REMARKS

Applicants request reconsideration in view of the amendments above and the following remarks.

STATUS OF THE CLAIMS

Claims 15, 17, and 20 -28 have been amended. Support for the amendments can be found throughout the specification, at for example, page 6, lines 14-16; page 11, lines 11-23. No new matter is introduced. Applicants reserve the right to pursue any canceled subject matter in this, in a continuing, or in another application.

THE CLAIMED INVENTION

The claimed invention relates to stable extended release reconstituted powder for suspension composition consisting of core of an active ingredient coated with a coating layer comprising one or more release controlling agent. These coated cores form a homogeneous suspension composition upon reconstitution to a suspension. Further, the claimed composition exhibits no significant leaching of the active ingredient from the coated cores into the suspension base. The inventors unexpectedly found that leaching of the drug from the coated cores into the suspension base can be prevented when ratio of the osmolality of the external phase (suspension base without multiple coated cores of the active ingredient) to the osmolality of the internal phase (coated cores of the active ingredient) is at least about 1. The portion from the instant specification demonstrating the experiments performed and results obtained is given below. (see the Specification at page 34, line 15 to page 35, line 3)

Effect of Osmolality on Metformin Leaching

Example	Osmolality (osmol/kg) of the solution	Metformin Content (%)
6A	0.910	67.3
6B	1.787	30.3
6C	3.574*	2.9
6D	5.361*	1.8
6E	7.148*	1.7
6F	8.935*	1.0

*Extrapolated using values of dilute solutions

> **[0189]** From the above data, it is evident that the leaching of metformin from the coated beads into the solution was decreasing as the osmolality of the solution was increasing from Examples 6A-6F. The leaching is found to be significantly reduced from Example 6C onwards. The osmolality of Example 6C i.e., 3.574 is considered as osmolality of the internal phase.
>
> Osmolality Ratio 1.176

A unique feature of the claimed invention is that it can be used for a wide variety of drugs, for example, drug having high dose such as Metformin hydrochloride, and drugs having low dose such as Guanfacine hydrochloride, drugs having high aqueous solubility such as Metformin hydrochloride, and drugs having low aqueous solubility. Additionally, the claimed invention can be used for ionic as well as non-ionic drugs.

Further, it is a challenge to develop the extended release composition which does not exhibit any leaching of the drug from the coated cores into the suspension base during storage upon reconstitution while ensuring consistent extended release profile of the drug devoid of any fast or burst release from the composition into the gastrointestinal tract after administration of the composition (*in-vivo* release).

CLAIM REJECTIONS- 35 U.S.C. § 103

Claims 15, 17-29 stand rejected as being obvious over Gandhi (WO 2011/107855 A2) in view of Schwarz et al. (US 2008/0008765 A1) and Hollenbeck et al. (US 2010/0092562 A1) and as evidenced by Santus (US 5460828 A), for reasons detailed in the Office Action. Applicants traverse.

Gandhi's suspension dosage form is a ready-to-use formulation and thus does not require reconstitution before administration.

> The present invention is to provide a sustained release oral liquid suspension dosage form of pharmaceutically active ingredients, which is ready to use and does not require reconstitution before oral administration.
>
> Gandhi, Page 3, lines 13-15.

> Above pellets are suspended in purified water along with Sucralose, Propylene Glycol, Glycerin, Sorbitol soln (Non crystallizing), Citric acid monohydrate, Sodium bicarbonate, Methyl Paraben, Propyl Paraben, Selecta Banana Flavour (844439) and filled in bottle for ready to use suspension.
>
> Gandhi, Page 23, lines 15-18.

Further, to prevent drug leaching, the ready-to-use suspension dosage form of Gandhi is prepared by a process which involves application of the protective coating to the drug coated pellets. Gandhi on Page 8, line 23 states: "The polymers described above may also be used as a constituent of protective coating, which protects drug leaching." Amended claims recite 'consisting of', which excludes the use of protective coating in the claimed composition.

