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Formulation of Paracetamol Suspension using A Novel Bio Anti-Settlant agent from *Vigna mungo*

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Abstract: The current aim for our research work is to isolate a novel bio- material from the seeds of *Vigna mungo* and to evaluate its anti-settling property by formulating a suspension using paracetamol as model API. The bio material was separated from the seeds of *Vigna mungo* by a simplified economic process. The isolated bio-material was subjected to various physico-chemical properties like particle size, viscosity, particle shape, colour changing point. Bio suspensions were formulated using paracetamol as a model API, bio- material and other processing agents. The formulated suspensions were compared and evaluated for its parameters like particle size, sedimentation volume, redispersibility, pH, density and viscosity with FM1. Our experimental results reveal that the formulated bio suspension showed significant stability in respect to sedimentation volume, redispersibility, pH and viscosity in comparision with the marketed preparation. Finally, the conclusion was drawn that the isolated bio-material can serve as a potential bio anti-settlant agent for formulation of various pharmaceutical suspensions.
Key words: paracetamol, suspension, vigna mungo, bio material.

Introduction and Experimental:

The current aim for our research work is to isolate a novel bio- material from the seeds of *Vigna mungo* and to evaluate its anti-settling property by formulating a suspension using paracetamol as model API. The bio material was separated from the seeds of *Vigna mungo* by a simplified economic process. Black gram consists of the seeds of *vigna mungo*, belonging to the family fabaceae. It is highly nutritious. It is composed of moisture(10.9%), protein(24.0%), fat(1.4%), fibre(0.9%), minerals(3.2%), carbohydrates(59.6%). Black gram is used as an demulcent, aphrodiasic, in diabetes, in nervous disorders and in hair disorders.

A Pharmaceutical suspension is a coarse dispersion in which internal phase is dispersed uniformly throughout the external phase.(1,2) The internal phase consisting of insoluble solid particles having a specific range of size which is maintained uniformly through out 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.(3,4)

Classification(1,2)

Based On General Classes

Oral suspension
Externally applied suspension
Parenteral suspension

Based On Proportion Of Solid Particles

Dilute suspension (2 to10%w/v solid)
Concentrated suspension (50%w/v solid)

Based On Electrokinetic Nature Of Solid Particles

Flocculated suspension

Deflocculated suspension
Based On Size Of Solid Particles
Colloidal suspension (< 1 micron)
Coarse suspension (>1 micron)
Nano suspension (10 ng)

Materials:

The model drug paracetamol was obtained from syncom laboratories ltd., dehradun as a gift sample. All the reagents were of analytical grade. Double distilled water was used throughout the experiment.

Isolation of the Bio-polymer from *S*eeds of V*igna mungo*
250gms of the seeds of. *Vigna mungo* were soaked in water for 12 hours and the supernatant was collected and subjected to dehydration in a controlled manner for two hours and constant stirring. The isolated material was dried by treating with two volumes of acetone and passed through #120.

Formulation of Paracetamol Suspensions using Bio-material(5,6)
Suspensions were formulated by using paracetamol, anti settling agent, glycerine, sodium benzoate, tween 80, water and citric acid. The formulated suspensions were compared with the marketed preparation for various evaluation parameters.(Table No.1)

Table no.1 Formulations prepared

S.NO.	FORMULATION	FV-1	FV-2
1.	Biomaterial(mg)	200	400
2.	Paracetamol(mg)	200	200
3.	Glycerine(ml)	5	5
5.	Tween 80(ml)	5	5
7.	water	q.s	q.s

Evaluation Parameters:

The suspensions were evaluated for the following parameters,
Particle size- The particle size was determined by optical microscopy method.
Viscosity- The viscosity of the suspensions were measured by using *ostwald viscometer* .
Surface tension- The surface tension was measured using stalagmometer and was compared with sodium lauryl sulphate..
pH- The ph of was measured in digital ph meter using ph 7 as standard.
Sedimentation volume- the sedimentation vilume was determined in order to establish the stability of the suspensions and evaluate the suspending ability of the bio-material.
In-vitro release studies- The in-vitro release studies in case of suspensions were performed using dissolution apparatus for 2 hrs.

