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FORMULATION AND EVALUATION OF LIQUID ORAL SUSPENSION OF PARACETAMOL USING NEWLY ISOLATED CELLULOSE FROM '*CITRUS LIMETTA' PEEL* (Emcell) AS SUSPENDING AGENT.

1Javeriya Azam Khan Pathan, 2Mrs. Laxmi Jamagondi, 3Mohammed Khalid Nazir Ahmed Konda

1student , 2professor, 3student

1solapur university,

2solapur universirty,

3solapur

ABSTRACT

The objective of this study was to demonstrate and evaluate the suspending property of newly isolated and purified EmCell in liquid oral suspensions of paracetamol. Isolation of cellulose from *Citrus limetta* was done by following the process and modifying it for citrus limetta that is described by Sania Naz et.al[11]. , and then it was characterized by solubility, pH, flow rate and viscosity. The characterized cellulose was then used as a suspending agent for the preparation of suspensions containing paracetamol as a model drug. The prepared formulations were then evaluated for different parameters such as sedimentation volume, redispersibility, flow rate, pH, viscosity, and other physical examination. The isolated cellulose is a polysaccharide with no impurities and nontoxic in nature. It has got enough swellability and good viscosity. The prepared suspensions were evaluated, and the results such as sedimentation volume, redispersibility, flow rate, pH, viscosity, and other physical examination showed its suspending property. The comparative study shows that EmCell showed the suspending ability, various concentration of EmCell is used and the suspension is formulated and evaluated. Thus, by this study, it can be stated that the EmCell possesses all the criteria needed by a standard suspending agent.

Keywords: EmCell (cellulose obtained from *Citrus limetta*), suspending agent, sedimentation volume.

INTRODUCTION.

Cellulose is a comparatively low-priced, exceptionally multipurpose bio-based renewable material with various profitable properties, i.e., non-toxicity and biodegradability [1]. These materials obtained from renewable resources are drawing fast growing attention, equally from the perspective of evolving novel functional and structural macroscopic materials as well as a fundamental scientific point of view [2]. Addition of significant value and low-energy consumption makes nanocellulose extraction from agricultural waste one of the finest substitutions for waste treatment. Numerous methods for the isolation and purification of nanocellulose have been described and merging these procedures affects the morphology of the fibres [1]. The cellulose-based nanomaterials such as nanocellulose fibres, crystalline nanocellulose, cellulose composites etc. have high surface area and aspect ratio [3, 4]. The agriculture waste such as wood, cotton, flax, hemp, jute, ramie, straws, sugarcane bagasse and fruits remains are major sources of cellulose [4]. Cellulose applicability in versatile processes in industries: namely, high-quality paper products; cosmetics; food industry; and texturing agent; mouldable light weight, high strength materials; materials for electronics;

and pharmaceutical make it important to search for high cellulose containing materials. Industrial grade microcrystalline cellulose has a high proportion of sub-micron size colloidal microcrystals which are excellent stabilising agents for water (H2O)-based latex paints as well as for industrial coating and suspensions [1,4].

A suspension is a pharmaceutical product in which it is a coarse dispersion as insoluble particles (1 μm) are dispersed in a liquid aqueous medium. The preparation of suspensions on a small scale, the powdered drug can be mixed with the suspending agent and some of the vehicle. Liquid oral suspension is comparatively quick to prepare and allow in the dosage form. Based on the Noyes–Whitney equation, if the dispersed drug in the suspension has a large surface area, then this will enhance dissolution and increase absorption. The different dosages can be measured from a single strength of preparations. It has been stated that the suspensions were a very useful dosage forms for insoluble or poorly water-soluble drugs for oral administration. As the use of natural excipients is been profoundly increasing in medicines, in this work, *Citrus limetta* peel was used for isolating the cellulose(EmCell), and used in the formulation of dosage form that is suspension.

MATERIALS AND METHODS

Materials:

Paracetamol was used as model drug, carboxymethylcellulose, tragacanth were used of laboratory grade, the cellulose was obtained from citrus limetta peel that is collected from local market and extracted in laboratory, sucrose, glycerine are used of laboratory grade.

