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(54) **Title:** SOLID DISPERSIONS OF CEFPODOXIME PROXETIL AND PROCESSES FOR THEIR PREPARATION

(57) **Abstract:** The technical field of the present invention relates to solid dispersions of cefpodoxime proxetil, processes for their preparation, and pharmaceutical compositions that include solid dispersions of cefpodoxime proxetil. The solid dispersion includes cefpodoxime proxetil dispersed in a carrier.

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SOLID DISPERSIONS OF CEFPODOXIME PROXETIL AND PROCESSES FOR THEIR PREPARATION

Filed of Invention

The technical field of the present invention relates to solid dispersions of cefpodoxime proxetil, processes for their preparation, and pharmaceutical compositions that include solid dispersions of cefpodoxime proxetil.

Background of the Invention

Cefpodoxime proxetil, a prodrug ester of cefpodoxime, is a third generation cephalosporin antibiotic which on absorption is esterified to its active metabolite cefpodoxime. It exhibits its antibiotic action by binding to penicillin-binding protein, therebycausing abnormal bacterial cell wall synthesis and lysis.

Cefpodoxime proxetil is categorized as a Class IV drug according to the biopharmaceutical classification of drugs, having poor solubility and poor absorbability. Further, its solubility is reported to be highly pH dependent, with favored solubility in acidic media. The bioavailability of cefpodoxime proxetil from pharmaceutical compositions is considered to be dissolution rate limited, with an absolute bioavailability of only around 50%.

Development of pharmaceutical compositions of class IV drugs having an acceptable dissolution and bioavailability characteristics is always a challenging task. In the prior art, few strategies and methods have been proposed and used to enhance the dissolution properties and, potentially, the bioavailability of these drugs. One of the common approaches to improve the solubility characteristics of these dugs involves the use of solid dispersions.

For example, U.S. Patent No. 5,776,495 describes the production of a solid dispersion of at least one therapeutic agent in a hydrophilic carrier, having enhanced solubility in an aqueous media with a non-ionic surface active agent, selected from the polyoxyethylenic esters of sorbitan and saturated or unsaturated fatty acids having at least 8 carbon atoms, polyoxyethylenic ethers of fatty alcohols of at least 8 carbon atoms and the polyoxyethylenic esters of stearic acid, having a HLB > 12.

Nonetheless, the inventors are not aware of any method described in the prior art that is particularly suitable for cefpodoxime proxetil.

Summary of the Invention

In one general aspect, there is provided a solid dispersion that includes cefpodoxime proxetil dispersed in a carrier.

Embodiments of the solid dispersion may include one or more of the following features. For example, the solid dispersion may further include one or more surfactants. The dissolution of the solid dispersion may be substantially pH independent.

The carrier may be selected from the group consisting of polymeric carriers and non-polymeric carriers. The non-polymeric carrier may be selected from one or more of polyethylene glycols, cyclodextrin, succinic acid, urea, and stearic acid. The polymeric carrier may be selected from one or more of polyvinyl pyrrolidone, hydroxyethyl cellulose, hydroxypropylcellulose, hydroxypropyl methylcellulose, polyethylene oxides, and polymethacrylates. In particular, the polymeric carrier may be polyvinyl pyrrolidone. A ratio of cefpodoxime proxetil to polyvinyl pyrrolidone may be between about 1:0.1 and about 1:10 by weight.

In another general aspect there is provided a process for the preparation of a solid dispersion of cefpodoxime proxetil. The process includes dispersing cefpodoxime proxetil in a carrier using one or more of hot-melt, co-melt and congealing, and solvent evaporation techniques.

Embodiments of the process may include one or more of the following features or those described above. For example, the solid dispersion of cefpodoxime proxetil may be prepared by the solvent evaporation technique. The solvent may be an alcohol selected from one or more of methanol, ethanol, and isopropyl alcohol. In particular, the solvent may be methanol. The solid dispersion may further include one or more surfactants.