The claimed composition pertains to a stable extended release reconstituted powder for suspension composition consisting of core of an active ingredient coated with a coating layer comprising one or more release controlling agent. These coated particles form a homogeneous suspension composition upon reconstitution to a suspension. Gandhi, however, discloses a ready-to-use suspension formulation. Designing or developing a powder for suspension formulation capable of dispersing easily and does not form any aggregates upon reconstitution with a suspension base after applying minimal shear is a challenge, one that is not met or suggested by Gandhi. The portion from the instant specification is given below. (see the Specification at page 35, lines 4-13)

Dose Uniformity Data

The extended release suspension equivalent to 100 mL was prepared according to formula given in Example 6. This suspension was shaken manually for at least 20 minutes and then ten 7.5 mL samples were taken with a graduated syringe. The metformin content of each sample is determined by HPLC method [Inertsil ODS column (250 x 4.6 mm, 5 µm); mobile phase-buffer (pH 3.5):acetonitrile (95:5 v/v); flow rate of 1.5 mL/min; UV detection at 233 nm] The results are shown in Table 10.

Table 10: Metformin Content (%w/w) For Each 7.5 mL of Suspension

Sample Number	Metformin content (%) for each 7.5 mL of suspension
1	98.6
2	97.9
3	96.6
4	97.2
5	99.7
6	96.4
7	95.9
8	97.3
9	98.8
10	96.9
Mean value	97.5

From the above data, it is evident that the extended release suspension composition prepared as per Example 6 is homogeneous.

Schwarz discloses suspension compositions comprising coated particles comprising an active substance having an unpleasant and/or bitter taste and a suspension base comprising an osmotically active substance. The suspension composition disclosed in Schwarz exhibits a fast releases of the active substance in the environmental conditions as found in the gastrointestinal tract. This aspect of Schwarz's formulation exhibiting a fast drug release is stated at several places in the Specification.

> Furthermore, the pharmaceutical compositions of the invention, e.g. the ready-to-use suspension, show a fast and quantitatively sufficient release of the active

> substance in the environmental conditions as found in the gastrointestinal tract which means good bioavailability.
>
> Schwarz, paragraph [0036].
>
> Preferably, the suspension of the present invention shows a fast dissolution at a pH value of 6.8, which means 80% of the active substance are dissolved within 15 minutes measured by the dissolution test according to the US Pharmacopoea USP 27-NF 22 S2, 2004. This means that the active substance is released in sufficient quantity at an acceptable rate in the gastrointestinal tract, which generally indicates good bioavailability.
>
> Schwarz, paragraph [0099].

Contrariwise, the claimed reconstituted powder for suspension composition does not exhibit a fast dissolution at a pH value of 6.8. For example, extended release suspension composition prepared as per Example 1 released only 9 % drug in two hours and exhibited 75% of drug release after six hours (as depicted in Table 1 of the specification). The claimed reconstituted powder for suspension composition exhibits consistent *in vitro* release of the active ingredient throughout the shelf life of the composition upon reconstitution, which ensures a steady plasma concentration with no fluctuations throughout the shelf life of the composition.

Schwarz fails to cure Gandhi's many deficiencies as the combined teaching of Gandhi and Schwarz still does not arrive at the claimed invention.

Hollenbeck relates to controlled release liquid suspension comprising multiple coated cores comprising an active ingredient and a coating layer of release controlling polymer over the core and a suspension base. Further, the liquid suspension dosage form of Hollenbeck is prepared by a process which involves binding of drugs to ion-exchange matrices. The amended claims require the active ingredient **not** to be bound to an ion-exchange matrix. Thus, a person would not be motivated to refer to the disclosure of Hollenbeck since the disclosure requires binding of active ingredient to ion-exchange matrices.

Moreover, the liquid suspension dosage form as specifically disclosed in Hollenbeck is a liquid formulation which does not require reconstitution before administration. For example, coated pellets prepared for formulation X were added to the vehicle syrup under stirring to obtain the final product in Example 6. The claimed composition pertains to a stable extended release reconstituted powder for suspension composition consisting of core of an active ingredient

coated with a coating layer comprising one or more release controlling agent. Thus, Hollenbeck fails to cure Gandhi's deficiency.

The crux of Santus disclosure is to prepare size-reduced microgranules by milling theto get the desired particle size; the wetted mixture is subjected to the combined actions of the mixer and mill during kneading. Santus is lacking in much of its disclosure of the recited features of the claimed composition. For example, Santus also does not disclose the claimed reconstituted extended release powder for suspension composition having the recited osmolality or viscosity of the suspension base.

A person of ordinary skill in the art would not be motivated to add the teachings of Sanctus with that of Gandhi, Schwarz, and Hollenbeck and would not be able to do so with a reasonable expectation of success.