Table no.2 Physical properties of the bio-material

S. NO.	CHARACTERISTIC	BIO-MATERIAL
1.	Colour	YELLOW
2.	Odour	Characteristic
4.	Melting point	186-190ºc

Table no.3 Chemical properties of the bio-material

S. NO.	CHEMICAL CONSTITUENT	BIO-MATERIAL
1.	Carbohydrates	Present
2.	Proteins	Present

Table no.4 Evaluation parameters

S.NO.	EVALUATION TEST	MARKETED PREPARATION (FM-1)	Fv1	Fv2
1.	Particle Size(um)	30.73 – 31.12	29.61 – 30.43	26.32 – 27.39
2.	Sedimentation Volume(after 24 hours)	0.98	0.96	0.96
3.	Redispersibility (no.of cycles/second)	1/5	1/5	1/5
4.	pH	6.82	6.68	6.68
5.	Density(gm/cc)	1.30	1.05	1.25
6.	Viscosity(centipoises)	73.2	39.86	54.74

Results and Discussions:

Physicochemical properties of the bio-material:

A novel bio-polymer from *vigna mungo* was isolated by simplified economical process the yield was 1% per 100gms. The bio-polymer obtained was of pale yellow color with a colour changing point of 186-190°. The bio-polymer showed positive tests for the presence of proteins and carbohydrates. (Table no.2, Table no.3)

Evaluation Parameters:

Particle size and shape - the globules were observed to be spherical in shape with a size in the range 26-30 µm. (Table no. 4)

Sedimentation rate: the sedimentation volume was determined and it was found to be 0.96 for both the formulations after 24 hours(FIG. NO. 1)

Viscosity- The viscosity of the formulations were found to be 39-55centipoises.(FIG. NO. 4)

***In-vitro* release studies**- the in-vitro release data in all the formulations was performed in zero order, zero-first order, higuchi equation in order to evaluate its release mechanism. The result showed the zero-first order release pattern.(FIG. NO. 3).