The carrier may be selected from the group consisting of polymeric carriers and non-polymeric carriers. The non-polymeric carrier may be selected from one or more of

polyethylene glycols, cyclodextrin, succinic acid, urea, and stearic acid. Polymeric carriers may be selected from one or more of polyvinyl pyrrolidone, hydroxyethyl cellulose, hydroxypropylcellulose, hydroxypropyl methylcellulose, polyethylene oxides, and polymethacrylates. In particular, the polymeric carrier may be polyvinyl pyrrolidone. A ratio of cefpodoxime proxetil to polyvinyl pyrrolidone may be between about 1:0.1 and about 1:10 by weight.

In another general aspect there is provided a pharmaceutical composition that includes a solid dispersion of cefpodoxime proxetil dispersed in a carrier, and one or more pharmaceutically inert excipients.

Embodiments of the pharmaceutical composition may include one or more of the following features. For example, the one or more pharmaceutically inert excipients may be selected from one or more of binders, fillers/diluents, disintegrants, lubricants/glidants, plasticizers and colors. The pharmaceutical composition may be a solid dosage form selected from tablets and capsules. The dissolution of the pharmaceutical composition may be substantially pH independent.

In another general aspect, there is provided a method for treating bacterial infections in a mammal. The method includes administering to the mammal a pharmaceutical composition that includes a solid dispersion of cefpodoxime proxetil dispersed in a carrier and one or more pharmaceutically inert excipients. Embodiments of the method of treating may include one or more of the features described above.

The details of various embodiments of the invention are set forth in the description below. Other features and advantages of the invention will be apparent from the description and the claims.

Detailed Description of the Invention

In our attempts to improve the solubility of cefpodoxime proxetil we have discovered that the solubility of cefpodoxime proxetil may be improved to a desired level using a solid dispersion technique.

Hence is one aspect, the inventors have developed a solid dispersion of cefpodoxime proxetil in which cefpodoxime proxetil dispersed in a carrier. In another aspect, there is provided a pharmaceutical composition that includes a solid dispersion of cefpodoxime proxetil and one or more pharmaceutically inert excipients. In another aspect, there is provided a process for the preparation of solid dispersion of cefpodoxime proxetil that includes the steps of dispersing cefpodoxime proxetil in a carrier, using hot-melt, co-melt and congealing, or solvent evaporation techniques. In another aspect, there is provided a method of improving solubility and bioavailability of cefpodoxime proxetil by using a solid dispersion that includes cefpodoxime proxetil dispersed in a carrier. Finally, in another aspect, there is provided a method for the treatment of bacterial infections in a mammal. The method includes administering to the mammal a pharmaceutical composition that includes a solid dispersion of cefpodoxime proxetil and one or more pharmaceutically inert excipient.

The term "cefpodoxime proxetil" as used herein includes cefpodoxime and any of its pharmaceutically acceptable derivatives.

The term "solid dispersion" as used herein refers to a solution or dispersion of cefpodoxime proxetil in a carrier, in a solid state. The solid dispersion improves the solubility and bioavailability of cefpodoxime proxetil from the pharmaceutical compositions. Cefpodoxime proxetil attains a high-energy state, thus rendering the drug more soluble by favoring the solvent action for dissolution to occur. Hence, when administered the cefpodoxime proxetil is released into the gastrointestinal tract in a highly dispersed form there is a manifold increase in the effective surface area available for dissolution. Further, use of a solid dispersion also helps in masking the bitter taste of cefpodoxime proxetil.

The term "carrier" as used herein refers to both polymeric and non-polymeric carriers capable of dissolving or dispersing cefpodoxime proxetil. Examples of polymeric carriers include one or more of polyvinyl pyrrolidone (PVP), hydroxypropyl methylcellulose (HPMC), hydroxypropylcellulose, hydroxyethylcellulose, polymethacrylates, polyethylene oxides and the like. Examples of non-polymeric carrier include one or more of polyethylene glycol, cyclodextrin, succinic acid, urea, stearic acid and the like. In particular PVP may be used as carrier and the ratio of cefpodoxime proxetil to PVP in the solid dispersion may vary

from about 1:0.1 to about 1:10 by weight. Examples of some of the grades of PVP that are suitable for the preparation of solid dispersions include PVP K-15, PVP K-25, PVP K-30, PVP K-60 and PVP K-90; which are available under the trade names Plasdone® and Kollidon®, commercially sold by ISP and BASF respectively.

