Part 2
to
EXHIBIT H

received and diluted quantitatively with HPLC mobile phase. The dilute sample was then injected directly on the HPLC column (Dupont Zorbax, 250mm x 4.6mm, 5μm) for Brimonidine tartrate assay in order to quantify the amount of Brimonidine tartrate. A control of 10.05% Brimonidine tartrate was prepared in the formulation vehicle at pH 6.3-6.5 and assayed before (untreated) and after (treated) centrifugation and filtration. This was done to evaluate the potential loss of Brimonidine tartrate in these two steps of the sample preparation. To ensure reproducibility, the study was repeated on consecutive days.

Table I. 0.5% Brimonidine tartrate in Ophthalmic Solution.

Ingredient	Percent (w/v)
Brimonidine tartrate	0.50
Benzalkonium Chloride, NF	0.0050
Polyvinyl Alcohol, USP	1.4
Sodium Chloride, USP	0.66
Sodium Citrate, Dihydrate, USP	0.45
Hydrochloric Acid, NF or Sodium Hydroxide, NF for pH adjustment	5-8
Purified Water, USP	QS

The solubility data for Brimonidine tartrate in the formulation vehicles are presented in Table II. The results show that the solubility of Brimonidine tartrate is highly pH-dependent and spans more than two orders of magnitude over the pH range of 5-8. The solubility decreases sharply as the pH increases. The results for the treated and untreated controls are very close, suggesting that centrifugation and filtration does not cause any significant loss of Brimonidine tartrate. The

two solubility profiles obtained on consecutive days agree with each other.

Table II. Solubility of Brimonidine tartrate in the Ophthalmic Solution Over pH Range of 5 to 8.

	STUDY 1		STUDY 2	
Sample	pH[a]	Solubility[a]	pH[a]	Solubility[a]
1	5.55	≥164.4[b]	5.50	≥200.6[b]
2	5.92	132.6	5.92	160.8
3	6.14	30.4	6.06	50.1
4	6.57	7.55	6.90	3.19
5	7.00	2.69	7.40	1.19
6	7.45	1.17	7.77	0.63
7	7.83	0.62	7.86	0.58
8	—	—	7.88	0.54
Control/ (untreated)	—	0.486[c]	—	—
Control/ (treated)	—	0.484[d]	—	—

[a] Measured after stirring for two-days before sample withdrawal for centrifugation and filtration.

[b] Represents theoretical concentration based on sample weight. The sample solution was clear indicating that all of the Brimonidine tartrate had dissolved.

[c] Concentration of Brimonidine tartrate in control before centrifugation and filtration step.

[d] Concentration of Brimonidine tartrate in control after centrifugation and filtration step.

[e] %w/v.

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EXAMPLE 2

The pH-solubility profiles of Brimonidine tartrate in compositions (solutions) containing SECs and oxy-chloro components were determined. Particularly, the effects of sodium carboxymethylcellulose (CMC), an SEC, on the solubility of Brimonidine tartrate at various pH conditions were determined. The various concentrations of CMC tested with Brimonidine tartrate were 0%, 0.056%, 0.17%, 0.5%, 1.5% (w/v), Table III.

The samples tested also contained isotonic components, buffer components, and stabilized chlorine dioxide (Purite™), Table III. Sodium carboxymethylcellulose, sodium chloride, potassium chloride, calcium chloride dihydrate, and magnesium chloride hexahydrate were USP grade. Boric acid and sodium borate decahydrate were NF grade.

Table III

	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	
Brimonidine tartrate	0.2%	0.2%	0.2%	0.2%	0.2%	(w/v)
CMC	0.0%	0.056%	0.17%	0.5%	1.5%	(w/v)
Stabilized chlorine dioxide[a]	0.005%	0.005%	0.005%	0.005%	0.005%	(w/v)
Sodium chloride	0.58%	0.58%	0.58%	0.58%	0.58%	(w/v)
Potassium chloride	0.14%	0.14%	0.14%	0.14%	0.14%	(w/v)
Calcium chloride, dihydrate	0.02%	0.02%	0.02%	0.02%	0.02%	(w/v)
Magnesium chloride, hexahydrate	0.006%	0.006%	0.006%	0.006%	0.006%	(w/v)
Boric acid	0.2%	0.2%	0.2%	0.2%	0.2%	(w/v)
Sodium tetraborate, decahydrate	0.14%	0.14%	0.14%	0.14%	0.14%	(w/v)

[a] Sold under the trademark Purite™ by Allergan, Inc.

