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DEVELOPMENT AND EVALUATION OF MORINGA SUSPENSION BY USING XANTHANGUM AND VEEGUM AND COMPARING WITH MARKETED PRODUCT

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Abstract

Moringa oleifera is a highly valued medicinal plant known for its extensive nutritional and pharmacological benefits. It contains various bioactive constituents such as flavonoids, phenolic compounds, alkaloids, vitamins, and minerals that exhibit antioxidant, anti-inflammatory, antimicrobial, and antidiabetic properties. Despite its therapeutic potential, the direct use of Moringa powder may present challenges such as poor palatability, variable dosing, and reduced bioavailability of certain phytoconstituents. To overcome these limitations, the present study was undertaken to develop and evaluate an oral Moringa suspension with improved stability, uniformity, and patient compliance. The suspension was formulated using suitable suspending agents such as xanthan gum and veegum to ensure proper dispersion of the Moringa extract. Additional excipients including preservatives, sweeteners, and flavoring agents were incorporated to enhance stability and acceptability. The formulated suspension was evaluated for various physicochemical parameters including organoleptic properties, pH, viscosity, sedimentation volume, redispersibility, particle size distribution, and in vitro stability studies. The results indicated that the prepared suspension exhibited satisfactory physical stability, good sedimentation characteristics with easy redispersibility, acceptable viscosity, and uniform drug content. Stability studies confirmed that the formulation remained stable under recommended storage conditions without significant changes in physical appearance or pH. The developed Moringa suspension demonstrated desirable pharmaceutical characteristics and improved patient compliance, making it a promising herbal oral dosage form for therapeutic use. This formulation approach may enhance the effectiveness and accessibility of Moringa-based herbal preparations in clinical practice.

INTRODUCTION

A suspension is a heterogeneous, biphasic system consisting of finely divided insoluble solid particles dispersed in a liquid medium, usually aqueous. The solid particles form the dispersed phase, while the liquid acts as the continuous phase. Suspensions may be flocculated or deflocculated depending on particle interactions [1]. Oral Suspension An oral suspension contains one or more active pharmaceutical ingredients dispersed in a suitable vehicle. Although particles may settle during storage, they should be easily redispersed by shaking. Oral suspensions are especially useful for drugs that are poorly soluble in water [2].

Advantages of Oral Suspensions [3-4]

- Suitable for pediatric and geriatric patients.
- Easier administration compared to tablets and capsules.
- Greater chemical stability than solutions for hydrolysis-prone drugs. Increased surface area may enhance dissolution and absorption.

Desirable Properties

An ideal suspension should:

- Exhibit slow sedimentation.
- Prevent hard cake formation.
- Be easily redispersible.
- Have acceptable viscosity and pourability.
- Contain suitable preservatives for stability.

Key Formulation Challenges

- Proper wetting of solid particles.
- Control of sedimentation and redispersibility.

- Prevention of particle aggregation and caking.

Selection of appropriate suspending agents, wetting agents, and stabilizers is critical to overcome these issues.

Evaluation Parameters [5].

- Sedimentation volume
- Rheological behavior
- Particle size analysis
- Stability studies

Taste Masking Techniques (Important Methods)

Taste masking is essential in oral formulations, especially for bitter drugs.

1. Flavoring Agents

Use of sweeteners and flavors to improve palatability.

2. Polymer Coating

Coating drug particles to prevent contact with taste buds.

3. Ion-Exchange Resins

Formation of drug-resin complexes (resinates) that are tasteless in the mouth but release the drug in the stomach.

4. Inclusion Complexation

Use of cyclodextrins to reduce drug solubility in saliva and mask bitterness.

5. Wax Embedding

Embedding drug in wax matrices to minimize direct exposure to taste receptors [6].

METHODOLOGY [7-8]

Procedure

The Erweka dissolution test apparatus (Model DT 6R, Germany) was used to determine the drug release profile of the aqueous Moringa oleifera root extract suspension. The procedure used by Azam and Haider, (2008) was adopted with some modifications. The dissolution medium used was 0.1 N NaOH. Dissolution medium (900 mL) was poured into a glass jar which was suspended in a water bath thermostatically maintained at 37 ± 0.5 °C. The paddle was set to rotate at 50 rpm and 25 mm away from the base of the glass jar. About 10 mL of the reconstituted suspension was introduced carefully into the bottom of the apparatus. Five (5) mL samples were withdrawn at specified time interval of 5, 15, 30, 45, and 60 minutes respectively and spectrophotometrically analyzed for aqueous Moringa oleifera root extract at 230 nm. After each withdrawal, same volume of the dissolution medium was replaced.

pH: pH is defined as the negative logarithm of hydrogen ion concentration.