In addition, a surfactant may also be included in the solid dispersion. Surfactants may include both non-ionic and ionic (cationic, anionic and zwitter-ionic) surfactants suitable for use in pharmaceutical dosage forms. These include polyethoxylated fatty acids and their derivatives, for example, polyethylene glycol 400 distearate, polyethylene glycol – 20 dioleate, polyethylene glycol 4 –150 mono dilaurate, polyethylene glycol –20 glyceryl stearate; alcohol – oil transesterification products, for example, polyethylene glycol – 6 corn oil; polyglycerized fatty acids, for example polyglyceryl – 6 pentaoleate; propylene glycol fatty acid esters, for example propylene glycol monocaprylate; mono and diglycerides, for example, glyceryl ricinoleate; sterol and sterol derivatives; sorbitan fatty acid esters and its derivatives, for example, polyethylene glycol – 20 sorbitan monooleate, sorbitan monolaurate; polyethylene glycol alkyl ether or phenols, for example, polyethylene glycol – 20 cetyl ether, polyethylene glycol – 10 – 100 nonyl phenol; sugar esters, for example, sucrose monopalmitate; polyoxyethylene – polyoxypropylene block copolymers known as "poloxamer"; ionic surfactants, for example, sodium caproate, sodium glycocholate, soy lecithin, sodium stearyl fumarate, propylene glycol alginate, octyl sulfosuccinate disodium, palmitoyl carnitine; and the like.

The solid dispersion of cefpodoxime proxetil may be prepared by techniques known in the art such as hot-melt, co-melt and congealing, solvent evaporation and the like. In particular, solvent evaporation technique may be employed for preparing solid dispersion of cefpodoxime proxetil. Solvent evaporation techniques are more suitable for thermolabile and amorphous drugs such as cefpodoxime proxetil, as they do not involve heating at high temperatures.

Effective solvent evaporation without leading to environmental hazards may be achieved by processes of spray drying, vacuum drying, evaporation in the expansion chamber of the fluidized bed coater, and the like.

In one of the embodiments, a solid dispersion of cefpodoxime proxetil is prepared by dissolving cefpodoxime proxetil and a carrier in a solvent; spray drying the solution to yield a free flowing mass; sieving the free flowing mass through suitable sieves to yield a homogenous powder of solid dispersion. Formation of the solid dispersion of cefpodoxime proxetil may be confirmed by techniques such as dissolution rate determination, differential scanning colorimetry (DSC), X-Ray diffraction (XRD), thermal gravimetric analysis (TGA) etc.

Optionally, the homogenous powder of solid dispersion may be subjected to milling to remove particles with a hollow core and/or an irregular surface with air entrapped within, which otherwise may lead to floating of particles on the surface of the media. A suitable solvent used for preparing solid dispersion is one in which both cefpodoxome proxetil and the carrier are sufficiently soluble but does not create any stability issues and/or environmental hazards. Specific examples of solvents include ethanol, methanol, isopropylalcohol and mixtures thereof.

In another embodiment, a solid dispersion of cefpodoxime proxetil is prepared by dissolving cefpodoxime proxetil and polyvinyl pyrrolidone in methanol, spray drying the solution to a free flowing mass, and sieving to obtain a homogenous powder.

Solid dispersion prepared by any of the methods above may be formulated into pharmaceutical compositions by further processing with one or more pharmaceutically inert excipients.

The pharmaceutical compositions described herein may be in the form of a solid dosage form selected from tablets, capsules, powders, and the like. The compositions may be formulated by conventional methods of admixture such as blending, filling, and granulation.