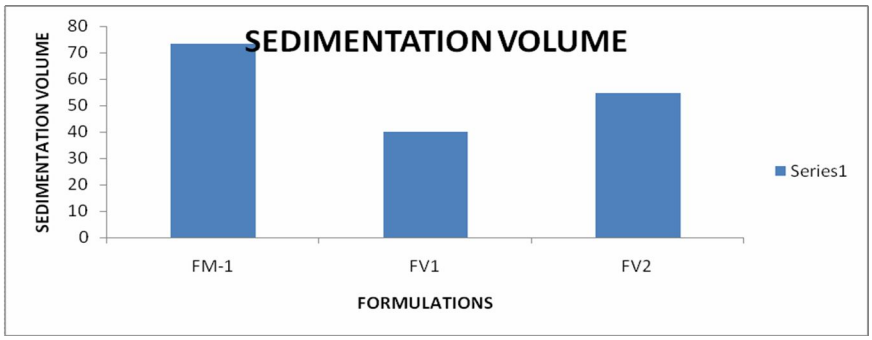

Fig. No. 1 Sedimentation Volume

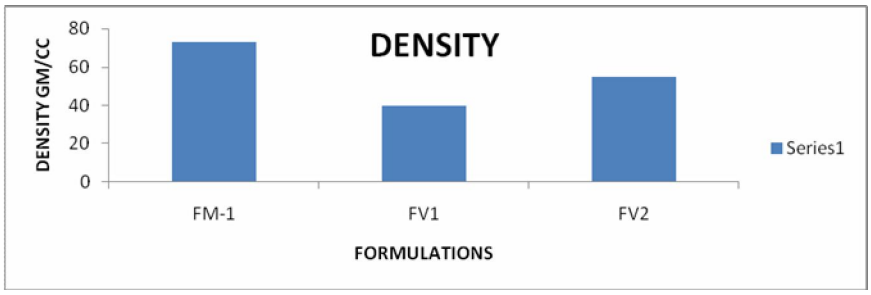

Fig no. 2 Density of the Formulations

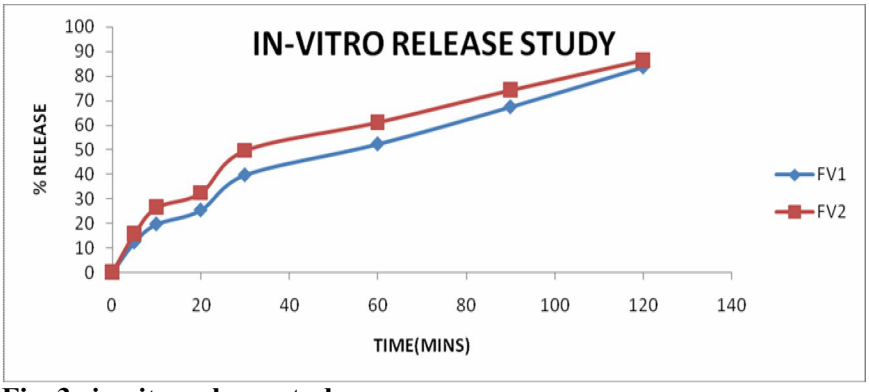

Fig. 3: *in-vitro* release study.

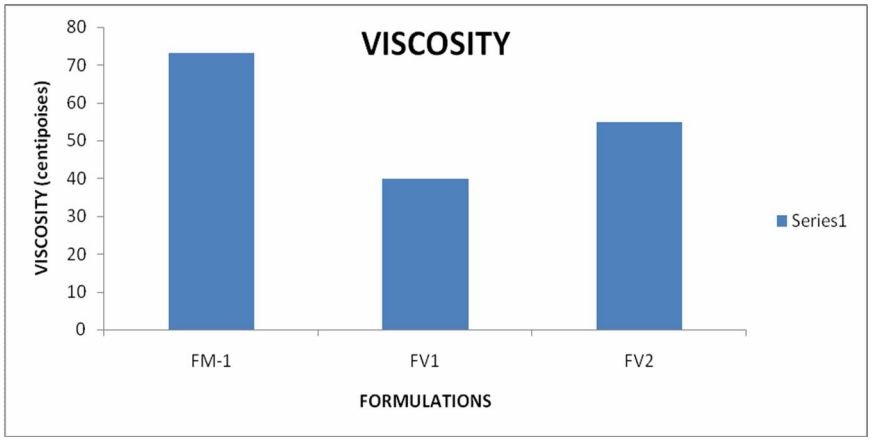

Fig. No. 4 viscosity of microemulsions

Discussions:

A novel bio-polymer from *vigna mungo* was isolated by simplified economical process the yield was 1% per 100gms. The bio-polymer obtained was of pale yellow colour with a colour changing point of 186-190˚. The bio-polymer showed positive tests for the presence of proteins and carbohydrates. Two different formulations were formulated using various proportions of bio-material for the preparation of suspensions of paracetamol. The in-vitro release data in all the formulations was performed in zero order, zero-first order, higuchi equation in order to evaluate its release mechanism. The result shows the zero-first order release pattern. The in-vitro release data in all the formulations was performed in zero order, zero-first order ,higuchi equation in order to evaluate its release mechanism. The result shows the zero-first order release pattern. Among the six formulations fv1 shows a particle size of 29.61-30.43 micrometer, density of 1.05gm/cc, viscosity of 39.86cp while fv2 had a particle size of 26.32-27.39, density of 1.25 gm/cc, viscosity of 54.74cp.

Conclusion:

Finally the experimental results shown a promising observations in terms of particle size, density, viscosity, in-vitro release study. Finally the conclusion was drawn that the isolated bio-material can serve as a potential bio-anti settling agent for formulation of various pharmaceutical suspensions.

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