The combined teaching of Gandhi, Schwarz, Hollenbeck and Santus would be hugely confusing to a person skilled in the art as that person would not know which parameters to pick from each disclosure to arrive at an improved composition over all four disclosures.

DOULBLE PATENTING

Applicants request that the double patenting rejection be held in abeyance until such time that the pending claims are otherwise found patentable.

CONCLUSION

Applicants request the Examiner pass the pending claims to an early allowance.

Respectfully submitted,

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AMENDMENTS TO THE CLAIMS:

This Listing of Claims will replace all prior versions and listings of claims in the present application.

1. (Withdrawn) A method for preparing a stable extended release suspension composition comprising multiple coated cores of an active ingredient and a suspension base, wherein the suspension base ensures substantially similar in-vitro dissolution release profile of the active ingredient upon storage of the suspension composition for at least seven days.

2. (Withdrawn) The method of preparation of claim 1, wherein the suspension base is characterized by having the features of:

(i) a viscosity in a range of about 500 cps to about 15,000 cps and

(ii) an osmolality of at least about 1 osmol/kg of the suspension base.

3. (Withdrawn) The method of preparation of claim 1, wherein the suspension base comprises:

(i) a suspending agent;

(ii) an osmogent; and

(iii) an aqueous vehicle.

4. (Withdrawn) The method of preparation stable extended release suspension of claim 1, wherein the stable extended release suspension composition is a suspension or a reconstituted powder for suspension.

5. (Withdrawn) The method of preparation stable extended release suspension of claim 1, wherein the coated core comprises a core of an active ingredient and a coating layer over said core comprising one or more release-controlling agents.

6. (Withdrawn) The method of preparation stable extended release suspension of claim 5, wherein the active ingredient is layered onto an inert particle to form the core.

7. (Withdrawn) The method of preparation of claim 6, wherein the inert particle is selected from the group comprising a non-pareil seed, a microcrystalline cellulose sphere, a dibasic

calcium phosphate bead, a mannitol bead, a silica bead, a tartaric acid pellet, or a wax based pellet.

8. (Withdrawn) The method of preparation of claim 3, wherein the osmogent is selected from the group comprising carbohydrates such as xylitol, mannitol, sorbitol, arabinose, ribose, xylose, glucose, fructose, mannose, galactose, sucrose, maltose, lactose, dextrose and raffinose; water-soluble salts of inorganic acids such as magnesium chloride, magnesium sulfate, potassium sulfate, lithium chloride, sodium chloride, potassium chloride, lithium hydrogen phosphate, sodium hydrogen phosphate, potassium hydrogen phosphate, lithium dihydrogen phosphate, sodium dihydrogen phosphate, potassium dihydrogen phosphate, and sodium phosphate tribasic; water-soluble salts of organic acids such as sodium acetate, potassium acetate, magnesium succinate, sodium benzoate, sodium citrate, and sodium ascorbate; water-soluble amino acids such as glycine, leucine, alanine, methionine; urea or its derivatives; propylene glycol; glycerin; polyethylene oxide; xanthan gum; hydroxypropylmethyl cellulose; and mixtures thereof.

9. (Withdrawn) The method of preparation of claim 3, wherein the suspending agent is selected from group consisting of cellulose derivatives such as co-processed spray dried forms of microcrystalline cellulose and carboxymethyl cellulose sodium, hydroxypropyl cellulose, hydroxyethyl cellulose, hydroxypropylmethyl cellulose, methylcellulose, carboxymethyl cellulose and its salts/derivatives, and microcrystalline cellulose; carbomers; gums such as locust bean gum, xanthan gum, tragacanth gum, arabinogalactan gum, agar gum, gellan gum, guar gum, apricot gum, karaya gum, sterculia gum, acacia gum, gum arabic, and carrageenan; pectin; dextran; gelatin; polyethylene glycols; polyvinyl compounds such as polyvinyl acetate, polyvinyl alcohol, and polyvinyl pyrrolidone; sugar alcohols such as xylitol and mannitol; colloidal silica; and mixtures thereof.

10. (Withdrawn) The method of preparation of claim 5, wherein the release-controlling agent is selected from the group comprising a pH-dependent release-controlling agent, a pH-independent release-controlling agent, or mixtures thereof.

