CLAIMS:

1. A method for improving the dissolution profile of a biologically active material, comprising the steps of:
dry milling a solid biologically active material and a millable grinding matrix in a mill comprising a plurality of milling bodies, for a time period sufficient to produce particles of the biologically active material dispersed in an at least partially milled grinding material.

2. The method of claim 1, wherein the particles have an average particle size equal or greater than 1µm determined on a particle number basis.

3. A method of claim 2, wherein the average particle size of the biologically active material has been reduced by a factor selected from the group consisting of: less than 5%, less than 10%, less than 20%, less than 30%, less than 40%, less than 50%, less than 60%, less than 70%, less than 80%, less than 90 %, less than 95% and less than 99%.

4. The method of any one of the claims 2 to 3, wherein the average particle size falls within the range selected from the group consisting of: 1-1000µm, 1-500µm, 1-300µm, 1-200µm, 1-150µm, 1-100µm, 1-50µm, 1-20µm, 1-10µm, 1-7.5µm, 1-5µm and 1-2µm.

5. The method of claim 1, wherein the particles have a median particle size selected from the group consisting of: equal or greater than 1µm; and equal or greater than 2µm, wherein the median particle size is determined on a particle volume basis.

6. The method of claim 5 wherein the percentage of particles greater than 1 µm on a particle volume basis is a percentage selected from the group consisting of: 50%, 60%, 70%, 80%, 90%, 100%.

7. The method of claim 5 wherein the percentage of particles greater than 2 µm on a particle volume basis is a percentage selected from the group consisting of: 50%, 60%, 70%, 80%, 90%, 100%.

8. A method of any one of claims 5 to 7, wherein the median particle size has been reduced by a factor selected from the group consisting of: less than 5%, less than 10%, less than 20%, less than 30%, less than 40%, less than 50%, less than 60%, less than 70%, less than 80%, less than 90 %, less than 95% and less than 99%.

9. The method of any one of claims 5 to 7, wherein the median particle size falls within the range selected from the group consisting of: 1-1000μm, 1-500μm, 1-300μm, 1-200μm, 1-150μm, 1-100μm, 1-50μm, 1-20μm, 1-10μm, 1-7.5μm, 1-5μm 1-2μm, 2-1000μm, 2-500μm, 2-300μm, 2-200μm, 2-150μm, 2-100μm, 2-50μm, 2-20μm, 2-10μm, 2-7.5μm and 2-5μm.

10. The method of any preceding claim, wherein the crystallinity profile of the biologically active material is selected from the group consisting of: at least 50% of the biologically active material is crystalline, at least 60% of the biologically active material is crystalline, at least 70% of the biologically active material is crystalline, at least 75% of the biologically active material is crystalline, at least 85% of the biologically active material is crystalline, at least 90% of the biologically active material is crystalline, at least 95% of the biologically active material is crystalline and at least 98% of the biologically active material is crystalline.

11. The method of any preceding claim, wherein the crystallinity profile of the biologically active material is substantially equal to the crystallinity profile of the biologically active material before the material was subject to the method of any one of the preceding claims.

12. The method of any preceding claim, wherein the amorphous content of the biological active material is selected from the group consisting of: less than 50% of the biologically active material is amorphous, less than 40% of the biologically active material is amorphous, less than 30% of the biologically active material is amorphous, less than 25% of the biologically active material is amorphous, less than 15% of the biologically active material is amorphous, less than 10% of the biologically active material is amorphous, less than 5% of the biologically active material is amorphous and less than 2% of the biologically active material is amorphous.

13. The method of any preceding claim, wherein the biologically active material has no significant increase in amorphous content before subjecting the material to the method of any one of the preceding claims.

14. The method of any preceding claim, wherein the milling time period is a range selected from the group consisting of: between 10 minutes and 2 hours, between 10 minutes and 1 hour, between 10 minutes and 45 minutes, between 10 minutes and 30 minutes, between 5 minutes and 30 minutes, between 5 minutes and 20 minutes, between 2

minutes and 10 minutes, between 2 minutes and 5 minutes, between 1 minutes and 20 minutes, between 1 minute and 10 minutes, and between 1 minute and 5 minutes.

15. The method of any preceding claim, wherein the dry milling is undertaken in a mechanically agitated attritor mill (horizontal or vertical), vibratory mill or nutating mill, wherein the milling medium is steel balls having a diameter selected from the group consisting of: between 1 and 20 mm, between 2 and 15 mm and between 3 and 10 mm.

16. The method of any preceding claim, wherein the total combined amount of biologically active material and grinding matrix in the mill at any given time is equal to or greater than a mass selected from the group consisting of: 200 grams, 500 grams, 1 kg, 2kg, 5 kg, 10 kg, 20 kg, 30 kg, 50 kg, 75 kg, 100kg, 150 kg, 200 kg.

17. The method of any preceding claim, wherein the biologically active material is selected from the group consisting of: fungicides, pesticides, herbicides, seed treatments, cosmeceuticals, cosmetics, complementary medicines, natural products, vitamins, nutrients, nutraceuticals, pharmaceutical actives, biologics, amino acids, proteins, peptides, nucleotides, nucleic acids, additives, foods and food ingredients and analogs, homologs and first order derivatives thereof.

18. The method of any preceding claim, wherein the biologically active material is selected from the group consisting of: indomethacin, diclofenac, naproxen, meloxicam, metaxalone, cyclosporin A, progesterone celecoxib, cilostazol, ciprofloxacin, 2,4-dichlorophenoxyacetic acid, anthraquinone, creatine monohydrate, glyphosate, halusulfuron, mancozeb, metsulfuron, salbutamol, sulphur, tribenuran and estradiol or any salt or derivative thereof.

19. The method of any preceding claim, wherein the grinding matrix is a single matrix or is a mixture of two or more matrices in any proportion.

20. The method of any preceding claim, wherein the grinding matrix is a single material or is a mixture of two or more materials in any proportion wherein the single material or a mixture of two or more materials is selected from the group consisting of: mannitol, sorbitol, Isomalt, xylitol, maltitol, lactitol, erythritol, arabitol, ribitol, glucose, fructose, mannose, galactose, anhydrous lactose, lactose monohydrate, sucrose, maltose, trehalose, maltodextrins, dextrin, Inulin, dextrates, polydextrose, starch, wheat flour, corn flour, rice flour, rice starch, tapioca flour, tapioca starch, potato flour, potato starch, other flours and starches, milk powder, skim milk powders, other milk solids and

dreviatives, soy flour, soy meal or other soy products, cellulose, microcystalline cellulose, microcystalline cellulose based co blended materials, pregelatinized (or partially) starch, HPMC, CMC, HPC, citric acid, tartaric acid, malic acid fumaric acid , ascorbic acid, succinic acid, sodium citrate, sodium tartrate, sodium malate, sodium ascorbate, potassium citrate, potassium tartrate, potassium malate, potassium ascorbate, sodium carbonate, potassium carbonate, magnesium carbonate, sodium bicarbonate, potassium bicarbonate and calcium carbonate. dibasic calcium phosphate, tribasic calcium phosphate, sodium sulfate, sodium chloride, sodium metabisulphite, sodium thiosulfate, ammonium chloride, Glauber's salt, ammonium carbonate, sodium bisulfate, magnesium sulfate, potash alum, potassium chloride, sodium hydrogen sulfate, sodium hydroxide, crystalline hydroxides, hydrogen carbonates, ammonium chloride, methylamine hydrochloride, ammonium bromide, silica, thermal silica, alumina, titanium dioxide, talc, chalk, mica, kaolin, bentonite, hectorite, magnesium trisilicate, clay based materials or aluminium silicates, sodium lauryl sulfate, sodium stearyl sulfate, sodium cetyl sulfate, sodium cetostearyl sulfate, sodium docusate, sodium deoxycholate, N-lauroylsarcosine sodium salt, glyceryl monostearate , glycerol distearate glyceryl palmitostearate, glyceryl behenate, glyceryl caprylate, glyceryl oleate, benzalkonium chloride, CTAB, CTAC, Cetrimide, cetylpyridinium chloride, cetylpyridinium bromide, benzethonium chloride, PEG 40 stearate, PEG 100 stearate, poloxamer 188, , poloxamer 338, poloxamer 407 polyoxyl 2 stearyl ether, polyoxyl 100 stearyl ether, polyoxyl 20 stearyl ether, polyoxyl 10 stearyl ether, polyoxyl 20 cetyl ether, polysorbate 20, polysorbate 40, polysorbate 60, polysorbate 61, polysorbate 65, polysorbate 80, polyoxyl 35 castor oil, polyoxyl 40 castor oil, polyoxyl 60 castor oil, polyoxyl 100 castor oil, polyoxyl 200 castor oil, polyoxyl 40 hydrogenated castor oil, polyoxyl 60 hydrogenated castor oil, polyoxyl 100 hydrogenated castor oil, polyoxyl 200 hydrogenated castor oil, cetostearyl alcohol, macrogel 15 hydroxystearate, sorbitan monopalmitate, sorbitan monostearate, sorbitan trioleate, Sucrose Palmitate, Sucrose Stearate, Sucrose Distearate, Sucrose laurate, Glycocholic acid, sodium Glycholate, Cholic Acid, Soidum Cholate, Sodium Deoxycholate, Deoxycholic acid, Sodium taurocholate, taurocholic acid, Sodium taurodeoxycholate, taurodeoxycholic acid, soy lecithin, phosphatidylcholine, phosphatidylethanolamine, phosphatidylserine, phosphatidylinositol, PEG4000, PEG6000, PEG8000, PEG10000, PEG20000, alkyl naphthalene sulfonate condensate/Lignosulfonate blend,Calcium Dodecylbenzene Sulfonate, Sodium Dodecylbenzene Sulfonate,Diisopropyl naphthaenesulphonate, erythritol distearate, Naphthalene Sulfonate Formaldehyde Condensate, nonylphenol ethoxylate (poe-30), Tristyrylphenol Ethoxylate, Polyoxyethylene (15) tallowalkylamines, sodium alkyl naphthalene sulfonate, sodium alkyl naphthalene sulfonate condensate, sodium

