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FORMULATION AND EVALUATION OF PEDIATRIC AZITHROMYCIN SUSPENSION

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ABSTRACT

Pediatric Azithromycin Suspension were formulated by employing various suspending agents in hydroxyl propyl methyl cellulose, sodium corboxy methyl cellulose, acacia, gum tragacanth and were evaluated for particles size, physical stability and dissolution rate. Pediatric Azithromycin Suspension formulated by employing various suspending agents exhibited good suspendability and give higher dissolution rate than those formulated with Azithromycin. Good linear relationships were observed between particle size and dissolution rate & efficiency i.e., Smaller Particles gave higher dissolution rate and efficiency values.

KEYWORDS

Azithromycin, suspending agent, hydroxyl propyl methyl cellulose, sodium corboxy methyl cellulose, acacia, gum tragacanth

INTRODUCTION

Suspensions are defined as heterogeneous system consisting of two phases. The continuous (or) semisolid (or) external phase and internal phase (or) dispersed phase which is made up of particulate matter i.e., insoluble in but dispersed throughout the continuous phase.

The particle size of dispersed phase ranges from 0.5µm- 5µm.

To formulate any type of dosage form different excipients are essential apart from active therapeutic agent. The preparation of suspension also requires a No. Of excipients (or) formulation additives so as to render it more stable and present it in desired form with desired properties.

The various excipients used in the formulation of suspension are:

Vehicles, Wetting agents, Suspending agents, Flocculating agents, Viscosity modifiers, Formulation additives

MATERIALS

SL.NO	NAME OF THE MATERIAL	SOURCE
1.	Azithromycin	Gift sample from Microlabs
2.	Sodium Lauryl Sulphate	S.D. fine chemicals Limited

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3.	Hydroxy Propyl Methyl Cellulose	Himedia Laboratories (P) Ltd.
4.	Sodium Carboxy methyl cellulose	Himedia Laboratories (P) Ltd
5.	Acaia	Nice Chemicals Pvt. Ltd.
6.	Gum Tragacanth	Nice Chemicals Pvt. Ltd.
7.	Aluminium Chloride	Nice Chemicals Pvt. Ltd.
8.	Sodium Benzoate	S.D. fine chemicals Limited
9.	Sucrose	Himedia Laboratories (P) Ltd
10.	Folin Ciocalteau reagent	Nice Chemicals Pvt. Ltd.

PROCEDURE

Procedure For Preparation Of Pediatric Azithromycin Suspension

Suspensions containing 104.8mg in 5ml were formulated as per formulae given in Table1. Accurately weighed quantity of Azithromycin was taken in a mortar. To that mucilage of suspending agent was added in divided portions. Sucrose was added as a solution in water while mixing other ingredients were added one added one after another mixed and the suspension was transferred to a measuring jar and adjusted to the volume.

In formulae 5,6,7 Sodium Lauryl sulphate were used as wetting agent. In those preparation surfactant were added before to the suspending agent as a mucilage.

(F7) Flocullated Suspension was prepared by adding aluminium chloride as a flocullating agent.Ingredients used in Each Formulae (F1 – F7)

Drug Content Uniformity

The Azithromycin Suspension, which were prepared and tested for drug content uniformity. From each formulated suspension equivalent to 100 mg of Azithromycin were taken and analyzed for drug content uniformity.

Estimation Of Azithromycin Dihydrate In Solid Dispersion By Visible Spectrophotometry

5 ml of formulated Azithromycin suspension were dissolved in 25 ml of methanol in 50 ml of volumetric flask and made up to mark with Sodium phosphate buffer pH 6 . Then that solution was properly diluted. To the diluted solution 2ml of Folin ciocalteu reagent and 2 ml of 20% Sodium carbonate solution were added & mixed well and kept for 15 minutes for maximum development of color .Then absorption was measured at 760 nm in a Visible spectrophotometer.

In Vitro Dissolution Studies Of Sample And Marketed Formulation

The dissolution of marketed formulation and formulated

Suspension were carried out, by using dissolution apparatus (Lab India Disso 2000, India).

Dissolution method:

Dissolution Medium : Sodium Phosphate Buffer pH 6

Volume : 900 ml.

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Apparatus : Paddle
Rotating Speed/Intensity : 100 RPM
Temperature : 37 ± 0.5 º C
Sampling Interval : 10, 20, 30, 45,60 minutes
Volume of Sample : 5 ml

900 ml. of 0.1 M, pH 6 sodium phosphate buffer was used as dissolution medium. Formulated suspensions and marketed Pediatric Azithromycin suspensions were placed in separate flasks. The USP I type apparatus was adjusted to 100 rpm and the temperature was maintained at 37°±1°C. 5 ml aliquot dissolution media was withdrawn at different time intervals and volume withdrawn was replaced with fresh quantity of dissolution media. The aliquot samples were filtered using whattman filter paper. Then poured in 10 ml volumetric flask to this 2 ml of folin ciocalteau reagent & 2 ml of 20% sodium carbonate solution were added and made up to volume with Dissolution medium.

The samples were analyzed for Azithromycin dihydrate by measuring absorbance at 760 nm using visible spectrophotometer. sodium phosphate buffer pH 6 was used as blank solution. The dissolution experiment work was conducted in triplicate. The Cumulative percentage of drug dissolved at various time intervals was calculated and plotted against time.

RESULTS AND DISCUSSIONS

The data obtained from the determination of sedimentation rates revealed that the formulations prepared with HPMC possessed higher sedimentation rations when compared with other formulations. Among the four formulations of HPMC, with increasing the concentration of polymer (HPMC) sedimentation ratios also increased.

The particle sizes were found to be in the range from 3.065 – 15.45µ. With increasing the concentration of HPMC, the particle size of the suspension was found to be decreased.

The p^H values of all the formulations were complied as per I.P. requirements.

The drug content of all formulations ranges from 98 – 99%. This formulation complies as per I.P. requirements i.e, 98 -102%.when sodium lauryl sulphate were added to suspension that enhances the *in vitro* drug release by enhancing the solubility.

Suspensions formulated employing 0.5% concentration HPMC gave significantly higher dissolution rate among all the formulations. Hence 0.5% concentration of HPMC was found to be optimum concentration.

Good linear relation ships were observed between the particle size and dissolution rate of Azithromycin from the suspensions. Smaller particles gave higher dissolution rates.

Formulated suspensions (F 5,6,&7) shown better dissolution profile compared to marketed formulation. Among the formulated suspensions F 6 showed better *in vitro* drug release profile as well as better physical stability compared to other formulated suspensions.

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