Each sample (1 through 5) was subjected to a range of pH's from about 7 to about 10. The vials containing the sample solutions were placed on a laboratory rotator and left for equilibration for fifteen days at room temperature (~21 °C). The sample solutions were filtered using a 25 mm diameter polysulfone cellulose acetate syringe type filter with 0.45μm pore size. The filtered solutions were assayed for Brimonidine.

Conventional HPLC and detection techniques were used to detect and determine the concentrations of soluble Brimonidine tartrate. Table IV. The solubility is plotted against pH for each CMC concentration. The experimental data points were fitted to a modified Henderson-Hasselbalch equation using a nonlinear least squares routine (Deltagraph version 4.0 DeltaPoint, Inc.), Fig. 1. The R^2 values show the goodness of fit between the experimental values and the theoretical equation to be better than 0.991.

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Table IV

Solubility of Brimonidine tartrate (%)

	pH	0%CMC	0.056%CMC	0.17%CMC	0.5%CMC	1.5%CMC
5	6.67		0.9302		1.4464	
	6.68	1.4256		1.4200		
	6.93			0.7302		
	7.10				0.3693	
	7.11	0.2064	0.2828			
10	7.35					0.1904
	7.56				0.1451	
	7.68	0.0786				
	7.77		0.0721			
	7.81			0.0735		
15	8.10					0.0498
	8.46				0.0313	
	8.50	0.0286				
	8.55			0.0328		
	8.67					0.0311
20	9.93		0.0234			
	9.94				0.0250	
	10.05			0.0241		
	10.09	0.0218				
	10.11					0.0222

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Fig. 1 clearly shows that the solubility of Brimonidine tartrate tends to increase with increasing CMC concentrations. For example, at pH 7.5, the sample with 0% CMC resulted in 1000 ppm of Brimonidine tartrate; 0.056% CMC, 1300 ppm; 0.17% CMC, 1300 ppm; and 0.5%, 1600 ppm. At pH 7.5, the sample with 1.5% CMC resulted in about 1400 ppm, which is less than that of a similar solution with CMC at 0.5%. It is unclear at this point what the cause of this observation may be. Nonetheless, Brimonidine tartrate is more soluble in solution with a 1.5% CMC than with no CMC.

CMC is also effective to solubilize Brimonidine tartrate in a biological environment, for example the biological environment of the cornea.

EXAMPLE 3

Brimonidine tartrate dimers.

Brimonidine tartrate is added to a test tube containing a composition including chlorite. The test tube was allowed to equilibrate for ten days. Samples obtained from the test tube is analyzed. It is observed that a portion of the Brimonidine tartrate monomer units conjugated to form dimers.

While this invention has been described with respect to various specific examples and embodiments, it is to be understood that the invention is not limited thereto and that it can be variously practiced with the scope of the following claims.

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WHAT IS CLAIMED IS:

1. A composition comprising:

an alpha-2-adrenergic agonist component in an amount effective to provide a therapeutic benefit to a patient to whom the composition is administered;

a solubility enhancing component in an amount effective to increase the solubility of the alpha-2-adrenergic agonist component in the composition relative to the solubility of an identical alpha-2-adrenergic agonist component in a similar composition without the solubility enhancing component; and

a liquid carrier component.

2. The composition of claim 1 wherein the alpha-2-adrenergic agonist component is selected from the group consisting of imino-imidazolines, imidazolines, imidazoles, azepines, thiazines, oxazolines, guanidines, catecholamines, derivatives thereof and mixtures thereof.

3. The composition of claim 1 wherein the therapeutically active component includes a quinoxaline component.

4. The composition of claim 3 wherein the quinoxaline component is selected from the group consisting of quinoxaline, derivatives thereof, and mixtures thereof.

5. The composition of claim 3 wherein the quinoxaline component is selected from the group consisting of quinoxaline, (2-imidozolin-2-ylamino) quinoxaline, 5-bromo-6-(2-imidozolin-2-ylamino) quinoxaline, and tartrate of 5-bromo-6-(2-imidozolin-2-

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ylamino) quinoxaline, derivatives thereof and mixtures thereof.