alkylbenzene sulfonate, sodium isopropyl naphthalene sulfonate, Sodium Methyl Naphthalene Formaldehyde Sulfonate, sodium n-butyl naphthalene sulfonate, tridecyl alcohol ethoxylate (poe-18), Triethanolamine isodecanol phosphate ester, Triethanolamine tristyrylphosphate ester, Tristyrylphenol Ethoxylate Sulfate, Bis(2-hydroxyethyl)tallowalkylamines.

21. The method of claim 20, wherein the concentration of the single material or the major component in a mixture of two or more materials is selected from the group consisting of: 5 - 99 % w/w, 10 - 95 % w/w, 15 - 85 % w/w, of 20 – 80% w/w, 25 - 75 % w/w, 30 - 60% w/w, 40 -50% w/w and the concentration of the second or subsequent material is selected from the group consisting of: 5 - 50 % w/w, 5 - 40 % w/w, 5 - 30 % w/w, of 5 – 20% w/w, 10 - 40 % w/w, 10 -30% w/w, 10 -20% w/w, 20 - 40% w/w, or 20 - 30% w/w or if the second or subsequent material is a surfactant or water soluble polymer the concentration is selected from 0.1 -10 % w/w, 0.1 -5 % w/w, 0.1 -2.5 % w/w, of 0.1 – 2% w/w, 0.1 -1 %, 0.5 -5% w/w, 0.5 -3% w/w, 0.5 -2% w/w, 0.5 – 1.5%, 0.5 -1 % w/w, of 0.75 – 1.25 % w/w, 0.75 -1% and 1% w/w. .

22. The method of any preceding claim, wherein the grinding matrix is selected from the group consisting of:

(a) lactose monohydrate or lactose monohydrate combined with at least one material selected from the group consisting of: xylitol; lactose anhydrous; microcrystalline cellulose; sucrose; glucose; sodium chloride; talc; kaolin; calcium carbonate; malic acid; trisodium citrate dihydrate; D,L-Malic acid; sodium pentane sulfate; sodium octadecyl sulfate; Brij700; Brij76; sodium n-lauroyl sacrosine; lecithin; docusate sodium; polyoxyl-40-stearate; Aerosil R972 fumed silica; sodium lauryl sulfate or other alkyl sulfate surfactants with a chain length between C5 to C18; polyvinyl pyrrolidone;; sodium lauryl sulfate and polyethylene glycol 40 stearate, sodium lauryl sulfate and polyethylene glycol 100 stearate, sodium lauryl sulfate and PEG 3000, sodium lauryl sulphate and PEG 6000, sodium lauryl sulphate and PEG 8000, sodium lauryl sulphate and PEG 10000, sodium lauryl sulfate and Brij700, sodium lauryl sulfate and Poloxamer 407, sodium lauryl sulfate and Poloxamer 338, sodium lauryl sulfate and Poloxamer 188; Poloxamer 407, Poloxamer 338, Poloxamer 188, alkyl naphthalene sulfonate condensate/Lignosulfonate blend; Calcium Dodecylbenzene Sulfonate (Branched); Diisopropyl naphthalenesulphonate; erythritol distearate; linear and branched dodecylbenzene sulfonic acids; Naphthalene Sulfonate Formaldehyde Condensate; nonylphenol ethoxylate, POE-30; Phosphate Esters, Tristyrylphenol Ethoxylate, Free Acid; Polyoxyethylene (15) tallowalkylamines; sodium alkyl naphthalene sulfonate; sodium alkyl naphthalene

sulfonate condensate; sodium alkylbenzene sulfonate; sodium isopropyl naphthalene sulfonate; Sodium Methyl Naphthalene; Formaldehyde Sulfonate; sodium salt of n-butyl naphthalene sulfonate; tridecyl alcohol ethoxylate, POE-18; Triethanolamine isodecanol phosphate ester; Triethanolamine tristyrylphosphate ester; Tristyrylphenol Ethoxylate Sulfate; Bis(2-hydroxyethyl)tallowalkylamines.

(b) lactose anhydrous or lactose anhydrous combined with at least one material selected from the group consisting of: lactose monohydrate; xylitol; microcrystalline cellulose; sucrose; glucose; sodium chloride; talc; kaolin; calcium carbonate; malic acid; trisodium citrate dihydrate; D,L-Malic acid; sodium pentane sulfate; sodium octadecyl sulfate; Brij700; Brij76; sodium n-lauroyl sacrosine; lecithin; docusate sodium; polyoxyl-40-stearate; Aerosil R972 fumed silica; sodium lauryl sulfate or other alkyl sulfate surfactants with a chain length between C5 to C18; polyvinyl pyrrolidone;; sodium lauryl sulfate and polyethylene glycol 40 stearate, sodium lauryl sulfate and polyethylene glycol 100 stearate, sodium lauryl sulfate and PEG 3000, sodium lauryl sulphate and PEG 6000, sodium lauryl sulphate and PEG 8000, sodium lauryl sulphate and PEG 10000, sodium lauryl sulfate and Brij700, sodium lauryl sulfate and Poloxamer 407, sodium lauryl sulfate and Poloxamer 338, sodium lauryl sulfate and Poloxamer 188; Poloxamer 407, Poloxamer 338, Poloxamer 188, alkyl naphthalene sulfonate condensate/Lignosulfonate blend; Calcium Dodecylbenzene Sulfonate (Branched); Diisopropyl naphthalenesulphonate; erythritol distearate; linear and branched dodecylbenzene sulfonic acids; Naphthalene Sulfonate Formaldehyde Condensate; nonylphenol ethoxylate, POE-30; Phosphate Esters, Tristyrylphenol Ethoxylate, Free Acid; Polyoxyethylene (15) tallowalkylamines; sodium alkyl naphthalene sulfonate; sodium alkyl naphthalene sulfonate condensate; sodium alkylbenzene sulfonate; sodium isopropyl naphthalene sulfonate; Sodium Methyl Naphthalene; Formaldehyde Sulfonate; sodium salt of n-butyl naphthalene sulfonate; tridecyl alcohol ethoxylate, POE-18; Triethanolamine isodecanol phosphate ester; Triethanolamine tristyrylphosphate ester; Tristyrylphenol Ethoxylate Sulfate; Bis(2-hydroxyethyl)tallowalkylamines.