11. (Withdrawn) The method of preparation of claim 10, wherein the pH-dependent release-controlling agent is selected from the group consisting of acrylic copolymers, including methacrylic acid and methyl methacrylate copolymers, *e.g.,* Eudragit® L 100 and Eudragit® S

100, methacrylic acid and ethyl acrylate copolymers, *e.g.,* Eudragit® L 100-55 and Eudragit® L 30 D-55, dimethylaminoethyl methacrylate and butyl methacrylate and methyl methacrylate copolymer *e.g.,* Eudragit® E 100, Eudragit® E PO, methyl acrylate and methacrylic acid and octyl acrylate copolymers, styrene and acrylic acid copolymers, butyl acrylate and styrene and acrylic acid copolymers, and ethylacrylate-methacrylic acid copolymer; cellulose acetate phthalate; cellulose acetate succinates; hydroxyalkyl cellulose phthalates including hydroxypropylmethyl cellulose phthalate; hydroxyalkyl cellulose acetate succinates, including hydroxypropylmethyl cellulose acetate succinate; vinyl acetate phthalates; vinyl acetate succinate; cellulose acetate trimelliate; polyvinyl derivatives such as polyvinyl acetate phthalate, polyvinyl alcohol phthalate, polyvinyl butylate phthalate, and polyvinyl acetoacetal phthalate; zein; shellac; and mixtures thereof.

12. (Withdrawn) The method of preparation of claim 10, wherein the pH-independent release-controlling agent is selected from the group consisting of cellulosic polymers, including ethyl cellulose, methyl cellulose, hydroxyethyl cellulose, hydroxypropyl cellulose, hydroxyethylmethyl cellulose, hydroxypropylmethyl cellulose, and carboxy methylcellulose; acrylic copolymers, including methacrylic acid copolymers, *e.g.,* Eudragit® RS, Eudragit® RL, Eudragit® NE 30 D; cellulose acetate; polyethylene derivatives *e.g.,* polyethylene glycol and polyethylene oxide; polyvinyl alcohol; polyvinyl acetate; gums *e.g.,* guar gum, locust bean gum, tragacanth, carrageenan, alginic acid, gum acacia, gum arabic, gellan gum, and xanthan gum; triglycerides; waxes, *e.g.,* Compritol®, Lubritab®, and Gelucires®; lipids; fatty acids or their salts/derivatives; a mixture of polyvinyl acetate and polyvinyl pyrrolidone, *e.g.,* Kollidon® SR; and mixtures thereof.

13. (Withdrawn) The method of preparation of claim 1, wherein the active ingredient is selected from the group consisting of metformin, acarbose, miglitol, voglibose, repaglinide, nateglinide, glibenclamide, glimepride, glipizide, gliclazide, chloropropamide, tolbutamide, phenformin, aloglitin, sitagliptin, linagliptin, saxagliptin, rosiglitazone, pioglitazone, troglitazone, faraglitazar, englitazone, darglitazone, isaglitazone, zorglitazone, liraglutide, muraglitazar, peliglitazar, tesaglitazar, canagliflozin, dapagliflozin, remogliflozin, sergliflozin, verapamil, albuterol, salmeterol, acebutolol, sotalol, penicillamine, norfloxacin, ciprofloxacin, ofloxacin, levofloxacin, moxifloxacin, cefpodoxime, tetracycline, demeclocycline

hydrochloride, amoxicillin, clavulanate potassium, azithromycin, losartan, irbesartan, eprosartan, valsartan, diltiazem, isosorbide mononitrate, ranolazine, propafenone, hydroxyurea, hydrocodone, delavirdine, pentosan polysulfate, abacavir, amantadine, acyclovir, ganciclovir, valacyclovir, valganciclovir, saquinavir, indinavir, nelfinavir, lamivudine, didanosine, zidovudine, nabumetone, celecoxib, mefenamic acid, naproxen, propoxyphene, cimetidine, ranitidine, albendazole, mebendazole, thiobendazole, pyrazinamide, praziquantel, chlorpromazine, sumatriptan, bupropion, aminobenzoate, pyridostigmine bromide, potassium chloride, niacin, tocainide, quetiapine, fexofenadine, sertraline, chlorpheniramine, rifampin, methenamine, nefazodone, modafinil, metaxalone, morphine, sevelamer, lithium carbonate, flecainide acetate, simethicone, methyldopa, chlorthiazide, metyrosine, procainamide, entacapone, metoprolol, propanolol hydrochloride, chlorzoxazone, tolmetin, tramadol, bepridil, phenytoin, gabapentin, fluconazole, terbinafine, atorvastatin, doxepine, rifabutin, mesalamine, etidronate, nitrofurantoin, choline magnesium trisalicylate, theophylline, nizatidine, methocarbamol, mycophenolate mofetil, tolcapone, ticlopidine, capecitabine, orlistat, colsevelam, meperidine, hydroxychloroquine, guaifenesin, guanfacine, amiodarone, quinidine, atomoxetine, felbamate, pseudoephedrine, carisoprodol, venlafaxine, etodolac, chondrotin, lansoprazole, pantoprazole, esomeprazole, dexlansoprazole, dexmethylphenidate, methylphenidate, sodium oxybate, valproic acid or its salts, divalproex, topiramate, carbamazepine, oxcarbazepine, and isotretinoin.