6. The composition of claim 1 wherein the therapeutically active component comprises a tartrate of 5-bromo-6-(2-imidozolin-2-ylamino) quinoxaline.

7. The composition of claim 1 wherein the alpha-2-adrenergic agonist component is substantially unionized.

8. The composition of claim 1 wherein the alpha-2-adrenergic agonist component is substantially unionized in a biological environment to which the composition is administered.

9. The composition of claim 1 wherein the alpha-2-adrenergic agonist component has increased diffusion through a lipid membrane relative to an identical alpha-2-adrenergic agonist component in a similar composition without the solubility enhancing component.

10. The composition of claim 1 wherein the alpha-2-adrenergic agonist component is selected from the group consisting of agonists of alpha-2A-adrenergic receptors, agonists of alpha-2B-adrenergic receptors, agonists of alpha-2D-adrenergic receptors and mixtures thereof.

11. The composition of claim 1 wherein the solubility enhancing component is effective to increase the solubility in a biological environment of the alpha-2-adrenergic agonist component relative to the solubility in a biological environment of an identical alpha-2-adrenergic agonist component in a similar composition without the solubility enhancing component.

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12. The composition of claim 1 wherein the solubility enhancing component comprises a polyanionic component.

13. The composition of claim 12 wherein said polyanionic component is selected from the group consisting of anionic cellulose derivatives, anionic polymers derived from acrylic acid, anionic polymers derived from methacrylic acid, anionic polymers derived from alginic acid, anionic polymers derived from amino acids and mixtures thereof.

14. The composition of claim 1 wherein the solubility enhancing component is selected from the group consisting of anionic cellulose derivatives and mixtures thereof.

15. The composition of claim 1 wherein the solubility enhancing component is selected from the group consisting of carboxymethylcelluloses and derivatives thereof.

16. The composition of claim 1 wherein the solubility enhancing component is present in an amount in a range of about 0.1% (w/v) to about 30% (w/v).

17. The composition of claim 1 wherein the solubility enhancing component is present in an amount in a range of about 0.2% (w/v) to about 10% (w/v).

18. The composition of claim 1 wherein the solubility enhancing component is present in an amount in a range of about 0.2% (w/v) to about 0.6% (w/v).

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19. The composition of claim 1 wherein the liquid carrier component is an aqueous liquid carrier component.

20. The composition of claim 1 which is a solution.

21. The composition of claim 1 which has a pH of about 7 or greater.

22. The composition of claim 1 which has a pH in a range of about 7 to about 9.

23. The composition of claim 1 which is ophthalmically acceptable.

24. A composition comprising:

an alpha-2-adrenergic agonist component in an amount effective to provide a therapeutic benefit to a patient to whom the composition is administered;

an anionic cellulose derivative in an amount effective to increase the solubility of the alpha-2-adrenergic agonist component; and

an aqueous liquid carrier component.

25. The composition of claim 24 wherein the alpha-2-adrenergic agonist component comprises a tartrate of 5-bromo-6-(2-imidozolin-2-ylamino) quinoxaline.

26. The composition of claim 24 wherein the anionic cellulose derivative comprises carboxymethylcellulose.

27. The composition of claim 24 wherein the anionic cellulose derivative is present in an amount in a range of about 0.2% (w/v) to about 0.6% (w/v).

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28. A composition comprising:

a tartrate of 5-bromo-6-(2-imidozolin-2-ylamino) quinoxaline in an amount effective to provide a therapeutic benefit to a patient to whom the composition is administered;

a solubility enhancing component in an amount effective to increase the solubility of the tartrate of 5-bromo-6-(2-imidozolin-2-ylamino) quinoxaline; and

an aqueous liquid carrier component.

29. The composition of claim 28 wherein the solubility enhancing component comprises a carboxymethylcellulose.

30. The composition of claim 28 which is ophthalmically acceptable.

31. A complex comprising monomer units derived from one or more quinoxaline components.

32. The complex of claim 31 wherein the quinoxaline component is selected from the group consisting of a quinoxaline, a (2-imidozolin-2-ylamino) quinoxaline, a 5-bromo-6-(2-imidozolin-2-ylamino) quinoxaline, a tartrate of 5-bromo-6-(2-imidozolin-2-ylamino) quinoxaline, derivatives thereof and mixtures thereof.