Phase 1: Extraction of cellulose from *Citrus Limetta.*

Isolation of cellulose is done by the process stated by Sania Naz et.al [].the peel are dried in sun for two days, and then grinded in mixer to fine powder, weigh the quantity of peel and soaked in organic solvent (toluene: ethanol, 1:2), after it is dried and treated with hydrogen peroxide to bleach it, after the bleaching cellulose is mixed with 6% NaOH solution and kept overnight neutralized with distilled water then again kept for 2 hour in 6%NaOH solution and then sonicated for 30 min, and then it is neutralized dilute hydrochloric acid 6%, and then washed several time to remove Salts. The obtained mass is then dried in vacuum oven at 80°C. The obtained cellulose is then used in the formulation of suspension as a suspending agent.

Phase 2: formulation of suspension using the obtained cellulose and with different suspending agent.

The suspension is made in a way that per 5ml of the suspension contains 120 mg of paracetamol, the CMC, tragacanth were kept at same quantity in formulations, and the EmCell is taken in three different concentrations to compare with the standard suspending agent. The quantity given in the following table weighed and the dry material is triturated in the mortar , gradually the syrup is added to make a uniform paste, then glycerine is added, after that volume is made up with distilled water.

FORMULATION TABLE :

	Table : List of Drugs and Chemicals		
Sr. No.	**Name**	**Category**	**Quantity**
1	Paracetamol	API	2.4gm (for each formulation)
2	EmCell	Suspending agent	0.5 gm
3	EmCell	Suspending agent	1.0 gm
4	EmCell	Suspending agent	1.5 gm
5	Tragacanth	Suspending agent	1.0 gm
6	CMC	Suspending agent	1.0 gm
7	Simple syrup	Vehicle	60 ml
8	Glycerine	Humectant	15ml
9	Distilled water	Volume makeup	Q.S for 100ml

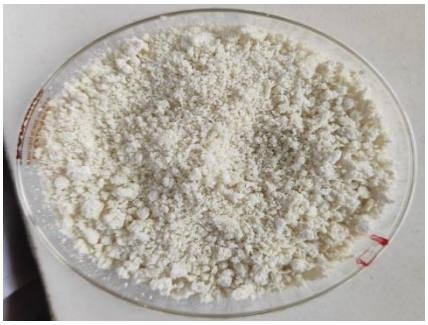

Fig no 1: Isolated Cellulose

Fig no 2: Paracetamol Suspensions

Optimizing the strength of suspending agent

The above-prepared suspensions were compared with the standard strengths of tragacanth (1%) and CMC (1%). The parameters analysed were its dispersibility, viscosity, uniformity, and flow character. Comparative evaluation of these prepared formulations using different methods

Comparative evaluation of these prepared suspension

1. **Determination of sedimentation volume**

Each suspension (50 mL) was stored in a 50 mL measuring cylinder for 4 days at 35°C. Observations were made every 24 h for 4 days. The sedimentation volume was then calculated using the following Equation.

$F = Vu \div Vo$

F: Sedimentation volume, Vu: Ultimate sediment volume, Vo: Initial sediment volume.

2. **Redispersibility**

The redispersibility was determined was determined by studying a number of strokes to redisperse the formed sediment at the end of 7 day of storage of the formulations (not >100 strokes =redispersibility)

3. **Determination of flow rate**

The time required for each suspension sample to flow through a 10 mL pipette was determined, and the apparent viscosity was calculated

using the equation.

$FR = V \div FT$

FR: Flow rate, V: Volume of pipette (mL), FT: Flow time (s).

4. Viscosity

The viscosity of selected formulations (Compound tragacanth, sodium CMC, and EmCell) determined at 25°C using Brookfield viscometer. All determinations were made in at least triplicate and the results obtained are expressed as the mean values.

5. pH

The pH of selected formulations (compound tragacanth, sodium CMC, and EmCell) was determined at 25°C using pH Meter.

RESULTS AND DISCUSSION

The cellulose obtained from *Citrus limetta* looks whitish in color and free-flowing powder. The purified cellulose powder is shown in Fig. 1. The percentage obtained was found to be as 65–70%. Percentage yield revealed that *Citrus limetta* peel contain a large amount of cellulose.

The solubility profile shows that the cellulose got dispersed in water then swelled and became highly viscous. In glycerine, the cellulose swelled, but it was not soluble. In other solvents, cellulose is not at all soluble.

1. **Sedimentation volume :** The result showed that the formulation containing EmCell 0.5% has lesser sedimentation volume than the other four formulations, but the EmCell containing 1% and 1.5% concentration suspension shows comparatively same sedimentation volume which express the stability of the suspensions. The viscosities are found to be fairly good and match with that of the limit required by the suspension.

