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FORMULATION AND EVALUATION OF ALBENDAZOLE SUSPENSION

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Abstract

Albendazole is an Anthelmintic agent used in the treatment of human intestinal helmintiasis as well as other infections. The formulation developed for Albendazole showed in this paper on the basis of three trials in which Xanthan gum, Sodium CMC, Sorbitol, Sugar are used in different concentration and also in combination. Evaluation done on the basis of the parameters like Redispersability, Sedimentation, Odor, Taste etc.

Keywords: - Suspension, Redispersability, Sedimentation, Stability Studies.

Introduction

Oral suspensions are oral liquids containing one or more active ingredients suspended in a suitable vehicle. Suspended solids may slowly separate on standing but are easily redispersed. Albendazole is an anthelmintic. [1] It prevents newly hatched insect larvae (worms) from growing or multiplying in your body. Albendazole is used to treat certain infections caused by worms such as pork tapeworm and dog tapeworm. [2] Its IUPAC name was Methyl [5-(propylthio)-1H-benzoimidazol-2-yl]carbamate.[3]

Oral suspensions are highly used now days in children. Another benefit in case of development is that it will not require drug to be soluble or in other way we can say that practically insoluble drugs can be administered by this formulation type. [4]

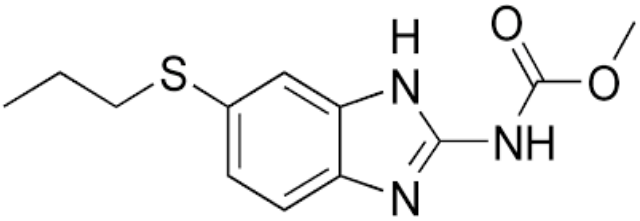

Figure no 1: - Structure of Albendazole.

Material And Methods: -

Albendazole was obtained from Drugs & chemicals Pvt. Ltd. as a gift sample. Xanthan Gum (Germany), Sodium CMC and Sodium Alginate were purchased from S.D. Fine chemicals limited, Mumbai. All the chemicals used were of analytical grades.

Formulation Of Suspension: -

Three different trials were planned to develop the formulation. In this Base (Sorbitol and sugar) and Suspending Agent (Xanthan Gum, Sodium CMC) were used in different concentration to develop the formulation and it is shown in table no 1.

Table no 1: - Three different trails of Formulation

s.no	Ingredients	F1	F2	F3
1	Albendazole	40.00	40.00	40.00
2	Sodium CMC	5.00	-	3.00
3	Xanthan Gum	-	3.00	0.50
4	Sorbitol	300.00	-	300.00
5	Sugar	-	500.00	-
6	Glycerin	-	-	50.00
7	Sodium methyl paraben	1.00	1.00	1.00
8	Sodium propyl paraben	0.10	0.10	0.10
9	Bronopol	0.10	0.10	0.10
10	Sodium saccharin	1.00	1.00	1.00
11	Sodium citrate	2.00	2.00	2.00
12	Citric acid	3.00	3.00	3.00
13	Quinoline yellow	0.05	0.05	0.05
14	Flavour Mango	5.00	5.00	5.00

Use Of Excipients: -

Different types of excipients are used for the development so their used explained down in the table.

Table No 2: - Use of excipients.

S.NO	INGREDIENTS	USE
1	Albendazole	Active
2	Sodium CMC	Suspending Agent
3	Xanthan Gum	Suspending Agent
4	Sorbitol	Base
5	Sugar	Base
6	Glycerin	Stabilizer
7	Sodium methyl paraben	Preservative
8	Sodium propyl paraben	Preservative
9	Bronopol	Preservative
10	Sodium saccharin	Sweetening Agent
11	Sodium citrate	Alkalizer
12	Citric acid	Acidifier
13	Quinoline yellow	Coloring Agent
14	Flavour Mango	Flavoring Agent

Procedure: -

1.Take 100ml purified water. Dissolve Sodium methyl paraben, Sodium propyl paraben, Bronopol, Sodium citrate, Sodium saccharin one by one with continuous stirring.

2.Soak Sodium CMC in hot purified water with continuous stirring until get smooth and add into step 1.

3.Soak Xanthan gum into hot purified water with continuous stirring until get smooth and add into step no 1.

4.Add Sorbitol and Glycerin into step no 1 with continuous stirring.

5.Dissolve Colour Quinoline yellow into purified water and add into step no 1 with continuous stirring.

6.Add Mango flavor into step no 1 with continuous stirring.

7.Adjust the pH with citric acid in between 4.5 to 5.5

8.Volume was making up with purified up to 1L.

Evaluation Of Antacid Suspension: - [5,6]

1.Determination of pH

The pH value conventionally represents the acidity or alkalinity of an aqueous solution. The pH value of a solution was determined potentiometrically by means of glass electrode. A digital pH meter was allowed to stabilize. Then the pH meter was standardized using buffer tablets. The suspension formulation was placed in the pH meter. The reading was noted when there is no fluctuation in the pH meter.

2.Determination of Weight per ml

A pre weighed 25ml volumetric flask was taken and the oral suspension was added up to the mark. The net volume was noted. Then weighed the above volumetric flask to evaluate weight per ml. Calculated the density accordingly.

3.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.

4.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. Signs that show the stage of redispersability are + (OK), ++ (Good), +++ (Very Good).

5.Accelerated stability study

F3 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: -

1. Evaluation of Suspension: -

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

Table no 3: - Evaluation of suspension on the basis of different parameters.

S.NO	PARAMETERS	F1	F2	F3
1.	Colour	Light yellow	Light yellow	Light yellow
2.	Odour	Mango	Mango	Mango
3.	Taste	Sweet	Sweet	Sweet
4.	pH	4.8	5.0	4.9
5.	Viscosity	7895	7794	8278
6.	Sedimentation on volume	0.98	0.89	0.70
7.	Redispersibility	+	++	+++

Accelerated Stability Studies: -

Table no 4: - Data of stability studies for Final Formulation (F3)

S.NO	PARAMETERS	INITIALS	TIME PERIODS		
			1 MONTH	2 MONTH	3 MONTH
1.	Colour	Light yellow	Light yellow	Light yellow	Light yellow
2.	Odour	Mango	Mango	Mango	Mango
3.	Taste	Sweet	Sweet	Sweet	Sweet
4.	pH	4.9	4.95	5.00	5.10
5.	Viscosity	8278	8234	8180	8100
6.	Sedimentation Volume	0.70	0.75	0.80	0.85
7.	Redispersibility	+++	+++	+++	+++

conclusion: -

The final Batch (F3) prepared with two different combination in which one is combination of Xanthan Gum and Sodium CMC and another is use of Sorbitol showed satisfactory result in every aspect of evaluation parameters and stability criteria in comparison with other formulation. So on the basis of above F3 formulation was selected.

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