(c) mannitol or mannitol combined with at least one material selected from the group consisting of: lactose monohydrate; xylitol; lactose anhydrous; microcrystalline cellulose; sucrose; glucose; sodium chloride; talc; kaolin; calcium carbonate; malic acid; trisodium citrate dihydrate; D,L-Malic acid; sodium pentane sulfate; sodium octadecyl sulfate; Brij700; Brij76; sodium n-lauroyl sacrosine; lecithin; docusate sodium; polyoxyl-40-stearate; Aerosil R972 fumed silica; sodium lauryl sulfate or other alkyl sulfate surfactants with a chain length between C5 to C18; polyvinyl pyrrolidone;; sodium lauryl sulfate and polyethylene glycol 40 stearate, sodium lauryl sulfate and polyethylene glycol 100 stearate, sodium lauryl sulfate and PEG 3000,

sodium lauryl sulphate and PEG 6000, sodium lauryl sulphate and PEG 8000, sodium lauryl sulphate and PEG 10000, sodium lauryl sulfate and Brij700, sodium lauryl sulfate and Poloxamer 407, sodium lauryl sulfate and Poloxamer 338, sodium lauryl sulfate and Poloxamer 188; Poloxamer 407, Poloxamer 338, Poloxamer 188, alkyl naphthalene sulfonate condensate/Lignosulfonate blend; Calcium Dodecylbenzene Sulfonate (Branched); Diisopropyl naphthalenesulphonate; erythritol distearate; linear and branched dodecylbenzene sulfonic acids; Naphthalene Sulfonate Formaldehyde Condensate; nonylphenol ethoxylate, POE-30; Phosphate Esters, Tristyrylphenol Ethoxylate, Free Acid; Polyoxyethylene (15) tallowalkylamines; sodium alkyl naphthalene sulfonate; sodium alkyl naphthalene sulfonate condensate; sodium alkylbenzene sulfonate; sodium isopropyl naphthalene sulfonate; Sodium Methyl Naphthalene; Formaldehyde Sulfonate; sodium salt of n-butyl naphthalene sulfonate; tridecyl alcohol ethoxylate, POE-18; Triethanolamine isodecanol phosphate ester; Triethanolamine tristyrylphosphate ester; Tristyrylphenol Ethoxylate Sulfate; Bis(2-hydroxyethyl)tallowalkylamines.

(d) Sucrose or sucrose combined with at least one material selected from the group consisting of: lactose monohydrate; lactose anhydrous; mannitol; microcrystalline cellulose; glucose; sodium chloride; talc; kaolin; calcium carbonate; malic acid; tartaric acid; trisodium citrate dihydrate; D,L-Malic acid; sodium pentane sulfate; sodium octadecyl sulfate; Brij700; Brij76; sodium n-lauroyl sacrosine; lecithin; docusate sodium; polyoxyl-40-stearate; Aerosil R972 fumed silica; sodium lauryl sulfate or other alkyl sulfate surfactants with a chain length between C5 to C18; polyvinyl pyrrolidone;; sodium lauryl sulfate and polyethylene glycol 40 stearate, sodium lauryl sulfate and polyethylene glycol 100 stearate, sodium lauryl sulfate and PEG 3000, sodium lauryl sulphate and PEG 6000, sodium lauryl sulphate and PEG 8000, sodium lauryl sulphate and PEG 10000, sodium lauryl sulfate and Brij700, sodium lauryl sulfate and Poloxamer 407, sodium lauryl sulfate and Poloxamer 338, sodium lauryl sulfate and Poloxamer 188; Poloxamer 407, Poloxamer 338, Poloxamer 188, alkyl naphthalene sulfonate condensate/Lignosulfonate blend; Calcium Dodecylbenzene Sulfonate (Branched); Diisopropyl naphthalenesulphonate; erythritol distearate; linear and branched dodecylbenzene sulfonic acids; Naphthalene Sulfonate Formaldehyde Condensate; nonylphenol ethoxylate, POE-30; Phosphate Esters, Tristyrylphenol Ethoxylate, Free Acid; Polyoxyethylene (15) tallowalkylamines; sodium alkyl naphthalene sulfonate; sodium alkyl naphthalene sulfonate condensate; sodium alkylbenzene sulfonate; sodium isopropyl naphthalene sulfonate; Sodium Methyl Naphthalene; Formaldehyde Sulfonate; sodium salt of n-butyl naphthalene sulfonate; tridecyl alcohol ethoxylate, POE-18; Triethanolamine isodecanol phosphate ester; Triethanolamine

tristyrylphosphate ester; Tristyrylphenol Ethoxylate Sulfate; Bis(2-hydroxyethyl)tallowalkylamines.

(e) Glucose or glucose combined with at least one material selected from the group consisting of: lactose monohydrate; lactose anhydrous; mannitol; microcrystalline cellulose; sucrose; sodium chloride; talc; kaolin; calcium carbonate; malic acid; tartaric acid; trisodium citrate dihydrate; D,L-Malic acid; sodium pentane sulfate; sodium octadecyl sulfate; Brij700; Brij76; sodium n-lauroyl sacrosine; lecithin; docusate sodium; polyoxyl-40-stearate; Aerosil R972 fumed silica; sodium lauryl sulfate or other alkyl sulfate surfactants with a chain length between C5 to C18; polyvinyl pyrrolidone;; sodium lauryl sulfate and polyethylene glycol 40 stearate, sodium lauryl sulfate and polyethylene glycol 100 stearate, sodium lauryl sulfate and PEG 3000, sodium lauryl sulphate and PEG 6000, sodium lauryl sulphate and PEG 8000, sodium lauryl sulphate and PEG 10000, sodium lauryl sulfate and Brij700, sodium lauryl sulfate and Poloxamer 407, sodium lauryl sulfate and Poloxamer 338, sodium lauryl sulfate and Poloxamer 188; Poloxamer 407, Poloxamer 338, Poloxamer 188, alkyl naphthalene sulfonate condensate/Lignosulfonate blend; Calcium Dodecylbenzene Sulfonate (Branched); Diisopropyl naphthalenesulphonate; erythritol distearate; linear and branched dodecylbenzene sulfonic acids; Naphthalene Sulfonate Formaldehyde Condensate; nonylphenol ethoxylate, POE-30; Phosphate Esters, Tristyrylphenol Ethoxylate, Free Acid; Polyoxyethylene (15) tallowalkylamines; sodium alkyl naphthalene sulfonate; sodium alkyl naphthalene sulfonate condensate; sodium alkylbenzene sulfonate; sodium isopropyl naphthalene sulfonate; Sodium Methyl Naphthalene; Formaldehyde Sulfonate; sodium salt of n-butyl naphthalene sulfonate; tridecyl alcohol ethoxylate, POE-18; Triethanolamine isodecanol phosphate ester; Triethanolamine tristyrylphosphate ester; Tristyrylphenol Ethoxylate Sulfate; Bis(2-hydroxyethyl)tallowalkylamines.

(f) Sodium chloride or sodium chloride combined with at least one material selected from the group consisting of: lactose monohydrate; lactose anhydrous; mannitol; microcrystalline cellulose; sucrose; glucose; talc; kaolin; calcium carbonate; malic acid; tartaric acid; trisodium citrate dihydrate; D,L-Malic acid; sodium pentane sulfate; sodium octadecyl sulfate; Brij700; Brij76; sodium n-lauroyl sacrosine; lecithin; docusate sodium; polyoxyl-40-stearate; Aerosil R972 fumed silica; sodium lauryl sulfate or other alkyl sulfate surfactants with a chain length between C5 to C18; polyvinyl pyrrolidone;; sodium lauryl sulfate and polyethylene glycol 40 stearate, sodium lauryl sulfate and polyethylene glycol 100 stearate, sodium lauryl sulfate and PEG 3000, sodium lauryl sulphate and PEG 6000, sodium lauryl sulphate and PEG 8000, sodium lauryl sulphate and PEG 10000, sodium lauryl

sulfate and Brij700, sodium lauryl sulfate and Poloxamer 407, sodium lauryl sulfate and Poloxamer 338, sodium lauryl sulfate and Poloxamer 188; Poloxamer 407, Poloxamer 338, Poloxamer 188, alkyl naphthalene sulfonate condensate/Lignosulfonate blend; Calcium Dodecylbenzene Sulfonate (Branched); Diisopropyl naphthalenesulphonate; erythritol distearate; linear and branched dodecylbenzene sulfonic acids; Naphthalene Sulfonate Formaldehyde Condensate; nonylphenol ethoxylate, POE-30; Phosphate Esters, Tristyrylphenol Ethoxylate, Free Acid; Polyoxyethylene (15) tallowalkylamines; sodium alkyl naphthalene sulfonate; sodium alkyl naphthalene sulfonate condensate; sodium alkylbenzene sulfonate; sodium isopropyl naphthalene sulfonate; Sodium Methyl Naphthalene; Formaldehyde Sulfonate; sodium salt of n-butyl naphthalene sulfonate; tridecyl alcohol ethoxylate, POE-18; Triethanolamine isodecanol phosphate ester; Triethanolamine tristyrylphosphate ester; Tristyrylphenol Ethoxylate Sulfate; Bis(2-hydroxyethyl)tallowalkylamines.

