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Research Article

FORMULATION AND *IN-VITRO* CHARACTERIZATION OF *HIBISCUS LOBATUS* LEAVES MUCILAGE AS SUSPENDING AGENT

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ABSTRACT

The aim of the present investigation was to evaluate the mucilage obtained from leaves of hibiscus lobatus as a suspending agent. Sulphamethoxazole suspension was prepared by using four different suspending agents each at two different concentrations. The prepared suspensions were evaluated for pH, viscosity, sedimentation volume, degree of flocculation and redispersibility. The suspending effect of hibiscus mucilage was compared with suspensions prepared by using other suspending agents. The results indicating that hibiscus mucilage could be used as suspending agent. The suspension having 2% mucilage has high viscosity, slightly basic pH and easily redispersible properties.

Keywords: Hibiscus lobatus, mucilage, suspending agent, sedimentation volume.

INTRODUCTION

Mucilages and gums are well known since ancient times for their medicinal use. In recent years, plant gums and mucilages have evoked tremendous interest due to their diverse applications in pharmacy in the formulation of both solid and liquid dosage forms. They are employed as suspending agent in the formulation containing indiffusible materials 1, 2. Naturally, demand for this substance is increasing and new sources are getting identified. In the present work, mucilage obtained from the leaves of Hibiscus lobatus was studied as suspending agent in the formulation of sulphamethoxazole suspensions. Sulphamethoxazole was selected as a model drug because it is stable and water insoluble in nature. Sulphamethoxazole is an antibacterial agent, official in almost all of the pharmacopoeias [3, 4].The plant Hibiscus lobatus belongs to the family Malvaceae, commonly known as tellbenda 5. The plant was found to contain mucilage. The present work is an attempt to investigate this mucilage as suspending agent in pharmaceutical formulations.

MATERIALS AND METHODS

Sulphamethoxazole (SMX) was obtained as gift sample from Aurobindo pharma Ltd., Hyderabad. Tragacanth, hydroxy propyl methyl cellulose, sodium carboxy methylcellulose, sodium benzoate and tween 80 were procured from local market. All other reagents and solvents used were of analytical grade.

Isolation of mucilage

The leaves were collected and sun dried for at least 7 days. The powdered leaves were defatted using petroleum ether (70-80o C) in a soxhlet apparatus. The defatted material (60 g) was soaked in distilled water (1000 ml) at room temperature for 12h. The resulting mass was stirred at about

100 rpm for 1h and strained through muslin cloth. To the filtrate, acetone was added until precipitation was complete. The precipitated mucilage was filtered through muslin cloth and the mucilaginous residue was spread on glass plates and dried at 40o C. Then it was dispersed in 250 ml water with stirring for 12h and ethanol was added in different proportions. Initially, the concentration of ethanol was made up to 20% in the solution. Some impurities that precipitated were removed by centrifugation. The ethanol concentration was further increased to 60% to precipitate the mucilage. The precipitated mucilage was filtered, treated with acetone to remove the traces of water and dried in an oven at 40^0C[6].

Preparation of suspension

Five milliliters of suspension containing 200 mg of SOX were prepared as per formulae given in Table 1. Suspensions were prepared using hydroxy propyl methyl cellulose, tragacanth, sodium CMC and hibiscus mucilage as suspending agent, tween 80 as wetting agent and sodium benzoate as preservative. Accurately weighed quantity of SOX was taken in a mortar and was levigated with a solution of wetting agent and a small portion of the mucilage of suspending agent. When smooth paste was formed, the rest of the mucilage was added in divided portions while triturating the contents. The preservative was added, mixed well and transferred to measuring jar and adjusted the volume.

Particle size measurement and sedimentation study

Size of the SOX particles in the suspension was measured by microscopy. Average particle size and standard deviation of 100 particles was estimated. The results are given in Table 2. Sedimentation volume is the most important parameter in the evaluation of suspension stability. Sedimentation volume F is the ratio of the ultimate height (Hu) of the sediment as a suspension settles in a cylinder under standard conditions to the initial height (Ho) of the total suspension [7]. It was determined by transferring measured volume in a graduated cylinder and was stored at room temperature. The volume of sediment formed was noted at regular intervals of time.

Redispersibility

Redispersibility of suspension can be estimated by shaking the suspension with the help of a mechanical device, which stimulates the motion of human arm during shaking r. fixed volume (50 ml) of the each suspension was kept in calibrated tubes, which were then stored at room temperature for various time intervals (5, 15, 25 days). At regular intervals (5, 15, 25 days) one tube was removed and shaken vigorously to redistribute the sediment and the presence of deposit if any is noted. The time taken to redisperse the sedimented suspension was recorded [8].

Determination of pH and viscosity

The pH of the suspension was determined at invervals of one week for 21 days using pH meter and their viscosity was determined at 25oC using brrokfied viscometer at 50rpm by spindle CP-52.

Table 1: Formulae of Sulphamethoxazole (SOX) suspensions

Ingredients (gm)	Formulations								
	F1	F2	F3	F4	F5	F6	F7	F8	F9
SOX	4.0	4.0	4.0	4.0	4.0	4.0	4.0	4.0	4.0
Hydroxy propyl methyl cellulose	-	1.0	2.0	-	-	-	-	-	-
Tragacanth	-	-	-	1.0	2.0	-	-	-	-
Sodium CMC	-	-	-	-	-	0.5	1.0	-	-
Hibiscus mucilage	-	-	-	-	-	-	-	1.0	2.0
Sodium benzoate	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2
Tween 80	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1
Purified water q.s. (ml)	100	100	100	100	100	100	100	100	100

Dissolution rate study

The dissolution rate of SOX from various suspensions was studied using USP XXI dissolution apparatus employing a paddle stirrer. In 900 ml of 0.1N HCl, a sample of suspension equivalent to 200 mg of SOX, a speed of 50 rpm and a temperature of 37± 0.5o were employed in each test. Aliquots of 5 ml dissolution medium collected at different intervals and were filtered through 0.45 µm filters. The amount of SOX was estimated by using Bratton and Marshall[9] colorimetric method.

