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RESEARCH ARTICLE
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FORMULATION AND DEVELOPMENT OF TASTE MASKED SUSPENSION USING ION EXCHANGE RESINS

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Abstract
In the present work the attempt was made to prepare taste masked suspension of Ambroxol Hydrochloride by abating the intensely bitter taste of Ambroxol Hydrochloride. Taste abatement was done by complexing of Ambroxol hydrochloride with different Ion Exchange Resins (IER) like Tulsion 335 and Indion 214 in different ratios. The prepared suspensions were evaluated for taste, drug content, particle size, viscosity, sedimentation volume and drug release. The resonates prepared with drug- T335 ratio (1:2) at pH 8, gave maximum drug loading. Suspension containing above resinates showed more than 80% *In vitro* drug release within 30 min. Prepared formulation also showed good stability and can retain its palatable taste. The developed formulation was an additional advantage like simplification of manufacturing procedure and is economical. Thus, the "patient friendly dosage form" of bitter drugs, especially for pediatric, geriatric, bedridden, and noncooperative patients, can be successfully formulated using this technology.

Keywords: AHS, Formulation, IER, Taste masking.

INTRODUCTION

Children are frequently failed to take medications properly because of unpleasant taste of medicament. Non-compliance can lead to worsening of diseased condition[1]. Numbers of taste masking technologies have been used to address the problem of patient compliance. In Ion exchange resin (IER) method weak cation exchange or weak anion exchange resins are used for taste masking, depending on the nature of drug[2]. The nature of the drug resin complex formed is such that the average pH of 6.7 and cation concentration of about 40meq/L in the saliva are not able to break the drug resin complex but it is weak enough to break down by hydrochloric acid present in the stomach. Thus the drug resin complex is absolutely tasteless with no after taste, and at the same time, its bioavailability is not affected. Children under the age of 8 are typically prescribed liquid medications because of smaller structure of a child's esophagus[3,4]. Ambroxol HCl is a highly bitter drug, used in the treatment of respiratory disorders associated with viscid mucous[5,6].

MATERIALS AND METHODS

Materials

Ambroxol HCl was gift sample from Alkem Pharmaceuticals Ltd., (Mumbai, India). Tulsion 335 was obtained as gift sample from Thermax, Pune and Indion 214 was purchased from Ion exchange India limited (Mumbai, India). Sucrose, Sorbitol, Glycerine, Xanthane gum, Aspartame, Methyl paraben

and Mangocandy flavour were purchased from S. D. Fine chemicals (Mumbai, India). All other chemicals/solvents were of analytical grade.

Methodology

Purification of ion exchange resin

Resins were purified using the method reported by Irwin et al[1]. The resins (5 g) were washed successively with distilled water, methanol (50 ml), benzene (50 ml), methanol (50 ml) and several times with distilled water to eliminate organic and color impurities. Then, the wet resins were activated by 0.1 M HCl 50 ml and washed several times with distilled water. All resins were dried overnight in hot air oven at 50^0C and kept in an amber glass vial.

Preparation of drug – resin complex: Drug-resin complex were prepared by batch process.
Step 1: Weigh all the ingredient accurately. Now add weighted quantity of resin in specific quantity of water and stir it for 15 min. under mechanical stirrer.
Step 2: Now add weighted quantity of Ambroxol HCl in to step 1 & stir it for 4 to 5 hr. continuously under stirrer.
Step 3: Take specific quantity of water boil it dissolve sugar & filter it. Now cool the syrup at room temperature and add sorbitol and glycerin in it & add into step 2 under continuous stirring.
Step 4: Take water & add xanthane gum and stir it to form a paste. Add this paste in step 3 slowly under stirring.
Step 5: Take warm water dissolve methylparaben, propylparaben & aspartame in to it & add in to above solution under stirring.
Step 6: Now add coloring, flavoring agent in step 5 & make volume of suspension up to required quantity by using purified water, pH of resin solution was adjusted to 8 by using 1 M KOH.

