# Formulation And Evaluation Of Oral Suspension For The Treatment Of Giardia Infestation.

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***Abstract-*** *In the present work, an attempt was made to formulation and evaluation of oral suspension for treatment of giardia infestation using lauric acid, Na CMC, xanthan gum, HPMC, span 20, glycerin, methyl paraben, propyl paraben. The result of this study showed that lauric acid can be formulated as an oral stable oral suspension. Formula SXG3 was the best formula since it showed good release rate , optimum sedimentation volume in addition to being easily dispersed.*

***Keywords***- G. Lamblia, oral suspension, Lauric acid.

## I. INTRODUCTION

Giardiasis is caused by protozoan parasite giardia lamblia. Giardia exist in cyst and trophozoite forms.[1] G. Duodenalis transmitted through fecal contamination from person to person. Direct observation test is the identification test of trophozoites and cysts.[2]

Major constituents for preparation of oral suspension : [3,4]

1. Wetting agent
2. Vehicle
3. Suspending agent and viscosity modifier
4. Preservatives

Advantages of suspension as a drug delivery system : [5,6,7]

1. Unstable drugs easily administered in solution form.
2. If drug is water insoluble then suspension is substitute for this.
3. Controlled rate of delivery in injections- Intra muscular, sub cutaneous.[8]

## II. MATERIAL AND METHOD

**Experimental work :**

The experiment was divided into the following parts :- A) Characterization of lauric acid. B)Characterization of excipients. C) Formulation of suspension. D) Evaluation of suspension.

**A) Characterization of lauric acid : [9]**

1) Organoleptic properties ,
2) Physicochemical characteristics ( Solubility in different solvents).
3) Spectrophotometric characterization using - [10]
a) UV visible spectrophotometry. b) IR spectrometry
4) Determination of thermal behavior -

**B) Characterization of excipients :**

I) Characterization of suspending agents and viscosity modifier [11,12,13,14,15]

The suspending polymers HPMC, Na CMC and xanthan gum were characterized as for -

1) Organoleptic properties
2) Spectrophotometric characterization using – IR spectrometry
3) Thermal behavior - melting range.

II) Characterization of glycerin [16]

1) Organoleptic properties
2) Determination of solubility of glycerin in different solvents.
3) Determination of specific gravity.

III) Characterization of wetting agent ( Span 20) [17]

1) Organoleptic properties
2) Determination of solubility of sorbitan monolaurate.
3) Determination of specific gravity.
4) Determination of acid value.
5) Determination of sapnofication value.
6) Determination of HLB value.

IV) Characterization of antimicrobial preservatives [18,19]

1) Organoleptic properties
2) Physicochemical characteristics
3) Melting point.

**C) Formulation of suspension :**

The work is divided into following parts –

1) Formulation of placebo suspension using different suspending agent.
2) Formulation of suspension using selected suspending agents.
3) Evaluation of suspension of lauric acid suspension.

**1) Formulation of placebo suspension using selected suspending agent and vehicle**

| Sr. No. | Name of ingredient | Role of ingredient | %w/w |
|---|---|---|---|
| 1 | Xanthan gum | Suspending agent and viscosity modifier | 0.05 - 0.5 |
| 2 | HPMC | Suspending agent and viscosity modifier | 1 - 2 |
| 3 | Na CMC | Suspending agent and viscosity modifier | 0.1 - 5 |
| 4 | Glycerin | Thickening agent | 10 |
| 5 | Span 20 | Wetting agent | 2.5 |
| 6 | Methyl paraben | Anti- microbial | 0.2 |
| 7 | Propyl paraben | Anti - microbial | 0.03 |
| 8 | Amaranth | Coloring agent | 0.02 |
| 9 | Cherry | Flavouring agent | 0.03 |
| 10 | Water | Aq. Phase | Q.S. up to 100 ml |

