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Optimization of natural and synthetic suspending agents present in diclofenac suspension

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ABSTRACT

Suspensions are coarse dispersions defined as a biphasic liquid dosage form of medicaments in which insoluble solid particles are suspended uniformly in a liquid. The size of the insoluble solid particles in liquid phase may exceed 0.1µm.Dispersed phase is also known as internal phase and continuous phase is also known as external phase. Present research work focuses on effect of suspending agents in diclofenac suspension. Both natural and synthetic suspending agents are used. The natural suspending agent is gelatin and synthetic suspending agent is carbopol. Different concentrations of gelatin (2%, 3%, and 4%) and carbopol ((2%, 3%, and 4%) was prepared. Six formulations with formulation code of F1, F2, F3, F4, F5, and F6 was formulated. The prepared suspensions are evaluated for viscosity,pH, sedimentation volume, degree of flocculation, particle size etc.

INTRODUCTION

Suspensions are choice of formulation when the drug is insoluble in aqueous and non aqueous solvent. Suspensions prolong the duration of action and increase the stability of drug which is liable to hydrolysis. [1] Suspensions offer more advantages than solid dosage forms. They are easy to swallow higher bioavailability and prolong the duration of action. The type of suspensions includessuspensions for oral use, parenteral use and external use. Suspensions are classified as flocculated and deflocculated suspension. Suspending agents are used to improve physical stability, and also enhance viscosity of the continuous phase by remaining as suspended particles in liquid for a long time. [2] Hydrocolloids are used for aqueous suspension, and sodium carboxy methyl cellulose was used for parenteral suspension.

The factors to be considered while selecting suspending agents are

1. Settling of particles
2. Pouring of suspension through the bottle
3. Spreading of suspension on the affected area of the skin

Some of the suspending agents are Natural like gelatin and sodium alginate and synthetic like carbopol, polyvinyl alcohol etc [3]

MATERIALS AND METHODS

All the chemicals used were of analytical grade. Chemicals used and their uses are shown in table no 1

Table no 1: Explanation of ingredients used in the formulation

S.No	Ingredients	Company	Category
1	Diclofenac	Madras pharmaceuticals	Anti -inflammatory
2	Gelatin	Nice chemicals	Natural suspending agent
3	Carbopol	Nice chemicals	Synthetic suspending agent
4	Potassium chloride	Nice chemicals	Buffer
5	Sucrose	Nice chemicals	Sweetening agent

Table no 2: Formulation Table

S.No	Ingredients	F1	F2	F3	F4	F5	F6
1	Diclofenac	1gm	1gm	1gm	1gm	1gm	1gm
2	Gelatin	2gm	3gm	4gm	-	-	-
3	Carbopol	-	-	-	2gm	3gm	4gm
4	Potassium chloride	1gm	1gm	1gm	1gm	1gm	1gm
5	Sucrose	10mg	10mg	10mg	10mg	10mg	10mg
6	Water	Q.S to 100ml	Q.S to 100ml	Q.S to 100ml	Q.S to 100ml	Q.S to 100ml	Q.S to 100ml

Method of preparation [4]

One gram of diclofenac was weighed and triturated in a mortar with a pestle. The suspending agents were added along with water, sucrose and potassium chloride. The slurry was transferred to 100ml measuring cylinder and make up the volume up to 100ml. The ingredients quantities are shown in table no 2.

Evaluation

Sedimentation volume [5]

Suspension of 100ml was stored in a 100ml measuring cylinder for 1hour at room temperature and observations were made for every 15 mins for 1 hour. The sedimentation volume was calculated using the following formula.

Sedimentation volume (F) = Hu/Ho

Ho = Initial height of suspension

Hu = Ultimate height of suspension

Degree of redispersibility [6]

Fixed volume of suspension 100ml was kept in a measuring cylinder which was stored at a room temperature for 1 hour at regular time intervals, measuring cylinder was moved upside, down until there was no sediment at the bottom of the cylinder.

Determination of pH [7]

Using pH meter the pH of diclofenac suspension was measured.

Viscosity determination

Using Brookfield viscometer the viscosity of the prepared suspension was measured. All the determinations were made in triplicate and results obtained were expressed in mean values.

Stability studies [8]

The shelf life of the product was fixed by performing stability studies for the prepared formulation. Accelerated stability studies was conducted for the prepared formulation by storing the containers at 40 ± 2^{0}C temperature and 75±5%RH and studied for one month.

RESULTS AND DISCUSSION

Sedimentation volume

Sedimentation volume (F) = Hu /Ho

Ho = Initial height of suspension

Hu = Ultimate height of suspension

The sedimentation volume results are shown in table No 3

Table No 3Sedimentation Volume of the prepared Diclofenac Suspension

S.No	Formulation code	Sedimentation Volume
1	F1	0.45±0.2
2	F2	0.54±0.4
3	F3	0.65±0.1
4	F4	0.89±0.5
5	F5	0.98±0.8
6	F6	0.97±0.9

pH test

The pH values are recorded for all the six formulations. The F5 formulation shows 7.23±0.3 pH which was nearer to the skin pH. The results are shown in table no 4.

Table No4 pH of the prepared Diclofenac Suspension

S.No	Formulation code	pH
1	F1	8.12±1.2
2	F2	8.53±0.8
3	F3	8.28±0.5
4	F4	6.92±0.1
5	F5	7.23±0.3
6	F6	6.50±0.2

All the values are expressed as mean ±SD,n=3

Viscosity test

The viscosity test was performed using Brookfield viscometer. The F3 formulation containing both natural and synthetic humectant shows better viscosity than other formulations. The results are shown in table no 5

Table no 5 Viscosity of prepared formulations

S.No	Formulation code	Viscosity
1	F1	21.4±0.6
2	F2	28.0±0.2
3	F3	52.1±0.4
4	F4	62.3±0.8
5	F5	65.5±0.2
6	F6	122.0± 0.5

All the values are expressed as mean ±SD,n=3

From the viscosity studies it was concluded that F5 formulation shows moderate viscous than other formulations, easily pourable from the container, and it has ability to retain in the skin for a long time.

Stability Studies

The stability study was conducted for the selected formulation F5 as per ICH guidelines for a period of 1 month. The stability results are shown in table no 6

Table no 6 stability studies reports of the selected formulation F5

S.No	Parameters	Initial	Final			
			1st week	2nd Week	3rd Week	4th week
1	Color	White	White	White	White	White
2	pH	7.23±0.3	**7.1**4±0.1	7.00±0.4	7.28±0.3	7.11±0.5
3	Viscosity (Centipoise)	65.5±0.2	63.2±0.3	64.5±0.1	65.2±0.4	64.5±0.6
4	Sedimentation Volume	0.98±0.2	0.97±1.2	0.98±0.4	0.96±0.1	0.99±1.3
5	Degree of re dispersibility	Readily redispersible	Readily re dispersible	Readily redispersible	Readily redispersible	Readily redispersible

All the values are expressed as mean ±SD,n=3

From the results it was found that the selected formulation F5 was found to be stable. There was no significant change from initial readings to final results after 1 month of stability studies.

CONCLUSION

The suspension was prepared by trituration method. F5 formulation was found to be best when compared to other formulations. The pH was found to be 7.23±0.3which are nearer to skin pH and viscosity was found to be 65.5±0.2. The sedimentation volume of the selected formulation was found to be0.98±0.2 which is near to 1 indicated good suspend ability where as other formulations are not near to 1.From the stability studies it was confirmed that the prepared formulation F5 was found to be stable. So the formulation F5 containing carbopol 3% is effective in all the aspects.

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