(g) xylitol or xylitol combined with at least one material selected from the group consisting of: lactose monohydrate; lactose anhydrous; mannitol; microcrystalline cellulose; sucrose; glucose; sodium chloride; talc; kaolin; calcium carbonate; malic acid; tartaric acid; trisodium citrate dihydrate; D,L-Malic acid; sodium pentane sulfate; sodium octadecyl sulfate; Brij700; Brij76; sodium n-lauroyl sacrosine; lecithin; docusate sodium; polyoxyl-40-stearate; Aerosil R972 fumed silica; sodium lauryl sulfate or other alkyl sulfate surfactants with a chain length between C5 to C18; polyvinyl pyrrolidone;; sodium lauryl sulfate and polyethylene glycol 40 stearate, sodium lauryl sulfate and polyethylene glycol 100 stearate, sodium lauryl sulfate and PEG 3000, sodium lauryl sulphate and PEG 6000, sodium lauryl sulphate and PEG 8000, sodium lauryl sulphate and PEG 10000, sodium lauryl sulfate and Brij700, sodium lauryl sulfate and Poloxamer 407, sodium lauryl sulfate and Poloxamer 338, sodium lauryl sulfate and Poloxamer 188; Poloxamer 407, Poloxamer 338, Poloxamer 188, alkyl naphthalene sulfonate condensate/Lignosulfonate blend; Calcium Dodecylbenzene Sulfonate (Branched); Diisopropyl naphthalenesulphonate; erythritol distearate; linear and branched dodecylbenzene sulfonic acids; Naphthalene Sulfonate Formaldehyde Condensate; nonylphenol ethoxylate, POE-30; Phosphate Esters, Tristyrylphenol Ethoxylate, Free Acid; Polyoxyethylene (15) tallowalkylamines; sodium alkyl naphthalene sulfonate; sodium alkyl naphthalene sulfonate condensate; sodium alkylbenzene sulfonate; sodium isopropyl naphthalene sulfonate; Sodium Methyl Naphthalene; Formaldehyde Sulfonate; sodium salt of n-butyl naphthalene sulfonate; tridecyl alcohol ethoxylate, POE-18; Triethanolamine isodecanol phosphate ester;

Triethanolamine tristyrylphosphate ester; Tristyrylphenol Ethoxylate Sulfate; Bis(2-hydroxyethyl)tallowalkylamines.

(h) Tartaric acid or tartaric acid combined with at least one material selected from the group consisting of: lactose monohydrate; lactose anhydrous; mannitol; microcrystalline cellulose; sucrose; glucose; sodium chloride; talc; kaolin; calcium carbonate; malic acid; trisodium citrate dihydrate; D,L-Malic acid; sodium pentane sulfate; sodium octadecyl sulfate; Brij700; Brij76; sodium n-lauroyl sacrosine; lecithin; docusate sodium; polyoxyl-40-stearate; Aerosil R972 fumed silica; sodium lauryl sulfate or other alkyl sulfate surfactants with a chain length between C5 to C18; polyvinyl pyrrolidone;; sodium lauryl sulfate and polyethylene glycol 40 stearate, sodium lauryl sulfate and polyethylene glycol 100 stearate, sodium lauryl sulfate and PEG 3000, sodium lauryl sulphate and PEG 6000, sodium lauryl sulphate and PEG 8000, sodium lauryl sulphate and PEG 10000, sodium lauryl sulfate and Brij700, sodium lauryl sulfate and Poloxamer 407, sodium lauryl sulfate and Poloxamer 338, sodium lauryl sulfate and Poloxamer 188; Poloxamer 407, Poloxamer 338, Poloxamer 188, alkyl naphthalene sulfonate condensate/Lignosulfonate blend; Calcium Dodecylbenzene Sulfonate (Branched); Diisopropyl naphthalenesulphonate; erythritol distearate; linear and branched dodecylbenzene sulfonic acids; Naphthalene Sulfonate Formaldehyde Condensate; nonylphenol ethoxylate, POE-30; Phosphate Esters, Tristyrylphenol Ethoxylate, Free Acid; Polyoxyethylene (15) tallowalkylamines; sodium alkyl naphthalene sulfonate; sodium alkyl naphthalene sulfonate condensate; sodium alkylbenzene sulfonate; sodium isopropyl naphthalene sulfonate; Sodium Methyl Naphthalene; Formaldehyde Sulfonate; sodium salt of n-butyl naphthalene sulfonate; tridecyl alcohol ethoxylate, POE-18; Triethanolamine isodecanol phosphate ester; Triethanolamine tristyrylphosphate ester; Tristyrylphenol Ethoxylate Sulfate; Bis(2-hydroxyethyl)tallowalkylamines.

(i) microcrystalline cellulose or microcrystalline cellulose combined with at least one material selected from the group consisting of: lactose monohydrate; xylitol; lactose anhydrous; mannitol; sucrose; glucose; sodium chloride; talc; kaolin; calcium carbonate; malic acid; tartaric acid; trisodium citrate dihydrate; D,L-Malic acid; sodium pentane sulfate; sodium octadecyl sulfate; Brij700; Brij76; sodium n-lauroyl sacrosine; lecithin; docusate sodium; polyoxyl-40-stearate; Aerosil R972 fumed silica; sodium lauryl sulfate or other alkyl sulfate surfactants with a chain length between C5 to C18; polyvinyl pyrrolidone;; sodium lauryl sulfate and polyethylene glycol 40 stearate, sodium lauryl sulfate and polyethylene glycol 100 stearate, sodium lauryl sulfate and PEG 3000, sodium lauryl sulphate and PEG 6000, sodium lauryl sulphate and PEG 8000, sodium lauryl sulphate and PEG 10000, sodium

lauryl sulfate and Brij700, sodium lauryl sulfate and Poloxamer 407, sodium lauryl sulfate and Poloxamer 338, sodium lauryl sulfate and Poloxamer 188; Poloxamer 407, Poloxamer 338, Poloxamer 188, alkyl naphthalene sulfonate condensate/Lignosulfonate blend; Calcium Dodecylbenzene Sulfonate (Branched); Diisopropyl naphthalenesulphonate; erythritol distearate; linear and branched dodecylbenzene sulfonic acids; Naphthalene Sulfonate Formaldehyde Condensate; nonylphenol ethoxylate, POE-30; Phosphate Esters, Tristyrylphenol Ethoxylate, Free Acid; Polyoxyethylene (15) tallowalkylamines; sodium alkyl naphthalene sulfonate; sodium alkyl naphthalene sulfonate condensate; sodium alkylbenzene sulfonate; sodium isopropyl naphthalene sulfonate; Sodium Methyl Naphthalene; Formaldehyde Sulfonate; sodium salt of n-butyl naphthalene sulfonate; tridecyl alcohol ethoxylate, POE-18; Triethanolamine isodecanol phosphate ester; Triethanolamine tristyrylphosphate ester; Tristyrylphenol Ethoxylate Sulfate; Bis(2-hydroxyethyl)tallowalkylamines.

(j) Kaolin combined with at least one material selected from the group consisting of: lactose monohydrate; xylitol; lactose anhydrous; mannitol; microcrystalline cellulose; sucrose; glucose; sodium chloride; talc; kaolin; calcium carbonate; malic acid; tartaric acid; trisodium citrate dihydrate; D,L-Malic acid; sodium pentane sulfate; sodium octadecyl sulfate; Brij700; Brij76; sodium n-lauroyl sacrosine; lecithin; docusate sodium; polyoxyl-40-stearate; Aerosil R972 fumed silica; sodium lauryl sulfate or other alkyl sulfate surfactants with a chain length between C5 to C18; polyvinyl pyrrolidone;; sodium lauryl sulfate and polyethylene glycol 40 stearate, sodium lauryl sulfate and polyethylene glycol 100 stearate, sodium lauryl sulfate and PEG 3000, sodium lauryl sulphate and PEG 6000, sodium lauryl sulphate and PEG 8000, sodium lauryl sulphate and PEG 10000, sodium lauryl sulfate and Brij700, sodium lauryl sulfate and Poloxamer 407, sodium lauryl sulfate and Poloxamer 338, sodium lauryl sulfate and Poloxamer 188; Poloxamer 407, Poloxamer 338, Poloxamer 188, alkyl naphthalene sulfonate condensate/Lignosulfonate blend; Calcium Dodecylbenzene Sulfonate (Branched); Diisopropyl naphthalenesulphonate; erythritol distearate; linear and branched dodecylbenzene sulfonic acids; Naphthalene Sulfonate Formaldehyde Condensate; nonylphenol ethoxylate, POE-30; Phosphate Esters, Tristyrylphenol Ethoxylate, Free Acid; Polyoxyethylene (15) tallowalkylamines; sodium alkyl naphthalene sulfonate; sodium alkyl naphthalene sulfonate condensate; sodium alkylbenzene sulfonate; sodium isopropyl naphthalene sulfonate; Sodium Methyl Naphthalene; Formaldehyde Sulfonate; sodium salt of n-butyl naphthalene sulfonate; tridecyl alcohol ethoxylate, POE-18; Triethanolamine isodecanol phosphate ester; Triethanolamine

tristyrylphosphate ester; Tristyrylphenol Ethoxylate Sulfate; Bis(2-hydroxyethyl)tallowalkylamines.