**2) Formulation of suspension of lauric acid taking increasing conc. of selected suspending agents.**.

| Sr. No. | Name of ingredient | SXG1 | SXG2 | SXG3 |
|---|---|---|---|---|
| 1 | Xanthan gum | 0.05 | 0.25 | 0.5 |
| 2 | Span 20 | 2.5 | 2.5 | 2.5 |
| 3 | Glycerin | 10 | 10 | 10 |
| 4 | Methyl paraben | 0.2 | 0.2 | 0.2 |
| 5 | Propyl paraben | 0.03 | 0.03 | 0.03 |
| 6 | Amaranth | 0.02 | 0.02 | 0.02 |
| 7 | Cherry | 0.03 | 0.03 | 0.03 |
| 8 | Purified water (q.s.) to make | 100 | 100 | 100 |

Formulation of placebo suspension containing increasing concentration of HPMC

| Sr. No. | Name of ingredient | SHPMC1 | SHPMC2 | SHPMC3 |
|---|---|---|---|---|
| 1 | HPMC | 0.5 | 1 | 2 |
| 2 | Span 20 | 2.5 | 2.5 | 2.5 |
| 3 | Glycerin | 10 | 10 | 10 |
| 4 | Methyl paraben | 0.2 | 0.2 | 0.2 |
| 5 | Propyl paraben | 0.03 | 0.03 | 0.03 |
| 6 | Amaranth | 0.02 | 0.02 | 0.02 |
| 7 | Cherry | 0.03 | 0.03 | 0.03 |
| 8 | Purified water (q.s.) to make | 100 | 100 | 100 |

Formulation of placebo suspension containing increasing concentration of Na CMC.

| Sr.No. | Name of ingredient | SSCMC1 | SSCMC2 | SSCMC3 |
|---|---|---|---|---|
| 1 | Sodium CMC | 0.1 | 1 | 2 |
| 2 | Span 20 | 2.5 | 2.5 | 2.5 |
| 3 | Glycerin | 10 | 10 | 10 |
| 4 | Methyl paraben | 0.2 | 0.2 | 0.2 |
| 5 | Propyl paraben | 0.03 | 0.03 | 0.03 |
| 6 | Amaranth | 0.02 | 0.02 | 0.02 |
| 7 | Cherry | 0.03 | 0.03 | 0.03 |
| 8 | Purified water (q.s.) to make | 100 | 100 | 100 |

**3) Formulation of Lauric acid suspension :**

| Sr. No. | Ratios (%w/v) Quantity taken | Lauric acid | Primary suspension |
|---|---|---|---|
| 1 | XG1 | 50 | SXG1 |
| 2 | XG2 | 50 | SXG2 |
| 3 | XG3 | 50 | SXG3 |
| 4 | HPMC1 | 50 | SHPMC1 |
| 5 | HPMC2 | 50 | SHPMC2 |
| 6 | HPMC3 | 50 | SHPMC3 |
| 7 | SCMC1 | 50 | SSCMC1 |
| 8 | SCMC2 | 50 | SSCMC2 |
| 9 | SCMC3 | 50 | SSCMC3 |

**D) Evaluation of suspension :** [20,21,22]

The suspensions of Lauric acid were evaluated for following parameter : - 1) Physical examination 2) pH 3) Viscosity 4) Determination of sedimentation volume 5) Assay

of Lauric acid 6) Particle size analysis 7) In vitro dissolution study 8) Differential Scanning calorimetry 9) Zeta potential [23]10) Efficacy test 11) Accelerated stability study

## III. RESULTS AND DISCUSSION

### A) Characteristics of Lauric acid :-

1) Organoleptic characteristics : [24]

| Sr. No | Characteristics | Reported | Experimental findings |
|---|---|---|---|
| i. | Physical state | Solid | Solid |
| ii. | Appearance | A crystalline powder | A crystalline powder |
| | **Organoleptic characteristics** | | |
| iii. | Color | White | White |
| iv. | Odor | Like oil of bay | Like oil of bay |
| v. | Taste | Soapy | Soapy |

2) Physicochemical characteristics :-

| Sr. No. | Test | Reported | Experimental finding |
|---|---|---|---|
| 1 | Alcohol | Soluble | Soluble (clear colorless solution) |

3) Spectral characteristics :-

a) UV Visible spectrometry :- [25]

I) λ max in hydro-alcoholic solvent system: (distilled water: alcohol) (6:4) :
The $\lambda_{max}$ of Lauric acid in distilled water : alcohol was nm (chromospheres C=C, C=O, and aromatic ring). The standard value is 256 nm.