The pharmaceutically inert excipients as used herein include one or more of diluents, binders, disintegrants, coloring agents, flavoring agents, stabilizers, lubricants/glidants and plasticizers.

Examples of diluents include calcium carbonate, calcium phosphate-dibasic, calcium phosphate-tribasic, calcium sulfate, cellulose-microcrystalline, cellulose powdered, dextrates,

dextrins, dextrose excipients, fructose, kaolin, lactitol, lactose, mannitol, sorbitol, starch pregelatinized, sucrose, sugar compressible, sugar confectioners and the like and combinations thereof.

Examples of binders include methylcellulose, hydroxypropyl cellulose, HPMC, gelatin, gum Arabic, ethyl cellulose, polyvinyl alcohol, pullulan, pregelatinized starch, agar, tragacanth, sodium alginate, propylene glycol and the like and combinations thereof.

Examples of disintegrants include microcrystalline cellulose, croscarmellose sodium and the like and combinations thereof.

Examples of lubricants and glidants include colloidal anhydrous silica, stearic acid, magnesium stearate, calcium stearate, talc, hydrogenated castor oil, sucrose esters of fatty acid, microcrystalline wax, yellow beeswax, white beeswax and the like and combinations thereof.

Examples of plasticizers include polyethylene glycol, triethyl citrate, triacetin, diethyl phthalate, dibutyl sebacate and the like and combinations thereof. Examples of stabilizers include antioxidants, buffers, acids and the like and combinations thereof. Examples of coloring agents include any FDA approved colors for oral use.

In another one of the embodiments, cefpodoxime proxetil tablets are prepared by blending a solid dispersion of cefpodoxime proxetil with a diluent, compacting in a roller compactor or by slugging, further blending with one or more pharmaceutically inert excipients, and compressing into suitable size tablets. Alternatively, direct compression or wet granulation techniques may also be used for preparing tablets.

The tablet prepared according to the above methods may be coated with one or more film forming polymers. Examples of film forming polymers include ethyl cellulose, hydroxypropyl methylcellulose, hydroxypropyl cellulose, methylcellulose, carboxymethylcellulose, hydroxymethylcellulose, hydroxyethylcellulose, cellulose acetate, hydroxypropyl methylcellulose phthalate, cellulose acetate phthalate, cellulose acetate trimellitate, waxes, methacrylic acid polymers such as Eudragit ® RL and RS, and mixtures thereof.

A coating may be formed by applying one or more film forming polymers, with or without other pharmaceutically inert excipients, as a solution/suspension using any conventional coating technique known in the art. Examples of such techniques include, for example, spray coating in a conventional coating pan or fluidized bed processor, and dip coating. Alternatively or in addition, the coating may be formed using commercially available ready to coat preparations such as Opadry-AMB, white-white, clear-clear, and the like.

In another embodiment, cefpodoxime proxetil capsules may be prepared by blending a solid dispersion of cefpodoxime proxetil with other pharmaceutically inert excipients and filling into suitable sized hard gelatin capsules. Alternatively, a solid dispersion of cefpodoxime proxetil may be dissolved or dispersed in a suitable additive and filled into soft gelatin capsules using conventional techniques known in the art.

The invention is further illustrated by the following examples, which are for illustrative purposes and are not to be construed as limiting the scope of the inventions.

Intrinsic solubility studies

Solid dispersions of cefpodoxime proxetil were prepared in different ratios with polyvinyl pyrrolidone K-30 (PVP K-30) by dissolving cefpodoxime proxetil and PVP K-30 in methanol and spray drying the resultant mixture. The water solubility of the solid dispersion was compared with corresponding physical mixtures and pure cefpodoxime proxetil. Physicial mixtures are simple admixtures of cefpodoxime proxetil and PVP K-30. An excess amount of these were dispersed in 100-500 ml of water and kept for between two and 24 hours under sonication or mechanical stirring for between ten minutes and two hours at room temperature, after which they were filtered and analyzed for cefpodoxime proxetil content at 290 nm using UV spectrophotometer.

