acid compared to each another. On the basis of ANC, these products are ranked as F 4> F3 > F 1> F2 for their acid neutralizing capacity. In buffering capacity test, the time at which pH falls below 2.75 was used as measure of buffering capacity wherein F3 showed pH below 2.75 and F4 showed pH below 2.75 between 10 to 15 minute intervals.

Table 3:- Acid neutralizing capacity of formulation.

Antacid formulations	mEq of acid consumed
F1 (Gleusil)	29.5
F2 (Himcocide)	26.5
F3 (Formula 1)	29.6
F4 (Formula 2)	29.6

Table 4:- Buffering capacity of formulations.

pH at time interval of minutes	Formulations			
	F1	F2	F3	F4
01 min.	01	01	2.5	03
04 min.	01	01	2.5	03
08 min.	01	01	2.5	03
10 min.	01	01	2.5	03
15 min.	-	1	2	2.5
20 min.	-	-	-	-

CONCLUSION

Thus it may be concluded that F3 and F4 possess more antacid potential than F1 and F2 wherein the formulation has shown varying results in acid neutralizing capacity and buffering capacity tests which may be associated with its composition may be acting synergistically while other may be antagonistic in action. The biological standardization is most importance in quality control of herbal medicine to establish its efficacy.

REFERENCES

1. www.srmuniv.ac.in/sites/default/files/downloads/Antacids.pdf
2. Upma, Pawan Jalwal, Balvinder Singh, Sneh Lata, Priti Mehndiratta. Formulation and Stabilization of Antacid Formulation. April-2015; 6(2): 1226-1229.
3. Subramanyam C.V.S. Text Book of Physical Pharmaceutics. 2nd ed., Page No. 374-387.
4. United States Pharmacopoeia (USP29). The United states Pharmacopoeial Convention, Rocville, 2006; 2561.
5. Indian pharmacopoeia. A govt. of India ministry of health and family welfare. Indian pharmacopoeia commission. Page no. 788: 2010.
6. Lachman leon. The theory and Practice of Industrial Pharmacy. 1st ed., CBS Publisher Pvt. Ltd. New Delhi, Page No. 534: 2011.
7. PRP Verma, A Shrivastava, A Pathria. Ancient Science of life, 1996; 2: 152 -155.
8. SK Pal; Y Shukla. Asian Pacific J of Cancer Prevention, 2003; 4: 281-288.
9. Dr. Uttam Singh Baghel, Pharmaceutical inorganic chemistry, 1st ed., S. Vikash and comp. Punjab: 2017; 64-68.

10. S. Sandhya, K Venkata Ramana, KR Vinod; R Chaitanya. Asian Pacific Journal of Tropical Biomedicine, 2012; S1487- S1492.
11. Aulton M. E. Second edition, "Suspension" Pharmaceutics. The Science of Dosage Form Design, Churchill Livingstone, Edinburgh, 2002; 273: 84-86.
12. Martin A. Fourth edition, "Coarse dispersion" Physical Pharmacy, Lippincott Williams and Wilkins, Philadelphia, 2001; 479 - 481.
13. Remington, "Colloidal Dispersions" The Science and Practice of Pharmacy, 20th ed., Lippincott Williams and Wilkins, Philadelphia, 2000; 298-307.
14. Cooper & Gun, Sixth edition, "Dispersed system" Tutorial Pharmacy, Page No. 75-78.
15. Ansel C., Allen L.V., Popovich N.G. Eighth edition "Disperse systems" Pharmaceutical Dosage Forms & Drug Delivery Systems, Lippincott Williams and Wilkins, Philadelphia 2005; 398: 387-389.
16. N. K. Jain, S. N. Sharma "A Textbook of Professional Pharmacy" 1st Edition 2015, vallabh Prakashan Industrial State G T Karnal Road, Delhi, Page No. 283.
17. Ingale Suvarna, Anisha Kumari, Patel Jeenal, Patel Tejas, Ingale Pramod. Biological standardization of some polyherbal formulations for antacid activity. Scholars Research Library, 2014; 6(1): 83-86.