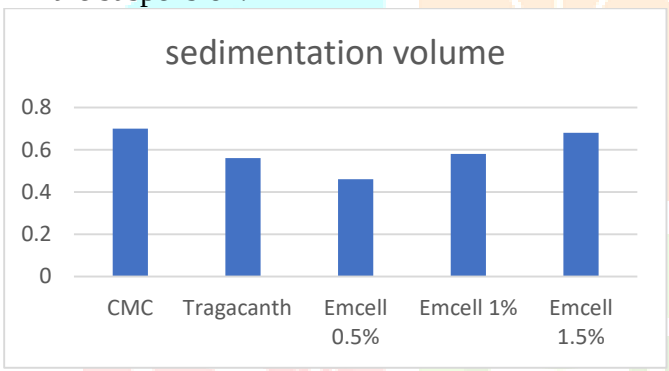

Fig no: 3 histogram of sedimentation volume

2. **Redispersibility:** The redispersibility of different suspensions were found out as, tragacanth(8 strokes), CMC (7 strokes), and EmCell (6 strokes). The data show that the suspensions are easily redispersible and there is no cake formation.

3. **Determination of flow rate:** The flow rate study results were analysed and the data interpreted as follows. The flow time taken by different suspensions is 0.5% EmCell is 10±1 s, 1% EmCell 12±1s, 1.5% EmCell 13±1s 1% CMC 11±1 s, and 1% tragacanth13±1 s. Flow rates of suspensions prepared from, tragacanth(0.76±0.02 mL/s), CMC (0.90±0.02 mL/s), 0.5% EmCell (1.0±0.02 mL/s), 1% EmCell (0.83±0.02 mL/s), 1.5% EmCell (0.76±0.02 mL/s). The flow rate for suspension containing EmCell 0.5% was found to be less when compared with other formulations.

   The order of flow rate of suspensions with different suspending agents is as follows: 0.5% EmCell>CMC>1% EmCell>tragacanth>1.5% EmCell

4. **Viscosity determination:** the viscosity of the suspension were determined on Brookfield viscometer in triplicate readings and a histogram is plotted using the average viscosity which shows that CMC is the highly viscous as compared to EmCell and tragacanth but as compared to the tragacanth suspension the EmCell suspension are more viscous.

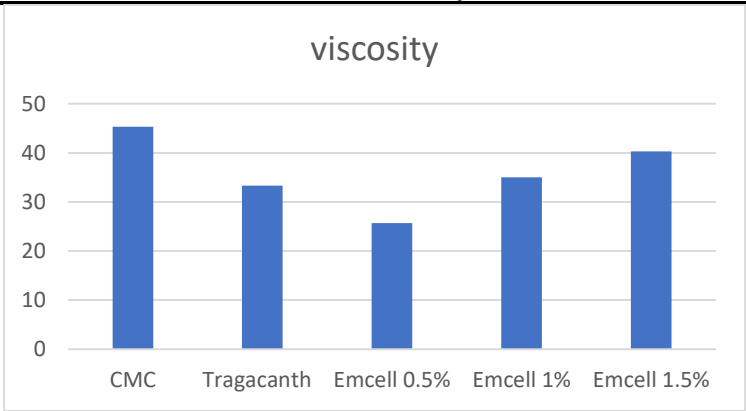

Fig no:4 histogram for viscosity

5. pH:

The pHs of formulations were found to be almost equal to that of the marketed formulations. The obtained pHs of suspension with tragacanth (5.6±0.1), suspension with sodium CMC (5.4±0.2), and suspension with EmCell (0.5%,1%,1.5%)all have same pH(5.8±0.1). The usual range is 2–6 and is suitable for oral administration[6].

Based on the results of different studies such as sedimentation volume, redispersibility, flow rate, pH, viscosity, and other physical examination it was found that EmCell can be used as a good suspending agent. The suspension with EmCell as the suspending agent has almost all the criteria needed by a suspending agent**.**

Conclusion: The study revealed that the same amount of cellulose can produce a good suspension with all the necessary properties as that of suspensions prepared from tragacanth and sodium CMC. By this study, it could be found out that same quantity of EmCell(1%) is required to prepare a suspension of paracetamol when compared with suspensions prepared of compound tragacanth (1%) and sodium CMC (1%) as a suspending agent.

Thus, by this study, it can be stated that the cellulose from *Citrus limetta* possesses all the criteria needed by a standard suspending agent.

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