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Preparation and Evaluation of Taste Masked Oral Suspension of Olopatadine

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Abstract

Due to bitter taste of a tablet, paediatric and geriatric patients are not easily swallowed tablets. In this method, the taste was masked by using a suitable polymer and drug ratio. A different technique was available in pharmaceutical but in this method, we have used the antisolvent technique of microencapsulation. Nearly pH 5 encapsulated particle will be absorbed by GIT. the drug was used with different polymer ratio such as (1:10) and (1:20). 1:20 ratio was select for suspension and drug entrapment efficiency was found to be 43% and 52% respectively. Three polymers were used such as HPMC (2%), Methylcellulose (2%), CMC (2 %), CMC (0.5%) as a suspending agent and evaluated by using sedimentation volume, degree of redispersibility, viscosity, flow rate and pH. the ratio was selected after suspension and taste-masked were evaluated by performed on human volunteers. Based on their responses, the prepared suspension was found to be tasteless. This method gives better taste masking oral suspension for paediatric and geriatric patients.

Keywords: Olopatadine; Taste mask suspension; Oral suspension; Methylcellulose;

Introduction

Paediatric and geriatric patients are frequently failed to take medication properly because of unpleasant taste of [1,2]. Medication non-compliance can lead to worsening of diseased condition.Numbers of taste masking have been used to address the problem of patient compliance. Use of sweeteners, amino acid and flavouring agent alone or often inadequate in masking the taste of highly bitter drug. Coating is more efficient technology for aggressively bitter drugs even though coating imperfection, if present, reduce the efficiency of the technique. Microencapsulation of potent bitter active agent such as olopatadine is insufficient provide to taste masking of liquid oral suspension [3].

Materials and Methods

Material

The following drug, excipients and chemicals were used for formulation and evaluation of taste masked olopatadine suspension. Olopatadine was gifted by Cipla Research Center, Eudragit E100 were purchased by evonic industries, Hydroxypropyl Methylcellulose (HPMC), Carboxymethyl Cellulose (CMC), Methylcellulose were purchased by chemdyes corporation Methylcellulose Hydrochloric Acid, Methanol, sodium hydroxide were purchased by Rankem Pvt Ltd [4-6].

Method

microparticle prepare by precipitation method

Formulation of drug polymer microencapsulation was done by the batch process; 100 mg of polymer (eudragit E100) was placed in a beaker containing 10 mL of 0.1N HCl and allowed to swell for a definite period of time. Accurately weighed amount of olopatadine (as per 1: 10 and 1: 20 drug polymer ratio) was added and stirred for desired period of time. This solution was added dropwise in 0.1N NaOH [7-9]. The mixture was filtered and residue was washed with deionized water.

method of preparation of suspension

Specific amount of microparticle and suspending agent were taken in mortar pestle and triturated for proper mixing. Then some water is added in same mortar pestle and again triturated the mixture. Then, the formed solution is mixed with water and shaken properly for some time. Meanwhile, suitable amount of preservative and flavoring agents was added. This results in formation of a suspension.

Evaluation

Sedimentation volume

50 ml of our suspension is taken in a measuring cylinder, and kept aside for 7 days to check the sedimentation rate **Table 2**. Visual analysis was performed [11] daily to analyze the rate of

sedimentation. The observed values were placed in pre-reported formula and results were recorded.

Formula- sedimentation volume = sediment volume/initial volume*100.

Formulation	Suspending Agent	Percentage	Sedimentation Volume
A	Hpmc	0.5	0.1 ± 0.2
B	Hpmc	1	0.18 ± 0.2
C	Hpmc	2	0.26 ± 0 0.4
D	Methyl Cellulose	0.5	0.15 ± 0.3
E	Methyl Cellulose	1	0.33 ± 0.2
F	Methyl Cellulose	2	0.41 ± 0.1
G	Carboxymethyl Cellulose	0.5	0.63 ± 0.2
H	Carboxymethyl Cellulose	1	0.88 ± 0.2
I	Carboxymethyl Cellulose	2	1 ± 0.5

Table 1: Sedimentation Volume of Oral Suspension.

Degree of redispersibility

Fixed volume of suspension (50ml) 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.

Formulation	Suspending Agent	Percentage	Redispersible
A	Hpmc	0.5	Dispersible
B	Hpmc	1	Redispersible
C	Hpmc	2	Redispersible
D	Methyl Cellulose	0.5	Low Redispersibility
E	Methyl Cellulose	1	Low Redispersibility
F	Methyl Cellulose	2	Low Redispersibility
G	Carboxymethyl Cellulose	0.5	Readily Redispersible
H	Carboxymethyl Cellulose	1	Redispersible
I	Carboxymethyl Cellulose	2	Low Redispersibility

Table 2: Degree of Redesprsibility of Oral Suspension.

Determination of pH

Firstly, caliberated the pH meter and suitable volume of suspension is placed on the pH meter and the readings are noted. This is the pH of prepared suspension [12].