The solubility profiles of pure cefpodoxime proxetil, a physical mixture (described above), and solid dispersions (as prepared above) in water are shown in Table 1.

Table 1: Solubility data of cefpodoxime proxetil, the physical mixture, and the solid dispersions in water

Cefpodoxime proxetil: PVP K-30 Ratio	**Attribute**	**Solubility in water (Mg/ml)**
Cefpodoxime proxetil	Amorphous powder	0.12
1:2	Physical mixture*	0.14
1:01	Solid dispersion	0.16
1:0.3	Solid dispersion	0.25
1:05	Solid dispersion	0.30
1:1	Solid dispersion	0.40
1:1.5	Solid dispersion	0.46
1:2	Solid dispersion	0.46
1:10	Solid dispersion	1.1
1:20	Solid dispersion	1.1622
1:40	Solid dispersion	1.027

* Simple admixture of cefpodoxime proxetil and PVP-K30 in the indicated ratio

From the solubility studies it was inferred that a ratio of between about 1:0.1 and about 1:10 of cefpodoxime proxetil to polyvinyl pyrrolidone is suitable. Moreover, as evident from Table 1, an almost four-fold increase in the solubility was observed in the solid dispersion as compared to the drug per se and the physical mixture of drug and carrier.

Example 1

Solid Dispersion of cefpodoxime proxetil

Cefpodoxime proxetil -	1 part
Polyvinyl pyrrolidone K-30 -	10 parts
Methanol -	q.s

Process

The cefpodoxime proxetil and polyvinylpyrrolidone K-30 were dissolved in the methanol. The solution was spray dried (using a Buchii 190 mini spray drier) under the conditions of an inlet temperature of 85°C, an outlet temperature of 50°C under N_2 pressure of

600-700 psi and spray rate of 5 ml/minute to yield a free flowing mass, which was sieved to get a homogenous powder.

Example 2

Solid Dispersion of cefpodoxime proxetil

Cefpodoxime Proxetil -	1 part
Polyvinylpyrrolidone K-30 -	10 parts
Sodium lauryl sulfate -	0.5 parts
Methanol -	q.s.

Process

The cefpodoxime proxetil, polyvinyl pyrrolidone K-30 and sodium lauryl sulfate were dissolved in the methanol. The solution was spray dried as described in Example 1 to yield a free flowing mass. The mass was sieved to get a homogenous powder.

Example 3

Cefpodoxime proxetil tablet

	Quantity / tablet
Cefpodoxime proxetil	200.0 mg
(Solid dispersion of Example 1 equivalent to Cefpodoxime base 100 mg)	
Microcrystalline Cellulose	120.0 mg
Croscarmellose sodium	28.0 mg
Magnesium Stearate	2.0 mg

The solid dispersion of Example 1 and microcrystalline cellulose were compacted in a roll compactor, the particle size fraction below a #20 mesh was collected and blended with the croscarmellose sodium and magnesium stearate in a double cone blender for five minutes. The resulting blend then was compressed using suitable size punches.

The dissolution studies of the prepared tablets were performed in water, pH 1.2, pH 3, pH 4.5 and pH 6.8 buffers using 900ml of the above-mentioned dissolution medium in USP apparatus-II at 75 rpm. At pre-determined time intervals 5 ml samples were withdrawn and replaced with an equal amount of the respective dissolution medium. The withdrawn samples

were analyzed for cefpodoxime proxetil content spectrophotometrically at 290 nm, after appropriate dilutions. The dissolution profiles of the tablets in various pH ranges are shown below in Table 2

Table 2: Effect of pH on drug release from the prepared tablets

Interval (Minutes)	**% Cefpodoxime dissolved**				
	pH 6.8 buffer	**pH 4.5 buffer**	**pH 3 buffer**	**pH 1.2**	**Water**
10	72.0	68.0	66.0	79.0	74.0
20	91.0	85.0	84.0	89.0	92.0
30	99.1	90.0	92.0	92.0	98.0
45	101.21	95.0	98.0	98.0	98.10

As evident from Table 2, the dissolution profiles of the prepared tablets were generally independent of pH of the medium, releasing around 95% to around 101% of its drug load in 45 minutes *in vitro*. This suggests that the prepared tablet is capable of releasing the drug uniformly throughout the gastrointestinal tract.

