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(RESEARCH ARTICLE)

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Development and evaluation of nanosuspension of famciclovir for ophthalmic application

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Abstract

Different excipients are used in formulation like Poloxamer-188, PVP K-90, different concentrations. F5 batch has shown the better results in high-speed homogenization Different excipients were shown variation in particle size, DSC study, drug content, entrapment efficiency and in-vitro dissolution study. Optimized formulation was chosen on the basis of results obtained from particle size and entrapment efficiency. The combination of excipients yields nanosuspension with the smallest average particle size and by the transformation of the nanosuspension into the physical stability of this system could be further enhanced.

Keywords: Nano Suspension; Famciclovir; Ophthalmic; Evaluation; Viral

1. Introduction

1.1 Nanosuspension

Nevertheless, pharmacokinetic studies of BCS class – II drugs showed that they have a low oral bioavailability, which may be due to the poor water solubility of the drug. There are many classical pharmaceutical ways to improve drug dissolution rates such as dissolution in aqueous mixtures with an organic solvent1 [9], the formation of ß-cyclodextrin complexes2, solid dispersions3 and drug salt form4.

During last 20 years a new technology, reducing drug particle size, has been developed to increase drug dissolution rate. According to Noyes–Whitney equation, drugs with smaller particle size have enlarged surface areas which lead to increase dissolution velocity. Higher the dissolution rate together with the resulting higher concentration gradient between the gastrointestinal lumen and systemic circulation could further increase oral bioavailability of drugs5. Nanosuspension is a submicron colloidal dispersion of drug particles which are stabilized by surfactants. A pharmaceutical nanosuspension is defined as very finely dispersed solid drug particles in an aqueous vehicle for oral, topical, parenteral or pulmonary administration. The particle size distribution of the solid particles in nanosuspensions is usually less than one micron with an average particle size ranging between 200 and 600 nm6. In nanosuspension technology, the drug is maintained in the required crystalline state with reduced particle size, leading to an increased dissolutionrateand therefore improved bioavailability. An increase in the dissolution rate of micronized particles (particle size < 10 µm) is related to an increase in the surface area and consequently the dissolution velocity. Nanosized particles can increase solution velocity and saturation solubility because of the vapor pressure effect. In addition; the diffusional distance on the surface of drug nanoparticles is decreased, thus leading to an increased concentration gradient. Increase in surface area, as well as concentration gradient, leading to a much more pronounced increase in the dissolution velocity as compared to a micronized product. Another possible explanation for the increased saturation solubility is the creation of high energy surfaces when disrupting the more or less ideal drug microcrystals to

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nanoparticles. Dissolution experiments can be performed to quantify the increase in the saturation solubility of a drug when formulated into a nanosuspension7.The stability of the particles obtained in the nanosuspension is attributed to their uniform particle size which is created by various manufacturing processes. The absence of particles with large differences in their size in nanosuspensions prevents the existence of different saturation solubilities and concentration gradients; consequently, preventing the Oswald ripening effect. Ostwald ripening is responsible for crystal growth and subsequently formation of micro-particles. It is caused by a difference in dissolution pressure/saturation solubility between small and large particles. Molecules diffuse from the higher concentration area around small particles which have higher saturation solubility to an area around larger particles possessing a lower drug concentration. This leads to the formation of a supersaturated solution around the large particles and consequently to drug crystallization and growth of the large particles.

Table 1 Formulation consideration for Nanosuspension

Excipients	Function	Examples
Stabilizers	Wet the drug particles thoroughly, prevent Ostwald's ripening and agglomeration of nanosuspensions, providing a steric or ionic barrier	Soya Lecithins, Poloxamers188/407, Polysorbate 80, HPMC E-15/E-50, PVP K-25/K-30
Co-surfactants	Influence phase behavior when microemulsions are used to formulate nanosuspensions	Bile salts, Dipotassium Glycyrrhizinate, Transcutol, Ethanol, Isopropanol
Organic solvent	Pharmaceutically acceptable less hazardous solvent for preparation of formulation.	Methanol, Ethanol, Chloroform, Isopropanol, Ethyl acetate, Ethyl formate, Butyl lactate, Triacetin, Propylene carbonate, Benzyl alcohol.
Other additives	According to the requirement of the route of administration or the properties of the drug moiety	Buffers, Salts, Polyols, Osmogens, Cryoprotectant etc.

