CLAIMS

1. A pharmaceutical composition for the treatment of diseases and conditions associated with the serotonin receptor 5-HT, comprising from about 10 mg to about 90 mg of 3-(4-cyclopropoxybenzyl)-1-(2,4-difluorobenzyl)-1-(1-methylpiperidin-4-yl)urea, or about an equivalent amount of a pharmaceutically acceptable salt and/or pharmaceutically acceptable salt hydrate thereof, as an active ingredient and one or more pharmaceutically acceptable excipients.

2. The pharmaceutical composition of claim 1, wherein the composition comprises about 25 mg to about 65 mg of 3-(4-cyclopropoxybenzyl)-1-(2,4-difluorobenzyl)-1-(1-methylpiperidin-4-yl)urea, or about an equivalent amount of a pharmaceutically acceptable salt and/or pharmaceutically acceptable salt hydrate thereof.

3. The pharmaceutical composition of any one of claims 1 and 2, wherein the composition comprises about 30 mg of 3-(4-cyclopropoxybenzyl)-1-(2,4-difluorobenzyl)-1-(1-methylpiperidin-4-yl)urea, or about an equivalent amount of a pharmaceutically acceptable salt and/or pharmaceutically acceptable salt hydrate thereof.

4. The pharmaceutical composition of any one of claims 1-3, wherein the composition comprises about 60 mg of 3-(4-cyclopropoxybenzyl)-1-(2,4-difluorobenzyl)-1-(1-methylpiperidin-4-yl)urea, or about an equivalent amount of a pharmaceutically acceptable salt and/or pharmaceutically acceptable salt hydrate thereof.

5. The pharmaceutical composition of any one of claims 1-4, wherein the active ingredient comprises 3-(4-cyclopropoxybenzyl)-1-(2,4-difluorobenzyl)-1-(1-methylpiperidin-4-yl)urea hemitartrate.

6. The pharmaceutical composition any one of claims 1-5, wherein the active ingredient comprises 3-(4-cyclopropoxybenzyl)-1-(2,4-difluorobenzyl)-1-(1-methylpiperidin-4-yl)urea hemitartrate monohydrate.

6. The pharmaceutical composition of any one of claims 1-6, wherein the composition is formulated for oral administration.

7. The pharmaceutical composition of any one of claims 1-7, wherein the composition is formulated for administration to a human once per day.

8. The pharmaceutical composition of any one of claims 1-8, wherein oral administration of to a human results in a mean $C_{max,ss}$ in the range of about 20 ng/mL to about 250 ng/mL.

9. The pharmaceutical composition of any one of claims 1-9, wherein oral administration of to a human results in a mean $C_{max,ss}$ in the range of about 30 ng/mL to about 90 ng/mL.

10. The pharmaceutical composition of any one of claims 1-9, wherein oral administration of to a human results in a mean $C_{max,ss}$ in the range of about 100 ng/mL to about 180 ng/mL.

11. The pharmaceutical composition of any one of claims 1-10, wherein the disease or condition associated with the serotonin receptor 5-HT is selected from the group consisting of Abnormal hormonal activity, Alzheimer's disease, Alzheimer’s disease dementia, Alzheimer’s disease psychosis, Addiction (alcohol, cocaine, methamphetamine, nicotine, and/or opioid), Addison’s disease, ADHD, Alzheimer's disease psychosis, Affective disorders, Aggressiveness, Agitation, Akathisia, Alcohol addiction, Alcohol withdrawal, Amenorrhea, Amyotrophic lateral sclerosis, Anhedonia, Anorexia, Anti-NMDAR encephalitis, Anxiety, Appetite disorders, Asthma, Athereosclerosis, Autism, Behavioral disorders, Behavioral disturbances associated with dementia, Binge eating disorder associated with impulse control disorder (ICD), Bipolar disorder, Blindness, Borderline disorder, Borderline personality