33. The complex of claim 31 wherein the quinoxaline component is a tartrate of 5-bromo-6-(2-imidozolin-2-ylamino) quinoxaline.

34. An oligomer comprising monomer units derived from a quinoxaline component.

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35. The oligomer of claim 34 wherein the quinoxaline component is selected from the group consisting of a quinoxaline, a (2-imidozolin-2-ylamino) quinoxaline, a 5-bromo-6-(2-imidozolin-2-ylamino) quinoxaline, a tartrate of 5-bromo-6-(2-imidozolin-2-ylamino) quinoxaline, derivatives thereof and mixtures thereof.

36. The oligomer of claim 34 wherein the quinoxaline component is a tartrate of 5-bromo-6-(2-imidozolin-2-ylamino) quinoxaline.

37. The oligomer of claim 34 which is a dimer.

38. The oligomer of claim 35 which is a dimer.

39. The oligomer of claim 36 which is a dimer.

40. A composition comprising:

an alpha-2-adrenergic agonist component in an amount effective to provide a therapeutic benefit to a patient to whom the composition is administered;

an oxy-chloro component in an effective amount to at least aid in preserving the composition; and

a liquid carrier component,

wherein the composition is substantially free of cyclodextrins.

41. The composition of claim 40 wherein the alpha-2-adrenergic agonist component is selected from the group consisting of imino-imidazolines, imidazolines, imidazoles, azepines, thiazines, oxazolines, guanidines, catecholamines, derivatives thereof and mixtures thereof.

42. The composition of claim 40 wherein the

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therapeutically active component includes a quinoxaline component.

43. The composition of claim 42 wherein the quinoxaline component is selected from the group consisting of quinoxaline, derivatives thereof, and mixtures thereof.

44. The composition of claim 40 which further includes a solubility enhancing component in an amount effective to increase the solubility of the alpha-2-adrenergic agonist component in the composition relative to the solubility of an identical alpha-2-adrenergic agonist component in a similar composition without the solubility enhancing component.

45. The composition of claim 44 wherein the solubility enhancing component is effective to increase the solubility in a biological environment of the alpha-2-adrenergic agonist component relative to the solubility in a biological environment of an identical alpha-2-adrenergic agonist component in a similar composition without the solubility enhancing component.

46. The composition of claim 44 wherein the solubility enhancing component comprises a polyanionic component.

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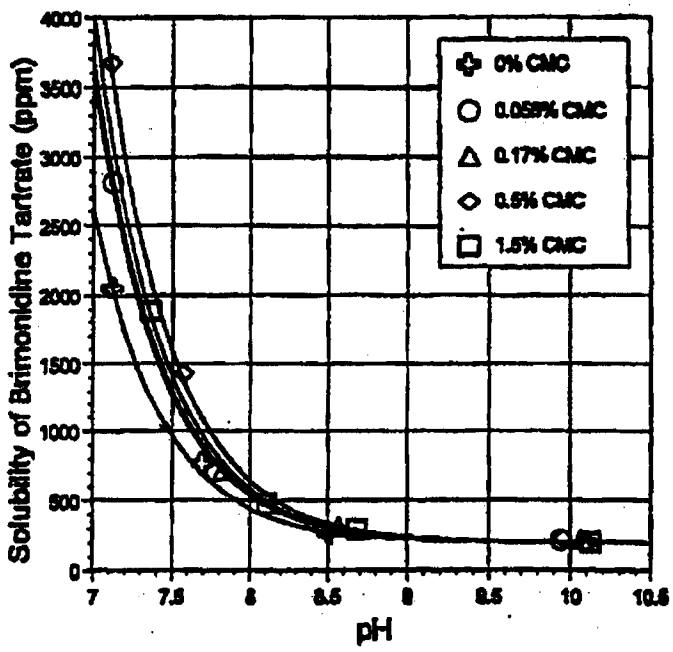
COMPOSITIONS CONTAINING ALPHA-2-ADRENERGIC AGONIST COMPONENTS

ABSTRACT OF THE DISCLOSURE

Compositions useful for improving effectiveness of alpha-2-adrenergic agonist components include carrier components, alpha-2-adrenergic agonist components, solubility enhancing components which aid in solubilizing the alpha-2-adrenergic agonist components. In one embodiment, the alpha-2-adrenergic agonist components include alpha-2-adrenergic agonists. In another embodiment, the solubility enhancing components include carboxymethylcellulose.