2. Material and Method

2.1 Material

Table 2 List of Materials

Sr. No.	List of Chemicals	Gifted by
1	Famciclovir	Srijan Pharma, Baddi.
2	Poloxamer 188	Srijan Pharma, Baddi.
3	Polyvinyl alcohol	Srijan Pharma, Baddi.
4	PVP K 90	Srijan Pharma, Baddi.
5	SLS	Srijan Pharma, Baddi.
6	Mannitol	Srijan Pharma, Baddi.
Solvents		
7	Methanol(AR grade)	S.K. Traders, Indore
8	Ethanol (AR grade)	S.K. Traders, Indore
9	Acetone (AR grade)	S.K. Traders, Indore

2.2 Methods

- Preformulation studies of drug
  - Colour, odour and appearance
  - UV analysis
  - Solubility
  - Melting point
  - FTIR
- Formulation of Nanosuspension by using High speed homogenization process
- Selection of optimized formulation
- Evaluation of Optimized Formulation
  - Particle size
  - Entrapment efficiency (%)
  - Redispersibility of nanosuspension
  - Scanning electron microscopy
  - In-Vitro Drug Release Study
  - Stability Studies

3. Result and Discussion

3.1 Organoleptic Properties of Drug

Table 3 Organoleptic Properties of Drug

Sr. no.	Parameter	Description
1	Color	White to off white
2	Odor	Odorless
3	Appearance	Non-hygroscopic white or whitish crystalline powder

3.1.1 Solubility Studies

The solubility in Ethanol, pH 7.4 and Distilled water, while optimized formulation is completely soluble in methanol, and poorly soluble in water, Ethanol, pH 7.4. of pure drug Famciclovir is completely soluble in methanol.

3.1.2 Identification Of Drug

Identification of artemether and lumefantrine is carried out by FTIR Spectrophotometry.

Table 4 Identification of Drug by FTIR Spectrophotometry

Sr. No.	Observed peaks (cm-1)	Reported peaks (cm-1)	Interpretation of chemical group	Intensity
1	1627.01	1620-1520	C= O Phenyl	Medium
2	1389.76	1454-1358	C-H	Strong
3	1182.40	1180-1185	C-O	Strong
4	893.07	991-802	-CH	Strong
5	3441.12	3400-3700	O-H	Medium-strong

