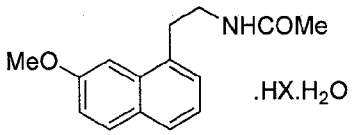
Claims:

1. An agomelatine hydrochloride hydrate of formula I:



(I)

wherein X is Cl.

2. An agomelatine hydrochloride hydrate of formula I according to claim 1 in the form of crystalline form, characterized by Bragg 2θ angle, interplanar spacing d and relative intensity as follows:

2-Theta	d (Å)	Relative Intensity (I%)
9.076	9.7360	11.24
13.635	6.4887	27.62
14.427	6.1345	16.38
16.872	5.2507	34.17
18.176	4.8767	100.00
21.610	4.1089	62.25
22.259	3.9905	7.94
22.794	3.8981	19.22
23.878	3.7235	31.32
24.214	3.6726	82.40
25.457	3.4960	41.45
25.714	3.4617	37.06
27.430	3.2488	31.69
29.207	3.0551	13.75

and which also includes crystals whose peak diffraction angles match within an error of ±0.2°.

3. A method for the preparation of the agomelatine hydrochloride hydrate according to claim 1 or 2, wherein agomelatine is reacted with HCl to produce the agomelatine hydrochloride hydrate.

4. The method for the preparation of the agomelatine hydrochloride hydrate according to claim 3, wherein agomelatine is reacted with HCl in an aqueous organic solvent to produce the agomelatine hydrochloride hydrate.

5. The method for the preparation of the agomelatine hydrochloride hydrate according to claim 4, wherein agomelatine is dissolved in organic solvent before aqueous HCl solution is added to precipitate the crystal of the product.

6. The method for the preparation of the agomelatine hydrochloride hydrate according to claim 5, wherein said aqueous HCl solution is added dropwise.

7. The method for the preparation of the agomelatine hydrochloride hydrate according to claim 4, wherein agomelatine is added to an aqueous organic solvent containing HCl to precipitate the crystal of the product.

8. The method for the preparation of the agomelatine hydrochloride hydrate according to claim 5 or 7, which further includes rinsing and drying the solid after crystallisation.

9. The method for the preparation of the agomelatine hydrochloride hydrate according to claim 5 or 7, wherein the reaction temperature is 0-20°C.

10. The method for the preparation of the agomelatine hydrochloride hydrate according to claim 5 or 7, wherein said organic solvent is ethyl acetate, methyl acetate, n-butyl acetate, acetone or acetonitrile.

11. The method for the preparation of the agomelatine hydrochloride hydrate according to claim 10, wherein said organic solvent is ethyl acetate.

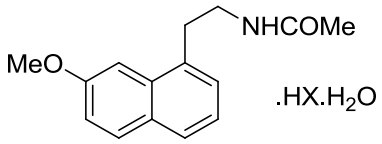
12. A pharmaceutical composition, comprising an agomelatine hydrochloride hydrate according to claim 1 or 2 in associated with pharmaceutically acceptable adjuvants or excipients.

13. Use of an agomelatine hydrochloride hydrate according to claim 1 or 2 for the treatment of melatoninergic system disorders, sleep disorders, stress, anxiety, seasonal affective disorder, major depression, cardiovascular diseases, digestive system diseases, insomnia and fatigue caused by jet lag, schizophrenia, phobia or depression disorders.

The invention claimed is:

1. An agomelatine hydrochloride hydrate of formula I:

(I)



wherein X is Cl and wherein the agomelatine hydrochloride hydrate is in a crystalline form having the following X-ray powder diffraction diagram expressed in terms of Bragg 2θ angle, interplanar spacing d and relative intensity:

2-Theta	d (Å)	Relative Intensity (I%)
9.076	9.7360	11.24
13.635	6.4887	27.62
14.427	6.1345	16.38
16.872	5.2507	34.17
18.176	4.8767	100.00
21.610	4.1089	62.25
22.259	3.9905	7.94
22.794	3.8981	19.22
23.878	3.7235	31.32
24.214	3.6726	82.40
25.457	3.4960	41.45
25.714	3.4617	37.06
27.430	3.2488	31.69
29.207	3.0551	13.75

including crystals whose peak diffraction angles match within an error of ±0.2°.

2. A method for the preparation of the agomelatine hydrochloride hydrate according to claim 1, wherein agomelatine is reacted with HCl to produce the agomelatine hydrochloride hydrate.

3. The method according to claim 2, wherein agomelatine is reacted with HCl in an aqueous organic solvent to produce the agomelatine hydrochloride hydrate.

4. The method according to claim 3, wherein agomelatine is dissolved in an organic solvent before an aqueous HCl solution is added to precipitate a crystal of the product.

5. The method according to claim 4, wherein the aqueous HCl solution is added dropwise.

6. The method according to claim 3, wherein agomelatine is added to an aqueous organic solvent containing HCl to precipitate a crystal of the product.

7. The method according to claim 4, further comprising rinsing and drying the solid after crystallisation.

8. The method according to claim 4, wherein the reaction temperature is 0-20° C.

9. The method according to claim 4, wherein the organic solvent is ethyl acetate, methyl acetate, n-butyl acetate, acetone or acetonitrile.

10. The method according to claim 9, wherein the organic solvent is ethyl acetate.

11. The method according to claim 6, further comprising rinsing and drying the solid after crystallisation.

12. The method according to claim 6, wherein the reaction temperature is 0-20° C.

13. The method according to claim 6, wherein the organic solvent is ethyl acetate, methyl acetate, n-butyl acetate, acetone or acetonitrile:

14. The method according to claim 13, wherein the organic solvent is ethyl acetate.

15. A pharmaceutical composition, comprising the ago-melatine hydrochloride hydrate according to claim 1 in combination with one or more pharmaceutically acceptable adjuvants or excipients.

16. A method of treating a condition selected from sleep disorders, stress, anxiety, major depression, and depression disorders in a subject in need thereof, comprising administration of an effective amount of the agomelatine hydrochloride hydrate according to claim 1.