While several particular forms of the invention have been illustrated and described, it will be apparent that various modifications and combinations of the invention detailed in the text can be made without departing from the spirit and scope of the invention. Accordingly, it is not intended that the invention be limited, except as by the appended claims.

WE CLAIM:

1. A solid dispersion comprising cefpodoxime proxetil dispersed in a carrier.

2. The solid dispersion according to claim 1 wherein the solid dispersion further comprises one or more surfactants.

3. The solid dispersion according to claim 1 wherein the carrier is selected from the group consisting of polymeric carriers and non-polymeric carriers.

4. The solid dispersion according to claim 3 wherein the polymeric carrier is selected from one or more of polyvinyl pyrrolidone, hydroxyethyl cellulose, hydroxypropylcellulose, hydroxypropyl methylcellulose, polyethylene oxides, and polymethacrylates.

5. The solid dispersion according to claim 4 wherein the polymeric carrier comprises polyvinyl pyrrolidone.

6. The solid dispersion according to claim 5 wherein a ratio of cefpodoxime proxetil to polyvinyl pyrrolidone comprises between about 1:0.1 and about 1:10 by weight.

7. The solid dispersion according to claim 3 wherein non-polymeric carrier is selected from one or more of polyethylene glycols, cyclodextrin, succinic acid, urea, and stearic acid.

8. The solid dispersion according to claim 1 wherein the dissolution of the solid dispersion is substantially pH independent.

9. A process for the preparation of a solid dispersion of cefpodoxime proxetil, the process comprising dispersing cefpodoxime proxetil in a carrier using one or more of hot-melt, co-melt and congealing, and solvent evaporation techniques.

10. The process according to claim 9 wherein the solid dispersion of cefpodoxime proxetil is prepared by the solvent evaporation technique.

11. The process according to claim 10 wherein the solvent comprises an alcohol selected from one or more of methanol, ethanol, and isopropyl alcohol.

12. The process according to claim 11 wherein the solvent comprises methanol.

13. The process according to claim 9 wherein the solid dispersion further comprises one or more surfactants.

14. The process according to claim 9 wherein the carrier is selected from the group consisting of polymeric carriers and non-polymeric carriers.

15. The process according to claim 14 wherein the polymeric carrier is selected from one or more of polyvinyl pyrrolidone, hydroxyethyl cellulose, hydroxypropylcellulose, hydroxypropyl methylcellulose, polyethylene oxides, and polymethacrylates.

16. The process according to claim 15 wherein the polymeric carrier comprises polyvinyl pyrrolidone.

17. The process according to claim 16 wherein a ratio of cefpodoxime proxetil to polyvinyl pyrrolidone comprises between about 1:0.1 and about 1:10 by weight.

18. The process according to claim 14 wherein the non-polymeric carrier is selected from one or more of polyethylene glycols, cyclodextrin, succinic acid, urea, and stearic acid.

19. A pharmaceutical composition comprising a solid dispersion of cefpodoxime proxetil dispersed in a carrier, and one or more pharmaceutically inert excipients.

20. The pharmaceutical composition according to claim 19 wherein the one or more pharmaceutically inert excipients are selected from one or more of binders, fillers/diluents, disintegrants, lubricants/glidants, plasticizers and colors.

21. The pharmaceutical composition according to claim 19 wherein the pharmaceutical composition comprises a solid dosage form selected from tablets and capsules.

22. The pharmaceutical composition according to claim 19 wherein the dissolution of the pharmaceutical composition is substantially pH independent.

23. A method for treating bacterial infections in a mammal, the method comprising administering to the mammal a pharmaceutical composition comprising a solid dispersion of cefpodoxime proxetil dispersed in a carrier and one or more pharmaceutically inert excipients.