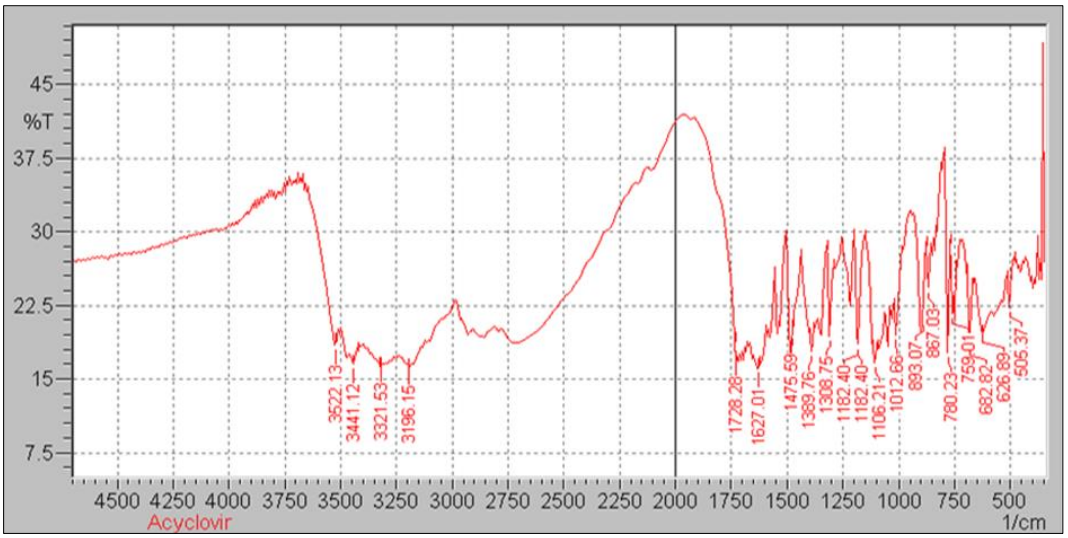

Figure 1 For FTIR

3.1.3 Differential scanning calorimetry (DSC)

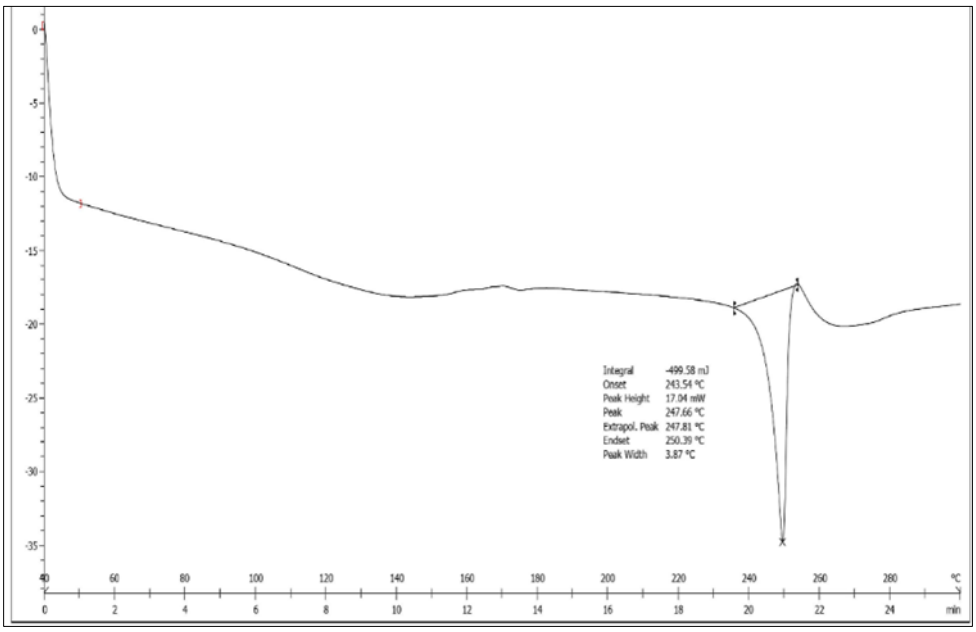

Figure 2 DSC graph of Famciclovir

3.1.4 In-Vitro Drug Release Study

Table 5 Drug release study

Sr.No	Time (min)	% Cumulative Drug Release
1	0	0
2	15	2.30
3	30	4.11
4	45	24.87
5	60	35.95
6	120	68.20
7	180	94.20

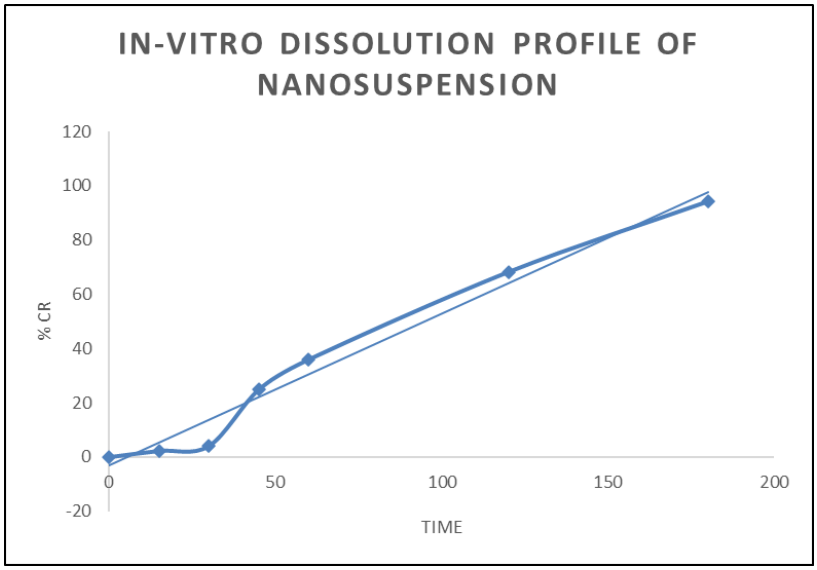

Figure 3 *In vitro* release study of the Optimized nanosuspension formulation

3.1.5 Stability study

Table 6 Stability Study

Sr. No.	Parameter	0 Month	1 Month	2 Month	3 Month
1	Particlesize (nm)	203.2 ± 0.45	204.7 ± 0.12	205.1 ± 0.3	206.6 ± 0.2
2	% Entrapment Efficiency (EE %)	90.6 ± 0.5	88.2 ± 0.30	84.2 ± 0.4	82.2 ± 1.0

4. Conclusion

Results conclusively prove that Famciclovir nanosuspension prepared by high-speed homogenization method. Different excipients are used in formulation like Poloxamer-188, PVP K-90, different concentrations. F5 batch has shown the better results in high-speed homogenization Different excipients were shown variation in particle size, DSC study, drug content, entrapment efficiency and in-vitro dissolution study. Optimized formulation was chosen on the basis of results obtained from particle size and entrapment efficiency. The combination of excipients yields nanosuspension with the smallest average particle size and by the transformation of the nanosuspension into the physical stability of this system could be further enhanced.

Compliance with ethical standards

Disclosure of conflict of interest

For the Institutional growth of the authors.

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