II) Calibration curve of Lauric acid in hydro-alcoholic solvent system (6:4)
The standard calibration curve of Lauric acid in alcohol and distilled water was found to be linear over the range of 10- 50 µg/ml.

III) $\lambda_{max}$ in phosphate buffer saline pH 7.4: alcohol (6:4):
The $\lambda_{max}$ of Lauric acid in phosphate buffer : Alcohol is 256 nm. The reported value is 252- 256 nm.

IV) Calibration curve of Lauric acid in phos. buffer (pH 7.4): alcohol (6:4)

The standard calibration curve of Lauric acid in phosphate buffer saline: alcohol (6:4): was occur to be linear in between of 10- 50 µg/ml.

V) λ max in phosphate buffer pH 6.8: alcohol (6:4):
The $\lambda_{max}$ of Lauric acid in phosphate buffer pH 6.8: Alcohol is 256 nm.The reported value is 252- 256 nm.

VI) Calibration curve of Lauric acid in phos. buffer pH 6.8: ethanol
The standard calibration curve of Lauric acid in phosphate buffer saline Ph 6.8: ethanol (6:4): was found.

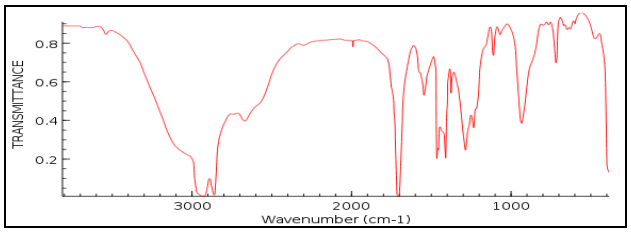
VII) λ max in 0.1N HCl: alcohol (6:4) :
The $\lambda_{max}$ of Lauric acid in0.1N HCl: Alcohol is 256 nm. The reported value is 252- 256 nm.

VIII) Calibration curve of Lauric acid in 0.1N HCL : ethanol (6:4):

The standard calibration curve of Lauric acid in0.1N HCl : Alcohol (6:4): was occur linear.

b) IR Spectrometry : - [26, 27]

**Interpretation of infrared (IR) spectrum of Lauric acid:**




| Sr. No. | Peak Point | Observed Frequency ($cm^{-1}$) | Probable functional group and type of molecular vibration |
|---|---|---|---|
| 1 | 1 | 2960 | C-H stretching $CH_3$ group |
| 2 | 2,3 | 2920,2855 | C-H stretching $CH_2$ group |
| 3 | 4 | 2660 | O-H stretching hydroxyl group |
| 4 | 5 | 1680 | C=O stretching carboxylic group |

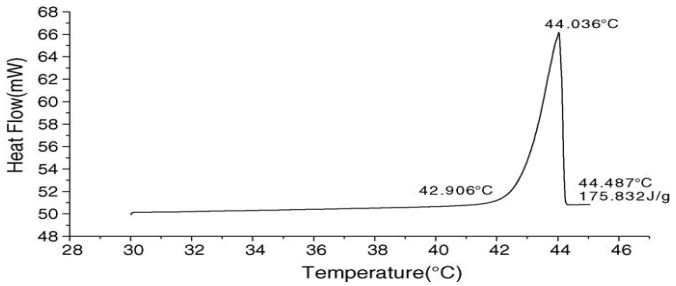
4) Thermal behavior :-

**Melting range:**

The melting point of Lauric acid is in between $45^0$C-$50^0$C. The reported value is $44^0$C –$46^0$C.