Mathematically it is written as:

$$pH = \log 1/[H2o]$$

Since the logarithm of 1 is zero,

the equation may also be written as:

$$pH = -\log(H3O+)$$

Determination of pH[80]

pH of suspension was determined by using pH meter. pH of the phases of suspension also contributes to stability and characteristic of formulations. pH of the suspension was recorded from time to time.

Viscosity

Viscosity of suspension is a great importance for stability and palatability of suspensions. Suspensions have least physical stability amongst all dosage forms due to sedimentation and cake formation.[78]

Sedimentation is governed by Stokes's Law:

V = d2(Ps-p1)g/18 n

V - terminal settling velocity

d –diameter of the settling particle

ρ_s – density of the settling solid (dispersed phase)

ρ_l - density of the liquid (dispersion medium)

g – Acceleration due to gravity

n – viscosity of dispersion medium

when the viscosity of dispersion medium increases the settling velocity decreases.

Determination of viscosity[81]

The viscosity of suspension was determined at ambient condition using Brookfield digital viscometer taking adequate amount of the sample.

Sedimentation Volume[80]

Sedimentation volume F is the ratio of equilibrium volume of sediment (Vu) to the total volume of suspension (Vo).[77]

$$F = Vu/Vo$$

Vu - Volume of sediment

Vo - total volume of suspension

The sedimentation volume F normally ranges from less than 1 to 1. When F=1, the sediment volume and the total volume are equal and such a suspension is pharmaceutically acceptable.

Determination of sedimentation volume[80]

Sedimentation volume was determined as a function of time. 50ml suspension was transferred to a 100 ml measuring cylinder of 2.5cm diameter. The sedimentation volume F was determined [9].

RESULTS AND DISCUSSION

Microbial Testing

Table 1: Colony Counting (Stability Conditions)

S.No	Observation	Accelerated condition 37° for 48 hrs	Real time condition 22.5° for 5 days	Refrigeration condition 1° for days
1	BEFORE INCUBATION a)Total bacterial count	Nil	Nil	Nil
	b)Total fungal count	Nil	Nil	Nil
2	AFTER INCUBATION a) Total bacterial count	Nil	Nil	Nil
	b) Total fungal count	Nil	Nil	Nil

Microbial Testing of Finished Product

This test is mainly performed to check whether the finished product has any presence of micro organism or not. For this test two media were commonly employed namely, Tryptone Soya Agar Medium (TSA) for bacteria. Sabouraud's Chloramphenicol Agar Medium (SCA) for yeast and moulds [10].

STEPS

1. TSA and SCA medium were prepared and autoclaved for 15 min at 121°C.
2. 10ml of the sample was added to the broth and mixed well.
3. By using a micropipette, 1 ml from the broth was transferred to two sterile petridishes, One for bacteria and the other for fungi.
4. 20 ml of the TSA and SCA medium was poured into their respective plates.
5. The plates were then rotated in clockwise and anti-clockwise directions for even spreading of the sample.
6. The plates were allowed for solidification.
7. TSA plate was incubated at 37°C for 48 hours in an inverted position.
8. SCA plate was incubated at 20 -25°C for 5 days in an upright position.
9. The colonies formed were counted and recorded [11].

Limits

Bacteria: not more than 300 colonies per plate.

Fungi: not more than 100 colonies per plate.