Flow rate

Fixed volume of suspension (10ml) is taken in a graduated pipette and allowed to flow freely in a container and noted down the time until the end of volume of suspension. The whole volume flows down freely were divided by time was considered as flow rate **Table 3**.

Formula–volume of suspension taken in pipette/ total flow time.

Formulation	Suspending Agent	Percentage	Flow Rate
		(W/V)	(In Ml/Min.)
A	HPMC	0.5	10.2
B	HPMC	1	9.5
C	HPMC	2	8.9
D	Methyl Cellulose	0.5	8.1
E	Methyl Cellulose	1	5.9
F	Methyl Cellulose	2	6.67
G	Carboxymethyl Cellulose	0.5	4
H	Carboxymethyl Cellulose	1	1.5
I	Carboxymethyl Cellulose	2	Too Viscous

Table 3: Flow Rate of Oral Suspension.

Viscosity

The viscosity was measured by Brookfield viscometer. 200 ml suspension was taken in a beaker and placed in Brookfield viscometer **Table 4**. The temperature is kept 25°C and spindle used is #5. The speed is kept at 50 revolution/ min. noted the reading in centipoise.

Formulation	Suspending Agent	Percentage (W/V)	Viscosity (In Cp)
A	HPMC	0.5	86
B	HPMC	1	142
C	HPMC	2	196
D	Methyl Cellulose	0.5	74
E	Methyl Cellulose	1	186
F	Methyl Cellulose	2	230
G	Carboxymethyl Cellulose	0.5	408
H	Carboxymethyl Cellulose	1	902
I	Carboxymethyl Cellulose	2	1360

Table 4: Viscosity of Oral Suspension.

Particle size analysis

Optical Microscope was used for the determination of the shape of prepared microparticles. Small quantities of microparticles were placed on a clean glass slide. The slide containing microparticles was mounted on the mechanical stage of microscope and observed [13].

Stability studies

The shelf life of the product was fixed by performing stability studies for the prepared formulation **Table 5**. Accelerated stability studies was conducted for the prepared formulation by storing the containers at 40±2°C temperature and studied for one month.

S. No.	Parameter	Initial	1st weak	2ndweak	3rdweak	4thweak
1	Sedimentation Volume	0.63 ± 0.2	0.62± 0.3	0.64 ± 0.2	0.62 ± 0.1	0.61 ± 0.3
2	Degree of Redispersible	Readily Redispersible	Readily Redispersible	Readily Redispersible	Readily Redispersible	Readily Redispersible
3	pH	7.23 ± 0.2	7.18 ± 0.1	7.15 ± 0.2	7.12 ± 0.1	7.09 ± 0.2
4	Flow rate	4	3.95	3.88	3.71	3.65
5	Viscosity	408 ± 0.2	407 ± 0.3	408 ± 0.2	407 ± 0.1	408 ± 0.3
6	Taste	Tasteless	Tasteless	tasteless	Tasteless	tasteless

Table 5: Stability Results of Oral Suspension.

Evaluation of taste masking

The taste masking was evaluated by written consent of human volunteers. 10 human volunteers are required for the studies. 5 ml suspension containing 100 mg microparticles were given to volunteers and told to spit out after 15 seconds. Readings were evaluated on the basis of 0 – tasteless, 1 – slight bitter, 2- bitter, 3- very bitter.

Results and Conclusion

Olopatadine drug was selected as a suitable drug candidate for this study because it is very bitter in taste. Thus, taste masking is very important for administration in patients mainly pediatric and geriatric. Microparticles were prepared by anti-solvent addition as it is a cheap, fast method and desired particle size range is achieved. Green synthesis was preferred for the formulation of microparticles because of the reported hazards [14]of adding organic solvent. Thus 0.1 N HCl used as solvent for dissolving drug and polymer. 0.1 N NaOH was used as antisolvent. Eudragit E 100 was preferred because it has reported taste masking capabilities. Characterization of microparticles was done on the basis of taste masking, size and shape, entrapment efficiency, DSC. Taste masking was performed on human volunteers. Based on their responses, it was evident that the prepared microparticles are tasteless. Size of microparticles were found uniform by optically microscopy. Entrapment efficiency was found to be 52% (1:20) and 43% (1:10). Suspension was formulated due to several advantage. Three polymers were used i.e. HPMC (2%), Methyl cellulose (2%), CMC (2 %), CMC (0.5%). Prepared suspension was characterized on the basis of parameters like sedimentation volume, degree of redispersibility, flow rate, viscosity. From the results, it was evident that suspension containing CMC (0.5%) was showing best results among all four formulations. From the stability study results it was found that the selected formulation D was found to be stable. There was no significant change from initial readings to final results after 1 month of stability studies.Taste masking evaluation was performed on human volunteers. Based on their responses, prepared suspension was found to be tasteless, thus taste masking was successfully done. The DSC curve showed the sharp peak at the respective melting point of Olopatadine. The melting point of Olopatadine was found to be 240- 250°C. DSC curve of olopatadine show its peak at its reported melting point of 248°C. figure 8 shows DSC curve of pure olopatadine. The result of DSC analysis also confirm that drug sample obtained were pure and could be used for further work

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