**Differential Scanning Colorimetry (DSC):**

There is single peak no additional.




**B) Characteristics of excipients :-**

**I) Characteristics of suspending agent: -** [28,29,30]
**II) Characteristics of thickening agent :** [31]
**III) Characteristics of Wetting agent :-** [32,33]
**IV) Characteristics of preservatives :-** [34,35]

**C) Characteristics of suspension :-**

**I)** All the suspensions formulations of Lauric acid were red colored liquid due to Amaranth with sweet in taste.

**II ) pH :** The pH of suspension ranged between 4.0-5.0 which can be considered acceptable. Since normal $p^H$ of small intestine is 4.0-7.0.

**III) Viscosity :-** The viscosity of suspension was in the order of **Xanthan gum > HPMC > Sodium CMC.** Formulation SXG3 have high viscosity tan other formulations.

**IV) Sedimentation volume :-** Sedimentation value is between in 0 to 1 limits. The sedimentation volume of **Xanthan gum > HPMC > sodium CMC.**

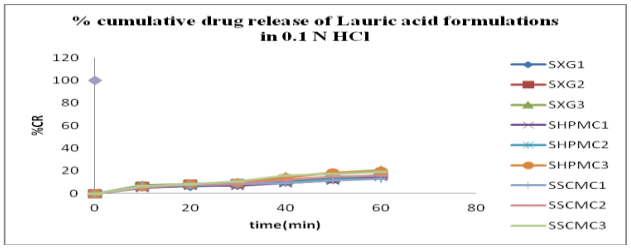
**V) Re dispersion analysis :-** The effect of redispersion was xanthan gum formulations was 100% redispersion was observed.

**VI) Drug content:** Drug content of Lauric acid was evaluated. This analysis was done by UV spectroscopy method. All formulations indicated the contents of Lauric acid in the range 94.5-98.5%.

**VII) Particle size analysis:** Particle size analysis is done by microscopic technique.
The SXG3 formulation particle is in between 5 to 30 which is good size for preparing stable suspension.

**VIII) Dissolution (in vitro) of Lauric acid :**

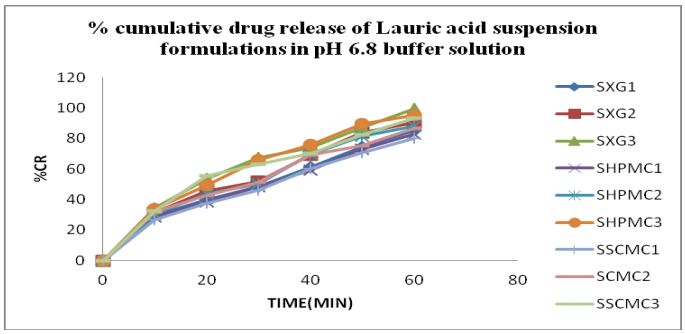
**a. Effect of Dissolution study in 0.1N HCl (pH 2.0)**




At pH 2.0 (0.1N HCl) showed lesser than 20% drug release in 60 min and for 3 hours does not showed a significant increase in drug release

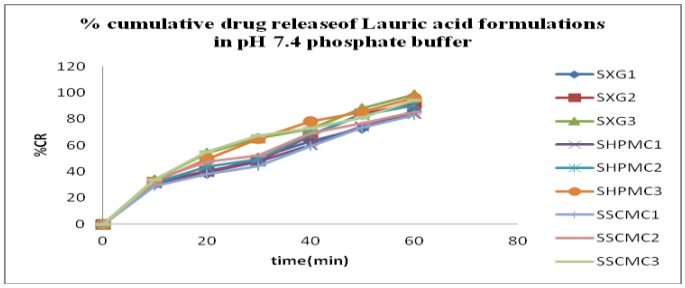
**b) Effect of Dissolution study in pH 6.8 phosphate buffer:**

High amount of drug is released at pH 6.8 in 60 min. 80%-99% drug release occur in all formulations.