FORMULA (CFU/ML) = (No.of colonies X Amount of Sample taken)/(Dilution factor)

PATHOGEN TESTING[82]

This test is done only if the inoculated plate shows coloured colonies which indicates the presence of pathogens. The pathogens are:

- Escherichia coli
- Salmonella species

Table2: Formulation of Suspension

S.No	Ingredients	S-1	S-2	S-3	S-4	S-5	S-6
1	Erythromycin (g)	10	10	10	10	10	10
2	Indion-204 (g)	2.5	5	7.5	10	20	25
3	Sucrose (g)	300	300	300	300	300	300
4	Xanthan gum (g)	1.5	1.5	1.5	0	0	0
5	Tween 80 (g)	0.5	0.5	0.5	0.5	0.5	0.5
6	Vegum	0	0	0	1.5	1.5	1.5
7	Methyl paraben (g)	1	1	1	1	1	1
8	Sodium citrate (g)	1.5	1.5	1.5	1.5	1.5	1.5
9	Sodium chloride (mg)	1.25	1.25	1.25	1.25	1.25	1.25
10	Glycerin (g)	50	50	50	50	50	50
11	Mint flavour (ml)	10	10	10	10	10	10
12	Sunset yellow FCF (mg)	25	50	50	50	50	50
13	DM Water	q.s	q.s	q.s	q.s	q.s	q.s

Evaluation Parameters

Evaluation of Moringa Suspension

Preparation of Moringa Suspension
↓
Initial Physical Observation
(Color • Odor • Appearance • Homogeneity)
↓
pH Determination
(Digital pH meter)
↓
Viscosity Measurement
(Brookfield Viscometer)
↓
Rheological Study
(Flow behavior – Pseudoplastic / Plastic)
↓
Sedimentation Study
(Calculate Sedimentation Volume, F = Vu/Vo)
↓
Redispersibility Test
(Number of shakes required)
↓
Particle Size Analysis
(Optical Microscopy / Analyzer)
↓
Drug Content Uniformity
(UV–Visible Spectrophotometry)
↓
In-Vitro Drug Release Study
(USP Type II – Paddle Method)
↓
Microbial Load Test
(Total Bacterial & Fungal Count)
↓
Stability Studies
(Room Temperature & Accelerated Conditions)
↓
Final Evaluation & Interpretation

Stability Studies

Stability Studies of the Finished Product Stability of a drug can be defined as the time from date of manufacture and packaging of the formulation until its chemical or

biological activity is not less than a predetermined level of labeled potency and its physical characteristics have not changed appreciably or deleteriously. Although there are exceptions, 90% of labeled potency is recognized as the minimum acceptable potency level. The international conference on Harmonization (ICH) Guideline titled "stability testing of new drug substance and products" (QIA) describes the stability test requirements for drug registration application in the European Union, Japan and USA [12].

ICH specifies the length of study and storage conditions.

- Long term testing 25°C ± 2°C /60 % RH ± 5% for 12 months
- Accelerated testing 40°C ± 2°C /75% RH ± 5% for 6 months

Inference

As the concentration of the resin was increased, the release of the drug from the formulation was sustained, Formulation S-1 & S-2 showed maximum release within 30 min [13].

Table 3: Stability Studies of formulated Moringa suspension

S.No	Test for evaluation	Accelerated condition 37° for 48 hrs	Real time condition 22.5° for 5 days
1	Taste	No change	No change
2	Colour	No change	No change
3	pH	3.74	3.67
4	Viscosity (Cps)	660	665
5	Sedimentation volume(F)	0.99	0.99
6	Drug Content (%)	99.06±0.0236	98.97±0.0423

Table 4: Stability Studies of formulated Moringa suspension under Refrigeration condition (Formulation S-6)

S.No	Test for evaluation	Refrigeration condition 1° for days
1	Colour	No change
2	pH	3.74
3	Viscosity (Cps)	660
4	Sedimentation volume(F)	0.99
5	Drug Content (%)	99.06±0.0236
6	Apperarance	Suspension is homogenous free from formation of crystals

Time (min)	CUMULATIVE %DRUG RELEASE					
	S-1	S-2	S-3	S-4	S-5	S-6
10	79.44	74.62	72.05	69.05	67.02	65.44
20	95.81	91.86	83.43	80.89	80.12	78.47
30	99.79	99.88	93.18	84.31	86.12	81.21
40	-	-	95.31	88.12	84.18	83.24
50	-	-	97.92	93.25	92.72	86.19
60	-	-	99.82	99.12	99.70	99.86