(k) Talc combined with at least one material selected from the group consisting of: lactose monohydrate; xylitol; lactose anhydrous; mannitol; microcrystalline cellulose; sucrose; glucose; sodium chloride; kaolin; calcium carbonate; malic acid; tartaric acid; trisodium citrate dihydrate; D,L-Malic acid; sodium pentane sulfate; sodium octadecyl sulfate; Brij700; Brij76; sodium n-lauroyl sacrosine; lecithin; docusate sodium; polyoxyl-40-stearate; Aerosil R972 fumed silica; sodium lauryl sulfate or other alkyl sulfate surfactants with a chain length between C5 to C18; polyvinyl pyrrolidone;; sodium lauryl sulfate and polyethylene glycol 40 stearate, sodium lauryl sulfate and polyethylene glycol 100 stearate, sodium lauryl sulfate and PEG 3000, sodium lauryl sulphate and PEG 6000, sodium lauryl sulphate and PEG 8000, sodium lauryl sulphate and PEG 10000, sodium lauryl sulfate and Brij700, sodium lauryl sulfate and Poloxamer 407, sodium lauryl sulfate and Poloxamer 338, sodium lauryl sulfate and Poloxamer 188; Poloxamer 407, Poloxamer 338, Poloxamer 188, alkyl naphthalene sulfonate condensate/Lignosulfonate blend; Calcium Dodecylbenzene Sulfonate (Branched); Diisopropyl naphthalenesulphonate; erythritol distearate; linear and branched dodecylbenzene sulfonic acids; Naphthalene Sulfonate Formaldehyde Condensate; nonylphenol ethoxylate, POE-30; Phosphate Esters, Tristyrylphenol Ethoxylate, Free Acid; Polyoxyethylene (15) tallowalkylamines; sodium alkyl naphthalene sulfonate; sodium alkyl naphthalene sulfonate condensate; sodium alkylbenzene sulfonate; sodium isopropyl naphthalene sulfonate; Sodium Methyl Naphthalene; Formaldehyde Sulfonate; sodium salt of n-butyl naphthalene sulfonate; tridecyl alcohol ethoxylate, POE-18; Triethanolamine isodecanol phosphate ester; Triethanolamine tristyrylphosphate ester; Tristyrylphenol Ethoxylate Sulfate; Bis(2-hydroxyethyl)tallowalkylamines.

23. The method of any preceding claim, wherein a milling aid or combination of milling aids is used and wherein the milling aid is selected from the group consisting of: colloidal silica, a solid or semi solid surfactant, a liquid surfactant, a surfactant that can be manufactured into a solid or semisolid, a polymer, a stearic acid and derivatives thereof.

24. The method of claim 23, wherein the surfactant is selected from the group consisting of: polyoxyethylene alkyl ethers, polyoxyethylene stearates, poloxamers, sarcosine based surfactants, polysorbates, alkyl sulfates and other sulfate surfactants, ethoxylated castor oil, polyvinylpyrrolidones, deoxycholate based surfactants, trimethyl ammonium based surfactants, lecithin and other phospholipids and bile salts.

25. The method of claims 23 or 24, wherein the surfactant is selected from the group consisting of: sodium lauryl sulfate, sodium docusate, sodium deoxycholate, N-lauroylsarcosine sodium salt, benzalkonium chloride, cetylpyridinium chloride, cetylpyridinium bromide, benzethonium chloride, PEG 40 stearate, PEG 100 stearate, poloxamer 188, Brji 72, Brji 700, Brji 78, Brji 76, Cremophor EL, Cremophor RH-40, Dehscofix920, Kollidon 25, Kraftsperse 1251, Lecithin, Poloxamer 407, polyethyleneglycol 3000, polyethyleneglycol, 8000, polyvinylpyrrolidone, sodium dodecylbenzenesulphonic acid, sodium octadecyl sulphate, sodium pentane sulphonate, soluplus HS15, Teric305, Tersperse 2700, Terwet 1221, Terwet 3785, Tween 80 and polysorbate 61.

26. The method of any one of claims 23 to 25, wherein the milling aid has a concentration selected from the group consisting of: 0.1 -10 % w/w, 0.1 -5 % w/w, 0.1 -2.5 % w/w, of 0.1 – 2% w/w, 0.1 -1 %, 0.5 -5% w/w, 0.5 -3% w/w, 0.5 -2% w/w, 0.5 – 1.5%, 0.5 -1 % w/w, of 0.75 – 1.25 % w/w, 0.75 -1% and 1% w/w. .

27. The method of any preceding claim, wherein a facilitating agent is used or combination of facilitating agents is used where the facilitating agent is selected from the group consisting of: surfactants, polymers, binding agents, filling agents, lubricating agents, sweeteners, flavouring agents, preservatives, buffers, wetting agents, disintegrants, effervescent agents, agents that may form part of a medicament, including a solid dosage form.

28. The method of claim 27, wherein the facilitating agent is added during dry milling at a time selected from the group consisting of: with 100% of the total milling time remaining, with 1-5 % of the total milling time remaining, with 1-10 % of the total milling time remaining, with 1-20 % of the total milling time remaining, with 1-30 % of the total milling time remaining, with 2-5% of the total milling time remaining, with 2-10% of the total milling time remaining, with 5-20% of the total milling time remaining and with 5-20% of the total milling time remaining.

29. The method of any one of claims 27 to 28, wherein a facilitating agent is selected from the group consisting of: crosslinked PVP (crospovidone), cross linked carmellose (croscarmellose), sodium starch glycolate, Povidone (PVP), Povidone K12, Povidone K17, Povidone K25, Povidone K29/32 and Povidone K30

30. The method of any preceding claim, wherein the dissolution profile of the measurement sample or prototype formulation thereof is improved by a factor selected from the group

consisting of: wherein X is reached in 10 minutes, wherein X is reached within 10-20 minutes, wherein X is reached within 10-30 mins, wherein X is reached within 10-40 mins, wherein X is reached within 10-50 mins, wherein X is reached within 20-30 mins, wherein X is reached within 20-40 mins, wherein X is reached within 20-50 mins, wherein X is reached within 30-40 mins, wherein X is reached within 30-50 mins and wherein X is reached within 40-50 mins, wherein X is defined as the concentration equal to the dissolution concentration achieved by a control sample or prototype formulation thereof of the biologically active material or compound after 60 minutes.

31. The method of any preceding claim, wherein the dissolution profile of the measurement sample or prototype formulation thereof is improved by a factor selected from the group consisting of: wherein Y is reached in 5 minutes, wherein Y is reached within 10 minutes, wherein Y is reached within 10-15 mins, wherein Y is reached within 10-20 mins, wherein Y is reached within 10-25 mins, wherein Y is reached within 15-20 mins, wherein Y is reached within 15-25 mins, wherein Y is reached within 20-25 mins, wherein Y is defined as the concentration equal to the dissolution concentration achieved by a control sample (or prototype formulation thereof) of the biologically active material or compound after 30 minutes.

32. A composition comprising a biologically active material produced by the method of any one of claims 1-31.

33. A composition of claim 32, wherein the particles have an average particle size equal or greater than 1µm determined on a particle number average basis.

34. A composition of claim 33, wherein the average particle size of the biologically active material has been reduced by a factor selected from the group consisting of: less than 5%, less than 10%, less than 20%, less than 30%, less than 40%, less than 50%, less than 60%, less than 70%, less than 80%, less than 90 %, less than 95% and less than 99%.