**c) Effect of dissolution study in pH 7.4 phosphate buffer:**

In this study observed same release effect of Lauric acid over suspension agent as xanthan gum > HPMC > Na CMC.

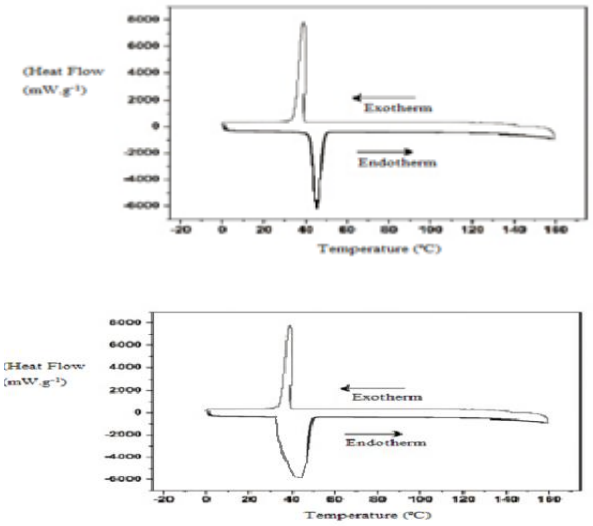



**The formulation SXG3 was selected for further characterization :**

1) Appearance 2) Particle size 3) Viscosity 4) Sedimentation 5) Drug content 6) In vitro dissolution study.

**IX) Particle size analysis :-** Sample was characterized on a Malware zeta seizer 2000 and was found to have a median particle size of 3.7 µm.

**X) DSC of Lauric acid :-** The DSC graph of physical mixture indicates that the slight change in endothermic peak towards left side indicates the slight change in M.P. as compared to that of Pure drug.




**XI) Zeta potential determination :** The implication for this study is that, Xanthan gum (SXG3)-containing formulations were stable (their electro kinetic property being more electronegative than SCMC or HPMC). The SXG3 formulation was stable

**XII) Efficacy test :-** In this efficacy test the Red worms motility was some worms are paralyzed and some are dead.

**XIII) Stability :-**The formulation does not show changes in parameters like appearance, taste, Ph, viscosity, % drug content & % CDR.

| No. of Red worms taken | Fresh SXG3 sample | Stability SXG3 sample | time |
|---|---|---|---|
| 10 |  |  | 1 min |
| 50 |  |  | 2 min |
| 75 |  |  | 2 min 30 sec |
| 100 |  |  | 3 min |

## REFERENCES


[1] Hawrelak j. Giardiasis: pathophysiology and management. Alternative medicine review 2003; 8(2): 129-32

[2] Giardiasis. The center for food security and public health. 2012 dec; 1-13.

[3] Subramanyam c.v.s. "suspensions" text book of physical pharmaceutics. 2nd ed. P. 374-87

[4] Ansel c, allen lv, popovich ng. "disperse systems" pharmaceutical dosage forms & drug delivery systems. 8th ed. Lippincott williams and Wilkins, Philadelphia; 2005, p. 387-9, 98.

[5] Cooper & gun. "dispersed system" tutorial pharmacy. 6th ed. P.75-8.

[6] Aulton me. "suspension" pharmaceutics-the science of dosage form design. 2nd ed. Churchill Livingstone, Edinburgh; 2002. P. 84-86, 273.

[7] Martin a. Fourth edition, "coarse dispersion" physical pharmacy. 4th ed. Lippincott williams and Wilkins: Philadelphia; 2001. P. 479-81.

[8] Rowe rc, sheskey pj, quinn me. Handbook of pharmaceutical excipients. 6th ed pharmaceutical press: london; 2009. P. 134-6, 283-6, 326-30, 383-5, 675-8, 782-6.

[9] Rowe rc, sheskey pj, quinn me. Handbook of pharmaceutical excipients. 6th ed pharmaceutical press: london; 2009. P. 383-5.