14. (Withdrawn) The method of preparation of claim 3, wherein the suspension base further comprises one or more pharmaceutically acceptable excipients selected from the group consisting of anti-caking agents, wetting agents, preservatives, buffering agents, flavoring agents, anti-oxidants, chelating agents, solubility enhancing agents, pH modifying agents, adsorbents, complexing agents, and combinations thereof.

15. (Currently amended) A stable extended release reconstituted powder for suspension composition comprising multiple coated cores of an active ingredient ~~and a suspension base,~~ wherein upon reconstitution with a ~~the~~ suspension base, the composition ensures substantially similar *in-vitro* dissolution release profile of the active ingredient upon storage of the ~~suspension~~ composition upon reconstitution for at least seven days; and wherein the active ingredient is not

bound to an ion-exchange matrix; and wherein the suspension base used for reconstitution of the composition is characterized by having the features of:

(i) a viscosity in a range of about 500 cps to about 15,000 cps and

(ii) an osmolality of at least 1 osmol/kg of the suspension base;

wherein the ~~stable extended release suspension~~ composition upon reconstitution is characterized by having an osmolality ratio of at least about 1, the osmolality ratio being the ratio of the osmolality of the external phase to the osmolality of the internal phase, the external phase being the suspension base without multiple coated cores of the active ingredient and the internal phase being the coated cores of the active ingredient;

wherein the osmolality of the internal phase is the osmolality of a solution which prevents significant leaching of the active ingredient from the coated cores into the solution when the coated cores are suspended in said solution;

significant leaching being more than 20% of the active ingredient is leached out from the coated cores into the solution:

wherein the coated cores consist of a core of an active ingredient and a coating layer over said core comprising one or more release-controlling agents and average diameter of the coated cores ranges from about 150 μm to about 500 μm, and wherein the composition is homogeneous.

16. (Cancelled)

17. (Currently amended) The stable extended release reconstituted powder for suspension composition of claim 15, wherein the suspension base comprises:

(i) a suspending agent;

(ii) an osmogent; and

(iii) an aqueous vehicle.

18. (Cancelled)

19. (Cancelled)

20. (Currently amended) The stable extended release reconstituted powder for suspension composition of claim 15, wherein the active ingredient is layered onto an inert particle to form the core.

21. (Currently amended) The stable extended release reconstituted powder for suspension composition of claim 20, wherein the inert particle is selected from the group consisting of a non-pareil seed, a microcrystalline cellulose sphere, a dibasic calcium phosphate bead, a mannitol bead, a silica bead, a tartaric acid pellet, and a wax based pellet.

22. (Currently amended) The stable extended release reconstituted powder for suspension composition of claim 17, wherein the osmogent is selected from the group consisting of carbohydrates; water-soluble salts of inorganic acids; water-soluble salts of organic acids; water-soluble amino acids; urea or its derivatives; propylene glycol; glycerin; polyethylene oxide; xanthan gum; hydroxypropylmethyl cellulose; and mixtures thereof.

23. (Currently amended) The stable extended release reconstituted powder for suspension composition of claim 17, wherein the suspending agent is selected from group consisting of cellulose derivatives; carbomers; gums; pectin; dextran; gelatin; polyethylene glycols; polyvinyl compounds; sugar alcohols; and mixtures thereof.

24. (Currently amended) The stable extended release reconstituted powder for suspension composition of claim 15, wherein the release-controlling agent is selected from the group consisting of a pH-dependent release-controlling agent, a pH-independent release-controlling agent, and mixtures thereof.