Preparation of Suspension

Suspensions were prepared as per Table No. 1

Table No. 1: Composition of Ambroxol HCl Suspension

Complex Preparation	F1	F2	F3	F4
Ambroxol HCl	100	100	100	100
Tulsion 335	100	200	-	-
Indion 214	-	-	100	200
Purified Water (ml)	2.5	205	2.5	2.5
Syrup preparation				
Sucrose (mg)	2.25	2.25	2.25	2.25
Glycerine (ml)	0.5	0.5	0.5	0.5
Xanthan Gum (mg)	20	20	20	20
Methyl Paraben (mg)	10	10	10	10
Propyl Paraben (mg)	4	4	4	4
Asparteme (mg)	15	15	15	15
Mango Candy Flavor (ml)	0.13	0.13	0.13	0.13
Quinoline yellow color (mg)	0.1	0.1	0.1	0.1

Evaluation of Ambroxol HCl Suspension

The suspensions were evaluated for physicochemical characterization like drug content, viscosity, sedimentation rate, invitro dissolution etc. (Table No. 2)

Table No. 2: Evaluation Parameter of Ambroxol HCl Suspension

Parameter	F1	F2	F3	F4
Appearance	uniform	uniform	uniform	uniform
Taste	Sweet, palatable	Sweet, palatable	Sweet, palatable	Sweet, palatable
pH	6.0	5.9	5.9	6.1
Viscosity (cps)	210	303	220	310
Sedimentation Ratio	0.92	0.96	0.93	0.94
Redispersibility	+++	+++	+++	+++
Drug content (% w/v)	92.7	97.2	91.54	94.6
In vitro dissolution (%)	89.56	94.20	88.69	90.05

RESULT AND DISCUSSION

Prepared suspensions showed satisfactory physical properties. Drug content for F1, F2, F3 and F4 were 92.7, 97.2, 91.54 and 93.6. Results shows that using Tulsion-335 and Indion 214 maximum drug loading were observed at 1:2 drug-resin ratio.

Dissolution profile of Suspension

In vitro release study was carried out in 0.1 N HCL using USP paddle apparatus at 50 rpm. The release data given (Figure-I) showed that the rate of drug release from the suspension was increase as drug: resin ratio increases. More than 70% of drug was released within 30 min from all formulations.

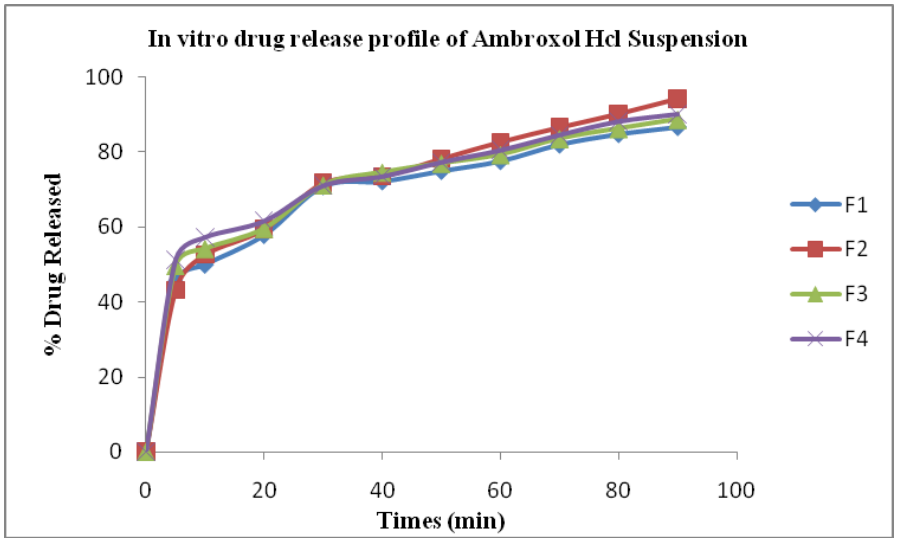

Figure 1: In vitro drug release profile of Ambroxol Hcl Suspension

CONCLUSION

Many parents are faced with the daily challenge of getting their children to take a medicine. The unpleasant flavor of the medicine can thwart the benefits of even the most powerful drug, and failure to consume medication may do the child harm, and in some cases, may be life-threatening. Use of ion exchange resin offers superior method for preaparing taste-masked substrates of Ambroxol HCl. Results obtained in this work show that drug-resin complexes effectively masked bitter taste of Ambroxol HCl. While liquid formulation provides easier way to administer and getting the child to swallow.

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