35. A composition of any one of the claims 33 to 34, wherein the average particle size falls within the range selected from the group consisting of: 1-1000µm, 1-500µm, 1-300µm, 1-200µm, 1-150µm, 1-100µm, 1-50µm, 1-20µm, 1-10µm, 1-7.5µm, 1-5µm and 1-2µm.

36. A composition of claim 32, wherein the particles have a median particle size selected from the group consisting of: equal or greater than 1µm; and equal or greater than 2µm, wherein the median particle size is determined on a particle volume basis.

37. A composition of claim 36, wherein the percentage of particles greater than 1 μm on a particle volume basis is a percentage selected from the group consisting of: 50%, 60%, 70%, 80%, 90%, 95%, and 100%.

38. A composition of claim 36, wherein the percentage of particles greater than 2 μm on a particle volume basis is a percentage selected from the group consisting of: 50%, 60%, 70%, 80%, 90%, 95% and 100%.

39. A composition of any one of claims 35 to 36, wherein the median particle size has been reduced by a factor selected from the group consisting of: less than 5%, less than 10%, less than 20%, less than 30%, less than 40%, less than 50%, less than 60%, less than 70%, less than 80%, less than 90 %, less than 95% and less than 99%.

40. A composition of any one of claims 35 to 36, wherein the median particle size falls within the range selected from the group consisting of: 1-1000μm, 1-500μm, 1-300μm, 1-200μm, 1-150μm, 1-100μm, 1-50μm, 1-20μm, 1-10μm, 1-7.5μm, 1-5μm 1-2μm, 2-1000μm, 2-500μm, 2-300μm, 2-200μm, 2-150μm, 2-100μm, 2-50μm, 2-20μm, 2-10μm, 2-7.5μm and 2-5μm

41. A composition of any one of claims 32 to 40, wherein the crystallinity profile of the biologically active material is selected from the group consisting of: at least 50% of the biologically active material is crystalline, at least 60% of the biologically active material is crystalline, at least 70% of the biologically active material is crystalline, at least 75% of the biologically active material is crystalline, at least 85% of the biologically active material is crystalline, at least 90% of the biologically active material is crystalline, at least 95% of the biologically active material is crystalline and at least 98% of the biologically active material is crystalline.

42. The composition of any one of claims 32 to 41, wherein the crystallinity profile of the biologically active material is substantially equal to the crystallinity profile of the biologically active material before the material was subject to the method of any one of the preceding claims 1 to 31.

43. A composition of any one of claims 32 to 42, wherein the amorphous content of the biologically active material is selected from the group consisting of: less than 50% of the biologically active material is amorphous, less than 40% of the biologically active

material is amorphous, less than 30% of the biologically active material is amorphous, less than 25% of the biologically active material is amorphous, less than 15% of the biologically active material is amorphous, less than 10% of the biologically active material is amorphous, less than 5% of the biologically active material is amorphous and less than 2% of the biologically active material is amorphous.

44. A composition of any one of claims 32 to 43, wherein the biologically active material has had no significant increase in amorphous content following subjecting the material to the method of any one of the preceding claims.

45. A composition of any one of claims 32 to 44, wherein the biologically active material is selected from the group consisting of: fungicides, pesticides, herbicides, seed treatments, cosmeceuticals, cosmetics, complementary medicines, natural products, vitamins, nutrients, nutraceuticals, pharmaceutical actives, biologics, amino acids, proteins, peptides, nucleotides, nucleic acids additives, foods and food ingredients and analogs, homologs and first order derivatives thereof.

46. A composition of any one of claims 32 to 45, wherein the biologically active material is selected from the group consisting of: indomethacin, diclofenac, naproxen, meloxicam, metaxalone, cyclosporin A, progesterone celecoxib, cilostazol, ciprofloxacin, 2,4-dichlorophenoxyacetic acid, anthraquinone, creatine monohydrate, glyphosate, halusulfuron, mancozeb, metsulfuron, salbutamol, sulphur, tribenuran and estradiol or any salt or derivative thereof.

47. A pharmaceutical composition comprising a biologically active material produced by the method of any one of claims 1-31 together with a pharmaceutically acceptable carrier.

48. A method of treating a human in need of such treatment comprising the step of administering to the human an effective amount of a pharmaceutical composition of claim 47.

49. Use of a pharmaceutical composition of claim 47 in the manufacture of a medicament for the treatment of a human in need of such treatment.

50. A method for manufacturing a pharmaceutical composition of claim 47 comprising the step of combining a therapeutically effective amount of a biologically active material prepared by a method according to any one of the claims 1 to 31 together with a

pharmaceutically acceptable carrier to produce a pharmaceutically acceptable dosage form.

51. A method for manufacturing a veterinary product comprising the step of combining a therapeutically effective amount of the biologically active material prepared by a method of any one of the claims of 1 to 31 together with an acceptable excipient to produce a dosage form acceptable for veterinary use.

52. A method for manufacturing an agricultural product comprising the step of combining an effective amount of the biologically active material prepared by a method of any one of the claims of 1 to 31 together with an acceptable excipient.

CLAIMS:

1. A method for improving the dissolution profile of a biologically active material, comprising the steps of:

   dry milling a solid biologically active material and a millable grinding matrix in a mill comprising a plurality of milling bodies, for a time period sufficient to produce particles of the biologically active material dispersed in an at least partially milled grinding matrix,

   wherein the particles have an average particle size falling within the range of 1 – 200 µm determined on a particle number basis,

   wherein the average particle size of the biologically active material has been reduced by less than 70% during dry milling and the dissolution of the biologically active material is improved such that a dissolution concentration of X is achieved in 10-30 minutes and X is the concentration equal to the dissolution concentration of the biologically active material prior to dry milling after 60 minutes,

   wherein the particle size of the millable grinding matrix is reduced by the dry milling,

   wherein the solid biologically active compound and the millable grinding matrix are milled with a facilitating agent,

   wherein the millable grinding matrix is selected from the group consisting of: lactose anhydrous, lactose monohydrate and mannitol,

   wherein the time period sufficient is a range selected between 5 minutes and 8 hours,

   wherein the milling bodies are balls having a diameter between 1mm and 20 mm, and

   wherein the biologically active material is selected from the group consisting of: anti-obesity drugs, central nervous system stimulants, carotenoids, corticosteroids, elastase inhibitors, anti-fungals, oncology therapies, anti-emetics, analgesics, cardiovascular agents, anti-inflammatory agents, such as NSAIDs and COX-2 inhibitors, anthelmintics, anti-arrhythmic agents, antibiotics, penicillins, anticoagulants, antidepressants, antidiabetic agents, antiepileptics, antihistamines, antihypertensive agents, antimuscarinic agents, antimycobacterial agents, antineoplastic agents, immunosuppressants, antithyroid agents, antiviral agents, anxiolytics, sedatives (hypnotics and neuroleptics), astringents, alpha-adrenergic receptor blocking agents, beta-adrenoceptor blocking agents, blood products and substitutes, cardiac

inotropic agents, contrast media, cough suppressants, expectorants, mucolytics, diagnostic agents, diagnostic imaging agents, diuretics, dopaminergics, anti-parkinsonian agents, haemostatics, immunological agents, lipid regulating agents, muscle relaxants, parasympathomimetics, parathyroid calcitonin and biphosphonates, prostaglandins, radio-pharmaceuticals, sex hormones, steroids, anti-allergic agents, stimulants and anoretics, sympathomimetics, thyroid agents, vasodilators, and xanthines.

2. The method of claim 1, wherein the average particle size of the biologically active material has been reduced by a factor selected from the group consisting of: less than 5%, less than 10%, less than 20%, less than 30%, less than 40%, less than 50%, and less than 60%.

3. The method of any one of the claims 1 or 2, wherein the average particle size falls within the range selected from the group consisting of: 1-150µm, 1-100µm, 1-50µm, 1-20µm, 1-10µm, 1-7.5µm, 1-5µm and 1-2µm.