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Figure 1



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60/218,200	07/14/2000		150	D-2892 P	1		

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Edward D.S. Kerslake, Charlestown, MA ;

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ACTION Wish to Convert
PROV App. to Utility App

Continuing Data as Claimed by Applicant

Foreign Applications

RESPONSE DUE June 14, 2001
ACTION PROV. Foreign filing

If Required, Foreign Filing License Granted 10/31/2000

Title

Compositions containing alpha-2-adrenergic agonist components

Preliminary Class

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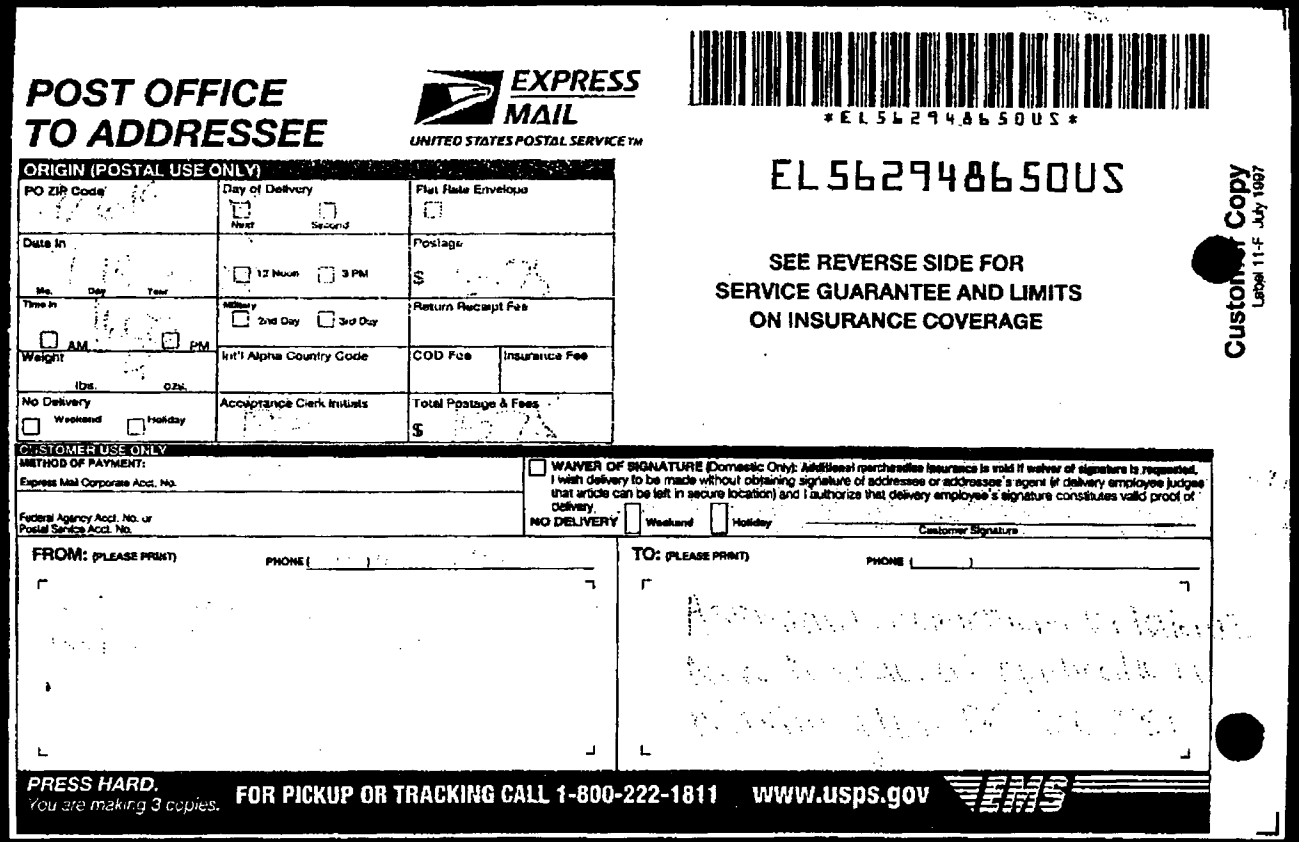
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