disorder, Bradykinesia, Bulimia, Buying associated with ICD, Cardiac arrhythmia, Cerebral vascular accidents, Charles Bonnet disease, Chemotherapy-induced emesis, Childhood autism, Chronic pain, Chronic insomnia, Chronic kidney disease, cocaine addiction, Cognitive disorders, craniofacial pain, temporomandibular joint (TMJ) / temporomandibular disorder (TMD), Cushing´s disease, Delusion, Dementia, Dementia with Lewy Body or Lewy Body dementia, dementia and psychosis associated with Creutzfeld-Jakob disease (CJD), Gerstmann-Strausser-Schenker disease (GSSD) and fatal familiar insomnia (FFI), Depression, Diabetes mellitus (non-insulin dependent), Diabetic peripheral neuropathy, Drug addiction, Double vision, Down´s syndrome, Dyskinesia, Dysthymia, Dystonia, Ejaculatory problem, Emphysema, Epilepsy, Extrapyramidal disorder, Fibromyalgia, Frailty, Friedrich´s Ataxia, Frontotemperal Dementia, Gambling associated with ICD, Galactorrhea, General anxiety disorder, Glaucoma, hallucinations associated with or arising from psychedelic drug usage, Hair loss or thinning, Hallucination, Headache, Hemorrhoids, Huntington's disease, Hyperprolactinemia, Hypertension, Hypersexuality associated with ICD, Hypotension, Hypoglutamateriga disorders, Impulse control disorder, Idiopathic thrombocytopenic purpura, Impotence, Incontinence, Increased intraocular pressure, Infertility, Inflammatory pain, Insomnia, Ischemia, Ischemic stroke, Lewy body disease (LBD), Learning disorders, Libido (decreased), Loss of libido, Low male fertility, Low sperm mobility, Lupus, Machado-Joseph disease, Major depression, Mania, Menopausal symptoms, Metabolic syndrome, methamphetamine addiction, Migraine, mild cognitive impairment (MCI), morphine addiction, Motor tics, Multi-infarct dementia, Multiple sclerosis, Multiplex development disorder, Myocardial infarction, Myoclonus, Neuropathic pain, Neurodegenerative disorder, Neuropsychiatric disease, Nicotine addiction, Non motor symptoms of Parkinson's disease selected from dementia, depression, apathy, hallucinations, dribbling saliva (sialorrhea), constipation, pain, genitourinary problems, Non-alcoholic Fatty Liver disease, and sleep disorders, Obsessive compulsive disorder, On/off phenomena, Opioid addiction, Osteoporosis, Pancreatis, Panic attacks, Parkinson-like disorders including Machado-Joseph disease, Pantothenate kinase-associated neurodegeneration (PKAN)/Neurodegeneration with brain iron accumulation 1 (NBAI1)/Hallervorden-Spatz disease, and Wilson's disease, Parkinson's disease, Parkinson's disease dementia, Parkinson's disease psychosis, Periodic limb movement during sleep (PLMS), Peripheral vascular disease, Borderline Personality disorder, Pituitary tumor, Postherpetic neuralgia, Progressive Supranucelar Palsy, Prion disease including Creutzfeld-Jakob disease (CJD), Gerstmann-Strausser-Schenker disease (GSSD) and fatal familiar insomnia (FFI), Postpartum depression, Postpartum psychosis, Prolactinoma,

Pseudobulbar affect (PBA), Psychomotor slowing, Psychosis, Psychoses associated with neurodegenerative disorders, Psychosomatic disorders, Psychotic depression, post-traumatic stress disorder (PTSD), Raynaud´s disease, Reflex sympathetic dystrophy, Restless legs syndrome, Retinal disease, Schizoaffective disorders, Schizophrenia, negative symptoms of schizophrenia, cognitive impairment associated with schizophrenia, Sepsis, Serotonin syndrome, Sexual dysfunction, Sexual dysfunction associated with antidepressant use, Sleep apnea, Sleep disorders, Sleep maintenance insomnia, social anxiety disorder, Spinal injury, Spinocerebellar Atrophy, Suicidal tendency, Thrombosis, Thrombotic stroke, Thrombotic thrombocytopenic purpura, Tinnitus, Tiredness, Tourette´s syndrome, Transient insomnia, Traumatic brain injury, Treatment-resistant depression, Treatment-resistant schizophrenia, Tremor, Vaginal dryness, Vascular disease, Vasospasm Wakefulness, vascular dementia, Hallucinations associated with Parkinson's disease, Delusions associated with Parkinson's disease; Hallucinations associated with Alzheimer's disease, Delusions associated with Alzheimer's disease; cancer, brain cancer, glioma, glioblastoma, Pancreatic cancer, Skin cancer, Hypoactive sexual desire disorder, adult type 2 diabetes mellitus with Parkinson's disease or dementia and Liver fibrosis.

12. The pharmaceutical composition of any one of claims 1-11, wherein the disease or condition associated with the serotonin receptor 5-HT is Alzheimer's disease psychosis (ADP).

13. The pharmaceutical composition of any one of claims 1-11, wherein the disease or condition associated with the serotonin receptor 5-HT is dementia related psychosis.

14. The pharmaceutical composition of any one of claims 1-13, wherein the composition is formulated as a capsule or a tablet.