4. A method for improving the dissolution profile of a biologically active material, comprising the steps of:
dry milling a solid biologically active material and a millable grinding matrix in a mill comprising a plurality of milling bodies, for a time period sufficient to produce particles of the biologically active material dispersed in an at least partially milled grinding matrix,
wherein wherein the particles have a median particle size falling within the range of 1 – 200 µm determined on a particle volume basis,
wherein the average particle size of the biologically active material has been reduced by less than 70% and the dissolution of the biologically active material is improved such that a dissolution concentration of X is achieved in 10-30 minutes and X is the concentration equal to the dissolution concentration of the biologically active material prior to dry milling after 60 minutes,
wherein the particle size of the millable grinding matrix is reduced by the dry milling,
wherein the solid biologically active compound and the millable grinding matrix are milled with a facilitating agent,

wherein the millable grinding matrix is selected from the group consisting of: lactose anhydrous, lactose monohydrate and mannitol,

wherein the time period sufficient is a range selected between 5 minutes and 8 hours,

wherein the milling bodies are balls having a diameter between 1mm and 20 mm, and

wherein the biologically active material is selected from the group consisting of: anti-obesity drugs, central nervous system stimulants, carotenoids, corticosteroids, elastase inhibitors, anti-fungals, oncology therapies, anti-emetics, analgesics, cardiovascular agents, anti-inflammatory agents, such as NSAIDs and COX-2 inhibitors, anthelmintics, anti-arrhythmic agents, antibiotics, penicillins, anticoagulants, antidepressants, antidiabetic agents, antiepileptics, antihistamines, antihypertensive agents, antimuscarinic agents, antimycobacterial agents, antineoplastic agents, immunosuppressants, antithyroid agents, antiviral agents, anxiolytics, sedatives (hypnotics and neuroleptics), astringents, alpha-adrenergic receptor blocking agents, beta-adrenoceptor blocking agents, blood products and substitutes, cardiac inotropic agents, contrast media, cough suppressants, expectorants, mucolytics, diagnostic agents, diagnostic imaging agents, diuretics, dopaminergics, anti-parkinsonian agents, haemostatics, immunological agents, lipid regulating agents, muscle relaxants, parasympathomimetics, parathyroid calcitonin and biphosphonates, prostaglandins, radio-pharmaceuticals, sex hormones, steroids, anti-allergic agents, stimulants and anoretics, sympathomimetics, thyroid agents, vasodilators, and xanthines.

5. The method of claim 4 wherein the percentage of particles greater than 1 µm on a particle volume basis is a percentage selected from the group consisting of: 50%, 60%, 70%, 80%, 90%, 100%.

6. The method of claim 4 wherein the percentage of particles greater than 2 µm on a particle volume basis is a percentage selected from the group consisting of: 50%, 60%, 70%, 80%, 90%, 100%.

7. The method of any preceding claim, wherein the facilitating agent is a surfactant.

8. The method of any preceding claim, wherein the surfactant is sodium lauryl sulphate.

9. The method of any one of claims 1 to 7, wherein X is reached within 10-20 minutes.

10. The method of any one of claims 1 to 8, wherein the dissolution of the biologically active material is improved such that a dissolution concentration of Y is achieved in 10-15 minutes and Y is the concentration equal to the dissolution concentration of the biologically active material prior to dry milling after 30 minutes.

11. A method of any one of claims 2 to 9, wherein the median particle size has been reduced by a factor selected from the group consisting of: less than 5%, less than 10%, less than 20%, less than 30%, less than 40%, less than 50%, less than 60%, less than 70%, less than 80%, less than 90 %, less than 95% and less than 99%.

12. The method of any one of claims 2 to 10, wherein the median particle size falls within the range selected from the group consisting of: 11-150μm, 1-100μm, 1-50μm, 1-20μm, 1-10μm, 1-7.5μm, 1-5μm 1-2μm, 2-1000μm, 2-500μm, 2-300μm, 2-200μm, 2-150μm, 2-100μm, 2-50μm, 2-20μm, 2-10μm, 2-7.5μm and 2-5μm.

13. The method of any preceding claim, wherein the crystallinity profile of the biologically active material is selected from the group consisting of: at least 50% of the biologically active material is crystalline, at least 60% of the biologically active material is crystalline, at least 70% of the biologically active material is crystalline, at least 75% of the biologically active material is crystalline, at least 85% of the biologically active material is crystalline, at least 90% of the biologically active material is crystalline, at least 95% of the biologically active material is crystalline and at least 98% of the biologically active material is crystalline.

14. The method of any preceding claim, wherein the crystallinity profile of the biologically active material is substantially equal to the crystallinity profile of

the biologically active material before the material was subject to the method of any one of the preceding claims.

15. The method of any preceding claim, wherein the amorphous content of the biological active material is selected from the group consisting of: less than 50% of the biologically active material is amorphous, less than 40% of the biologically active material is amorphous, less than 30% of the biologically active material is amorphous, less than 25% of the biologically active material is amorphous, less than 15% of the biologically active material is amorphous, less than 10% of the biologically active material is amorphous, less than 5% of the biologically active material is amorphous and less than 2% of the biologically active material is amorphous.

16. The method of any preceding claim, wherein the biologically active material has no significant increase in amorphous content before subjecting the material to the method of any one of the preceding claims.

17. The method of any preceding claim, wherein the milling time period is a range selected from the group consisting of: between 10 minutes and 2 hours, between 10 minutes and 1 hour, between 10 minutes and 45 minutes, between 10 minutes and 30 minutes, between 5 minutes and 30 minutes, between 5 minutes and 20 minutes, between 2 minutes and 10 minutes, between 2 minutes and 5 minutes, between 1 minute and 20 minutes, between 1 minute and 10 minutes, and between 1 minute and 5 minutes.

18. The method of any preceding claim, wherein the dry milling is undertaken in a mechanically agitated attritor mill (horizontal or vertical), vibratory mill or nutating mill, wherein the milling bodies are steel balls having a diameter selected from the group consisting of: between 2 and 15 mm and between 3 and 10 mm.

19. The method of any preceding claim, wherein the total combined amount of biologically active material and grinding matrix in the mill at any given time is equal to or greater than a mass selected from the group consisting of: 200 grams, 500 grams, 1 kg, 2kg, 5 kg, 10 kg, 20 kg, 30 kg, 50 kg, 75 kg, 100kg, 150 kg, 200 kg.

20. The method of any preceding claim, wherein the biologically active material is selected from the group consisting of: indomethacin, diclofenac, naproxen, meloxicam, metaxalone, cyclosporin A, progesterone, celecoxib, cilostazol, ciprofloxacin, 2,4-dichlorophenoxyacetic acid, anthraquinone, creatine monohydrate, glyphosate, halusulfuron, mancozeb, metsulfuron, salbutamol, sulphur, tribenuran and estradiol or any salt or derivative thereof.

21. The method of any preceding claim, wherein a milling aid or combination of milling aids is used and wherein the milling aid is selected from the group consisting of: colloidal silica, a polymer, a stearic acid and derivatives thereof.

22. The method of any one of claims 21, wherein the milling aid has a concentration selected from the group consisting of: 0.1 -10 % w/w, 0.1 -5 % w/w, 0.1 -2.5 % w/w, of 0.1 – 2% w/w, 0.1 -1 %, 0.5 -5% w/w, 0.5 -3% w/w, 0.5 -2% w/w, 0.5 – 1.5%, 0.5 -1 % w/w, of 0.75 – 1.25 % w/w, 0.75 -1% and 1% w/w.

23. The method of any preceding claim, wherein the facilitating agent is added during dry milling at a time selected from the group consisting of: with 100% of the total milling time remaining, with 1-5 % of the total milling time remaining, with 1-10 % of the total milling time remaining, with 1-20 % of the total milling time remaining, with 1-30 % of the total milling time remaining, with 2-5% of the total milling time remaining, with 2-10% of the total milling time remaining and with 5-20% of the total milling time remaining.

24. The method of any preceding claim, wherein the dissolution profile of a measurement sample or prototype formulation thereof is improved by a factor selected from the group consisting of: wherein X is reached in 10 minutes, wherein X is reached within 10-20 minutes, wherein X is reached within 10-30 mins, wherein X is reached within 10-40 mins, wherein X is reached within 10-50 mins, wherein X is reached within 20-30 mins, wherein X is reached within 20-40 mins, wherein X is reached within 20-50 mins, wherein X is reached within 30-40 mins, wherein X is reached within 30-50 mins and wherein X is reached within 40-50 mins, wherein X is defined as the

concentration equal to the dissolution concentration achieved by a control sample or prototype formulation thereof of the biologically active material or compound after 60 minutes.

25. The method of any preceding claim, wherein the dissolution profile of a measurement sample or prototype formulation thereof is improved by a factor selected from the group consisting of: wherein Y is reached in 5 minutes, wherein Y is reached within 10 minutes, wherein Y is reached within 10-15 mins, wherein Y is reached within 10-20 mins, wherein Y is reached within 10-25 mins, wherein Y is reached within 15-20 mins, wherein Y is reached within 15-25 mins, wherein Y is reached within 20-25 mins, wherein Y is defined as the concentration equal to the dissolution concentration achieved by a control sample (or prototype formulation thereof) of the biologically active material or compound after 30 minutes.