[10] Http://pubchem.ncbi.nlm.nih.gov/compound/lauric_acid#section=top

[11] Rowe rc, sheskey pj, quinn me. Handbook of pharmaceutical excipients. 6th ed pharmaceutical press: london; 2009. P. 326-30.

[12] Http://www.sciencedirect.com/science/article/pii/s2211601x11000460

[13] Http://www.ncbi.nlm.nih.gov/pubmed/12587111

[14] Rowe rc, sheskey pj, quinn me. Handbook of pharmaceutical excipients. 6th ed pharmaceutical press: london; 2009. P. 134-6.

[15] Rowe rc, sheskey pj, quinn me. Handbook of pharmaceutical excipients. 6th ed pharmaceutical press: london; 2009. P. 782-6.

[16] Rowe rc, sheskey pj, quinn me. Handbook of pharmaceutical excipients. 6th ed pharmaceutical press: london; 2009. P. 283-5.

[17] Rowe rc, sheskey pj, quinn me. Handbook of pharmaceutical excipients. 6th ed pharmaceutical press: london; 2009. P. 675-8.

[18] Rowe rc, sheskey pj, quinn me. Handbook of pharmaceutical excipients. 6th ed pharmaceutical press: london; 2009. P. 441-5.

[19] Rowe rc, sheskey pj, quinn me. Handbook of pharmaceutical excipients. 6th ed pharmaceutical press: london; 2009. P. 596-9.
[20] Dhanapal ck, manavalan r, chandar n, chenthilnathan a. Formulation development of pediatric rifampicin oral suspension. Scholar research library 2012, 4 (3):845-53.
[21] Aejaz a, ali a. Formulation and in vitro evaluation ofsuspension of ampiillin trihydrate. International journal of applied pharmaceutics 2010; 2(3): 27-30.
[22] Jain dk, darwhekar gn, choudhary n. Formulation and evaluation of reconstitutable oral suspension of ambroxol hcl and azithromycin. Int.j. Pharmtech res. 2011; 3(2): 741-6.
[23] Nep ei, conway br. Evaluation of grewia polysaccharide gum as a suspending agent. Int j pharm pharm sci, 2011; 3(2): 168-73.
[24] Lauric acid 99% fgk. Safety data sheet according to federal register. Rules and regulations 2012; 77(58): 2-5.
[25] Http://pubchem.ncbi.nlm.nih.gov/compound/lauric_acid#section=top
[26] Http://webbook.nist.gov/cgi/cbook.cgi?Id=c143077&type=ir-spec&index=1
[27] Rowe rc, sheskey pj, quinn me. Handbook of pharmaceutical excipients. 6th ed pharmaceutical press: london; 2009. P. 326-30.
[28] Aulton me. "suspension" pharmaceutics-the science of dosage form design. 2nd ed. Churchill Livingstone, Edinburgh; 2002. P. 84-86, 273.
[29] Rowe rc, sheskey pj, quinn me. Handbook of pharmaceutical excipients. 6th ed pharmaceutical press: london; 2009. P. 134-6.
[30] Rowe rc, sheskey pj, quinn me. Handbook of pharmaceutical excipients. 6th ed pharmaceutical press: london; 2009. P. 782-6.
[31] Rowe rc, sheskey pj, quinn me. Handbook of pharmaceutical excipients. 6th ed pharmaceutical press: london; 2009. P. 783-6.
[32] Rowe rc, sheskey pj, quinn me. Handbook of pharmaceutical excipients. 6th ed pharmaceutical press: london; 2009. P. 134-6, 283-6, 326-30, 383-5, 675-8, 782-6.
[33] More hn, hajare aa. Practical physical pharmacy. Nasik: carrier publications; 2007. P. 191-93.
[34] Sabri la, sulayman ht, ameen dw. Formulation of tinidazole as an oral suspension formulation. Ajps 2013; 13(1): 82-91.
[35] Sabri la, sulayman ht, ameen dw. Formulation of tinidazole as an oral suspension formulation. Ajps 2013; 13(1): 82-91.