Tab 5: Cumulative %Drug Release

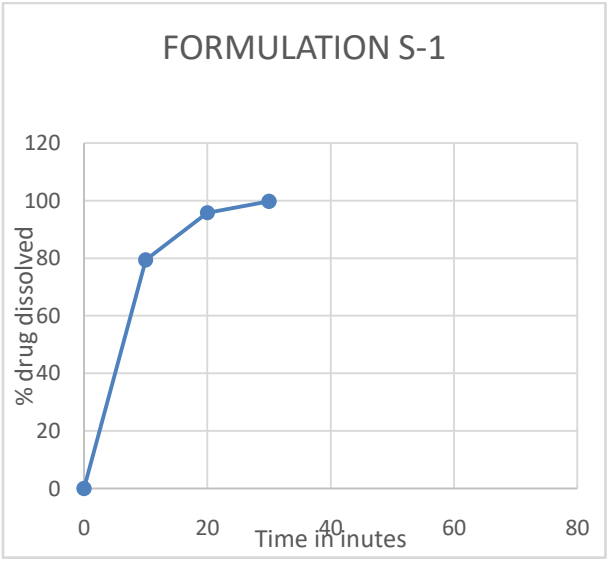

Fig no: In Vitro Drug Release of Formulated Moringa Suspension

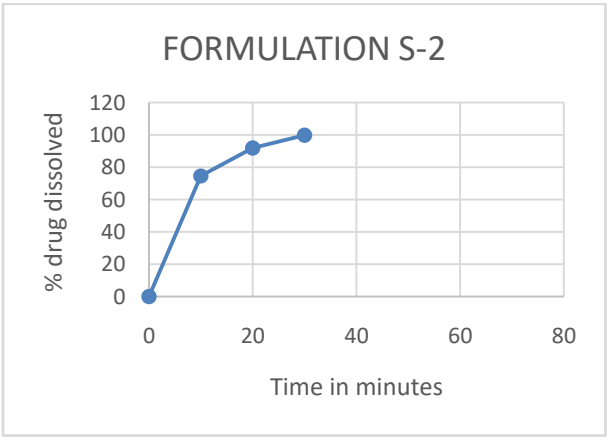

Fig No 3: In Vitro Studies Profile S-3

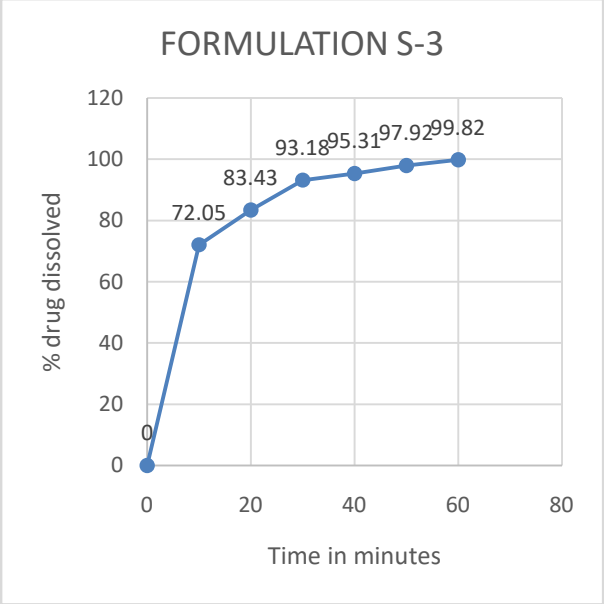

Fig no 3: IN VITRO STUDIES PROFILE S-3

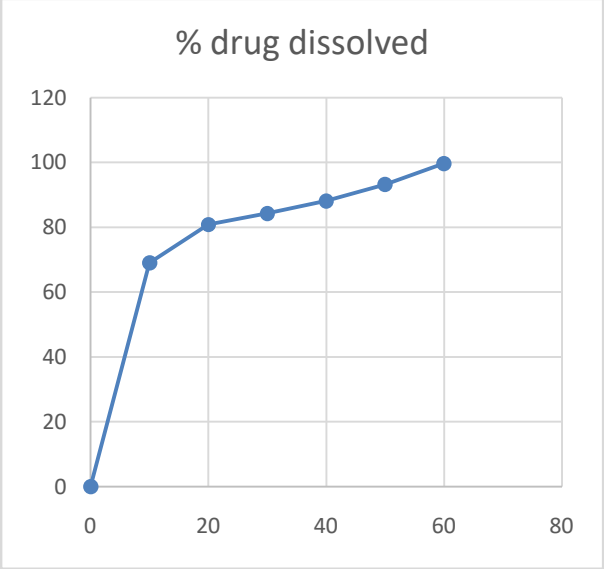

Fig No 3: In Vitro Studies Profile S-3

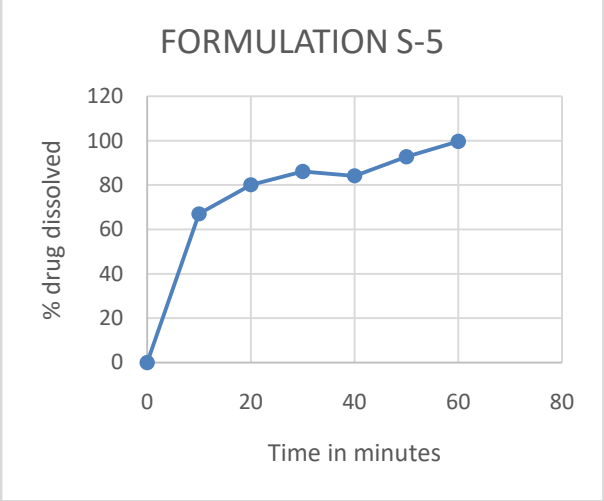

Fig No 4: In Vitro Studies Profile S-5

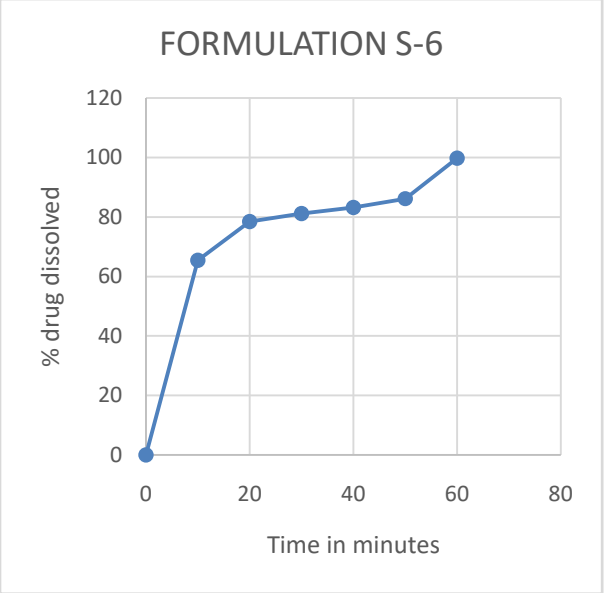

Fig No 6: In Vitro Studies Profile S-6

Table 6: Comparative Evaluation of Marketed Sample and Formulation S-7

S.No	Test for evaluation	Observation	
		Marketed sample	Formulation S-6
1	Taste	Slight Bitterness observed	Bitterness completely masked
2	pH	3.68	3.66
3	Viscosity (Cps)	660	665
4	Sedimentation volume (F)	0.99	0.99
5	Colour	Orange	Pale yellow
6	Drug content *(%)	99.03±0.0267 %	99.78±0.0245 %

Table 7: Comparative In-Vitro Drug Release Data

Time (minutes)	Marketed Sample (% Drug Release)	Formulation S-6 (% Drug Release)
10	61.68 ± 0.0929	59.82 ± 0.0568
20	75.35 ± 0.0513	75.02 ± 0.0512
30	83.98 ± 0.0953	84.02 ± 0.0611
40	89.26	89.26
50	96.43	96.43
60	99.68 ± 0.0624	99.70 ± 0.0850

SUMMARY AND CONCLUSION

Several formulations were carried out by Drug – resin complexation method.

- It was concluded that the formulation S-5 was satisfactory than other formulations
- S-1 ,S-2 ,S-3 ,S-4 & S-6.

- The formulation S-5 was compared with a leading brand of marketed sample and it was found to be match with formulation S-5 in all aspects.

FUTURE WORK

- Scale up studies of the optimized formulation.
- To send the desired formulated lots for Bioequivalence studies.
- To proceed for exhibit batches.

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CONFLICTS OF INTEREST

The authors declare no conflicts of interest.

AUTHOR CONTRIBUTION

All are contributed equally

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None

ETHICAL CONSIDERATIONS AND INFORM CONSENT

Not Applicable.

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