26. A composition comprising a biologically active material produced by the method of any one of claims 1 to 25.

27. A composition produced by the method for improving the dissolution profile of a biologically active material, comprising the steps of:
dry milling a solid biologically active material and a millable grinding matrix in a mill comprising a plurality of milling bodies, for a time period sufficient to produce particles of the biologically active material dispersed in an at least partially milled grinding matrix,
wherein the particles have an average particle size falling within the range of 1 – 200 µm determined on a particle number basis,
wherein the average particle size of the biologically active material has been reduced by less than 70% during dry milling and the dissolution of the biologically active material is improved such that a dissolution concentration of X is achieved in 10-30 minutes and X is the concentration equal to the dissolution concentration of the biologically active material prior to dry milling after 60 minutes,
wherein the particle size of the millable grinding matrix is reduced by the dry milling,
wherein the solid biologically active compound and the millable grinding matrix are milled with a facilitating agent,

wherein the millable grinding matrix is selected from the group consisting of: lactose anhydrous, lactose monohydrate and mannitol,

wherein the time period sufficient is a range selected between 5 minutes and 8 hours,

wherein the milling bodies are balls having a diameter between 1mm and 20 mm, and

wherein the biologically active material is selected from the group consisting of: anti-obesity drugs, central nervous system stimulants, carotenoids, corticosteroids, elastase inhibitors, anti-fungals, oncology therapies, anti-emetics, analgesics, cardiovascular agents, anti-inflammatory agents, such as NSAIDs and COX-2 inhibitors, anthelmintics, anti-arrhythmic agents, antibiotics, penicillins, anticoagulants, antidepressants, antidiabetic agents, antiepileptics, antihistamines, antihypertensive agents, antimuscarinic agents, antimycobacterial agents, antineoplastic agents, immunosuppressants, antithyroid agents, antiviral agents, anxiolytics, sedatives (hypnotics and neuroleptics), astringents, alpha-adrenergic receptor blocking agents, beta-adrenoceptor blocking agents, blood products and substitutes, cardiac inotropic agents, contrast media, cough suppressants, expectorants, mucolytics, diagnostic agents, diagnostic imaging agents, diuretics, dopaminergics, anti-parkinsonian agents, haemostatics, immunological agents, lipid regulating agents, muscle relaxants, parasympathomimetics, parathyroid calcitonin and biphosphonates, prostaglandins, radio-pharmaceuticals, sex hormones, steroids, anti-allergic agents, stimulants and anoretics, sympathomimetics, thyroid agents, vasodilators, and xanthines.

28. A composition of claim 27, wherein the average particle size of the biologically active material has been reduced by a factor selected from the group consisting of: less than 5%, less than 10%, less than 20%, less than 30%, less than 40%, less than 50%, less than 60%, less than 70%, less than 80%, less than 90 %, less than 95% and less than 99%.

29. A composition of any one of the claims 27 or 28, wherein the average particle size falls within the range selected from the group consisting of: 1-150µm, 1-100µm, 1-50µm, 1-20µm, 1-10µm, 1-7.5µm, 1-5µm and 1-2µm.

30. A composition produced by a method for improving the dissolution profile of a biologically active material, comprising the steps of:

dry milling a solid biologically active material and a millable grinding matrix in a mill comprising a plurality of milling bodies, for a time period sufficient to produce particles of the biologically active material dispersed in an at least partially milled grinding matrix,

wherein wherein the particles have a median particle size falling within the range of 1 – 200 µm determined on a particle volume basis,

wherein the average particle size of the biologically active material has been reduced by less than 70% during dry milling and the dissolution of the biologically active material is improved such that a dissolution concentration of X is achieved in 10-30 minutes and X is the concentration equal to the dissolution concentration of the biologically active material prior to dry milling after 60 minutes,

wherein the particle size of the millable grinding matrix is reduced by the dry milling,

wherein the solid biologically active compound and the millable grinding matrix are milled with a facilitating agent,

wherein the millable grinding matrix is selected from the group consisting of: lactose anhydrous, lactose monohydrate and mannitol,

wherein the time period sufficient is a range selected between 5 minutes and 8 hours,

wherein the milling bodies are balls having a diameter between 1mm and 20 mm, and

wherein the biologically active material is selected from the group consisting of: fungicides, pesticides, herbicides, seed treatments, cosmeceuticals, cosmetics, complementary medicines, natural products, vitamins, nutrients, nutraceuticals, pharmaceutical actives, biologics, amino acids, proteins, peptides, nucleotides, nucleic acids, additives, foods and food ingredients and analogs, homologs and first order derivatives thereof.

31. A composition of claim 30, wherein the percentage of particles greater than 1 µm on a particle volume basis is a percentage selected from the group consisting of: 50%, 60%, 70%, 80%, 90%, 95%, and 100%.

32. A composition of claim 30, wherein the percentage of particles greater than 2 μm on a particle volume basis is a percentage selected from the group consisting of: 50%, 60%, 70%, 80%, 90%, 95% and 100%.

33. A composition of any one of claims 30 to 32, wherein the median particle size has been reduced by a factor selected from the group consisting of: less than 5%, less than 10%, less than 20%, less than 30%, less than 40%, less than 50%, less than 60%, less than 70%, less than 80%, less than 90 %, less than 95% and less than 99%.

34. A composition of any one of claims 30 to 33, wherein the median particle size falls within the range selected from the group consisting of: 1-150μm, 1-100μm, 1-50μm, 1-20μm, 1-10μm, 1-7.5μm, 1-5μm 1-2μm, 2-1000μm, 2-500μm, 2-300μm, 2-200μm, 2-150μm, 2-100μm, 2-50μm, 2-20μm, 2-10μm, 2-7.5μm and 2-5μm.

35. A composition of any one of claims 30 to 34, wherein the crystallinity profile of the biologically active material is selected from the group consisting of: at least 50% of the biologically active material is crystalline, at least 60% of the biologically active material is crystalline, at least 70% of the biologically active material is crystalline, at least 75% of the biologically active material is crystalline, at least 85% of the biologically active material is crystalline, at least 90% of the biologically active material is crystalline, at least 95% of the biologically active material is crystalline and at least 98% of the biologically active material is crystalline.

36. The composition of any one of claims 30 to 35, wherein the crystallinity profile of the biologically active material is substantially equal to the crystallinity profile of the biologically active material before the material was subject to the method of any one of the preceding claims 1 to 25.

37. A composition of any one of claims 30 to 36, wherein the amorphous content of the biologically active material is selected from the group consisting of: less than 50% of the biologically active material is amorphous, less than 40% of the biologically active material is amorphous, less than 30% of the biologically active material is amorphous, less than 25% of the biologically active material

is amorphous, less than 15% of the biologically active material is amorphous, less than 10% of the biologically active material is amorphous, less than 5% of the biologically active material is amorphous and less than 2% of the biologically active material is amorphous.

38. A composition of any one of claims 30 to 37, wherein the biologically active material has had no significant increase in amorphous content following subjecting the material to the method of any one of the preceding claims.

39. The composition of any one of claims 30 to 38, wherein the facilitating agent is a surfactant.

40. The composition of any one of claims 30 to 39, wherein the surfactant is sodium lauryl sulphate.

41. A pharmaceutical composition comprising a biologically active material produced by the method of any one of claims 1 to 25 together with a pharmaceutically acceptable carrier.

42. Use of an effective amount of a pharmaceutical composition of claim 41 in the preparation of a medicament for the treatment of a medical disease, condition or disorder.

43. Use of a biologically active material produced by the method of any one of claims 1-25 in the manufacture of a medicament for the treatment of a human in need of such treatment.

44. A method for manufacturing a pharmaceutical composition of claim 41 comprising the step of combining a therapeutically effective amount of a biologically active material prepared by a method according to any one of the claims 1 to 25 together with a pharmaceutically acceptable carrier to produce a pharmaceutically acceptable dosage form.

45. A method for manufacturing a veterinary product comprising the step of combining a therapeutically effective amount of the biologically active material prepared by a method of any one of the claims of 1 to 25 together with an acceptable excipient to produce a dosage form acceptable for veterinary use.

46. A method for manufacturing an agricultural product comprising the step of combining an effective amount of the biologically active material prepared by a method of any one of the claims of 1 to 25 together with an acceptable excipient.