25. (Currently amended) The stable extended release reconstituted powder for suspension composition of claim 24, wherein the pH-dependent release-controlling agent is selected from the group consisting of acrylic copolymers; cellulose acetate phthalate; cellulose acetate succinates; hydroxyalkyl cellulose phthalates; hydroxyalkyl cellulose acetate succinates; vinyl acetate phthalates; vinyl acetate succinate; cellulose acetate trimelliate; polyvinyl derivatives; zein; shellac; and mixtures thereof.

26. (Currently amended) The stable extended release reconstituted powder for suspension composition of claim 24, wherein the pH-independent release-controlling agent is selected from the group consisting of cellulosic polymers; acrylic copolymers; cellulose acetate; polyethylene

derivatives; polyvinyl alcohol; polyvinyl acetate; gums; lipids; fatty acids or their salts/derivatives; a mixture of polyvinyl acetate and polyvinyl pyrrolidone; and mixtures thereof.

27. (Currently amended) The stable extended release reconstituted powder for suspension composition of claim 15, wherein the active ingredient is selected from the group consisting of metformin, acarbose, miglitol, voglibose, repaglinide, nateglinide, glibenclamide, glimepride, glipizide, gliclazide, chloropropamide, tolbutamide, phenformin, aloglitin, sitagliptin, linagliptin, saxagliptin, rosiglitazone, pioglitazone, troglitazone, faraglitazar, englitazone, darglitazone, isaglitazone, zorglitazone, liraglutide, muraglitazar, peliglitazar, tesaglitazar, canagliflozin, dapagliflozin, remogliflozin, sergliflozin, verapamil, albuterol, salmeterol, acebutolol, sotalol, penicillamine, norfloxacin, ciprofloxacin, ofloxacin, levofloxacin, moxifloxacin, cefpodoxime, tetracycline, demeclocycline hydrochloride, amoxicillin, clavulanate potassium, azithromycin, losartan, irbesartan, eprosartan, valsartan, diltiazem, isosorbide mononitrate, ranolazine, propafenone, hydroxyurea, hydrocodone, delavirdine, pentosan polysulfate, abacavir, amantadine, acyclovir, ganciclovir, valacyclovir, valganciclovir, saquinavir, indinavir, nelfinavir, lamivudine, didanosine, zidovudine, nabumetone, celecoxib, mefenamic acid, naproxen, propoxyphene, cimetidine, ranitidine, albendazole, mebendazole, thiobendazole, pyrazinamide, praziquantel, chlorpromazine, sumatriptan, bupropion, aminobenzoate, pyridostigmine bromide, potassium chloride, niacin, tocainide, quetiapine, fexofenadine, sertraline, chlorpheniramine, rifampin, methenamine, nefazodone, modafinil, metaxalone, morphine, sevelamer, lithium carbonate, flecainide acetate, simethicone, methyldopa, chlorthiazide, metyrosine, procainamide, entacapone, metoprolol, propanolol hydrochloride, chlorzoxazone, tolmetin, tramadol, bepridil, phenytoin, gabapentin, fluconazole, terbinafine, atorvastatin, doxepine, rifabutin, mesalamine, etidronate, nitrofurantoin, choline magnesium trisalicylate, theophylline, nizatidine, methocarbamol, mycophenolate mofetil, tolcapone, ticlopidine, capecitabine, orlistat, colsevelam, meperidine, hydroxychloroquine, guaifenesin, guanfacine, amiodarone, quinidine, atomoxetine, felbamate, pseudoephedrine, carisoprodol, venlafaxine, etodolac, chondrotin, lansoprazole, pantoprazole, esomeprazole, dexlansoprazole, dexmethylphenidate, methylphenidate, sodium oxybate, valproic acid or its salts, divalproex, topiramate, carbamazepine, oxcarbazepine, and isotretinoin.

28. (Currently amended) The stable extended release reconstituted powder for suspension composition of claim 17, wherein the suspension base further comprises one or more pharmaceutically acceptable excipients selected from the group consisting of anti-caking agents, wetting agents, preservatives, buffering agents, flavoring agents, anti-oxidants, chelating agents, solubility enhancing agents, pH modifying agents, adsorbents, complexing agents, and combinations thereof.

29. (Cancelled)