In this study, mucilage of hibiscus leaves was evaluated as suspending agent. The average yield of dried mucilage obtained from hibiscus mucilage was 11.5%w/w. Suspension was prepared as per the formulae given in Table 1. All the suspending agents used in the study produced acceptable suspension. The drug content was found to be in the range of 100 ± 2 % in all the formulations. The average particle size in F1 suspension was found to be 20.1 µ where as the average particle size in remaining suspensions was found to be less than 14.5 µ.

The pH of suspensions prepared with hibiscus mucilage was in the range of 8.05-8.12, the viscosity values were 49.21, 64.32. The sedimentation profile of suspensions with hibiscus mucilage, hydroxy propyl methyl cellulose, tragacanth and sodium CMC are represented in Table 3 and in Figure 1.

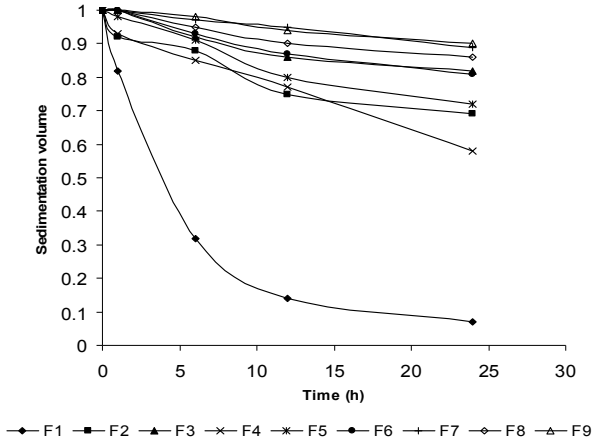

Figure 1: Sedimentation curves of SOX suspensions as a function of time

Table 2: Determination of viscosity, pH and redispersibility of SOX suspension

Formulation	Viscosity (Centipoise)	pH after storage				Rate of redispersiblity (cycles)		
		0th day	7th day	14th day	21st day	5 days	15 days	25 days
F1	20.39	4.17	4.25	4.46	4.60	48	59	71
F2	31.26	4.39	4.51	4.62	4.79	29	35	42
F3	72.79	4.41	4.55	4.65	4.81	21	29	35
F4	32.05	4.21	4.38	4.59	4.71	31	39	49
F5	64.58	4.23	4.39	4.58	4.72	25	31	46
F6	53.46	5.37	5.51	5.73	5.95	22	26	29
F7	76.32	5.48	5.59	5.78	6.21	15	19	22
F8	49.21	8.05	8.21	8.37	8.50	25	28	31
F9	64.32	8.12	8.29	8.41	8.53	14	16	21

Table 3: Sedimentation volume and dissolution data of SOX suspensions

Formulation	Sedimentation volume (Time in h)					% Dissolved in 30 minutes
	0	1	6	12	24	
F1	1	0.82	0.32	0.14	0.07	39.54
F2	1	0.92	0.88	0.75	0.69	67.29
F3	1	1	0.92	0.86	0.82	62.34
F4	1	0.93	0.85	0.77	0.58	62.56
F5	1	0.98	0.91	0.8	0.72	57.25
F6	1	1	0.93	0.87	0.81	49.56
F7	1	1	0.97	0.95	0.89	43.26
F8	1	1	0.95	0.9	0.86	69.76
F9	1	1	0.98	0.94	0.9	63.29

The dispersed particles of sulphamethoxazole prepared using hibiscus mucilage at 2% concentration was found to sediment same as that of suspension containing 0.5% of sodium CMC and at lower rate than those prepared with tragacanth and hydroxy propyl methyl cellulose, slightly higher than that of 1% sodium CMC. Since the suspension produces sediment on storage, it must be readily dispersible to ensure the uniformity of the dose. Less is the time taken to redisperse the sediment, the better is the redispersibility. The suspension prepared by sodium CMC and hibiscus mucilage showed better redispersibility than hydroxy propyl methyl cellulose and tragacanth. The values were shown in Table 2.

Dissolution profile of sulphamethoxazole from various suspensions were summarized Table 3. Formulations containing hibiscus mucilage exhibited higher dissolution rate followed by the formulations containing hydroxy propyl methyl cellulose, tragacanth and sodium CMC. The higher dissolution rate might be due to lower viscosity of respective formulations containing hibiscus mucilage. From this discussion, hibiscus mucilage was found to be a potential suspending agent in the formulation of suspensions.

CONCLUSION

Results of the present study indicating that suspension can be formulated by using mucilage obtained from the leaves of hibiscus lobatus. The suspension having 1% and 2% of mucilage exhibiting the same physical properties as that of suspension containing 0.5% sodium carboxy methyl cellulose. Suspension containing hibiscus mucilage was superior to suspension prepared by using tragacanth and hydroxy propyl methyl cellulose in terms of characteristics of suspension. From the results it was found that the redispersibility of suspension having 2% mucilage was promising. Hence, it was concluded that suspension prepared using hibiscus leaves mucilage in concentration of 2% can be suitable for formulation and long term usage.

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