CLAIMS

1) An oral pharmaceutical composition ~~exhibiting delayed transit through the gastrointestinal tract~~ comprising:
(a) one or more active agents;
(b) fenugreek fibers comprising soluble and insoluble dietary fibers in a ratio of insoluble to soluble fibers of 0.2 to 5 and protein content of less than 10% by weight of the fiber and having viscosity greater than 10,000 cps at 2%w/v at 25°C; and
(c) at least one pharmaceutically acceptable excipient;
wherein ~~said fenugreek fiber comprises of soluble and insoluble dietary fibers and has viscosity greater than 10,000 cps at 2%w/v at 25°C and protein content of less than 10% by weight of the fiber~~(i) the composition is in the form of gastroretentive dosage form, (ii) the dosage form swells such that at least two dimensions of the dosage form are greater than 10 mm within one hour in 0.1N HCl, and (iii) the dosage form, after swelling, maintains integrity and remains in the gastric cavity for at least 2 hours.

2) The composition of claim 1 wherein the transit time of said composition through the gastrointestinal tract is delayed from 2 hours to 24 hours.

3) The composition of claim 1 wherein said fenugreek fiber is present in an amount of 5% to ~~t~~ 95% by weight of said composition.

4) The composition of claim 1 wherein said soluble dietary fiber is present in an amount of 5% to 95% by weight of said fenugreek fiber.

5) The composition of claim 1 wherein said insoluble dietary fiber is present in an amount of 5% to 95% by weight of said fenugreek fiber.

~~6) The composition of claim 1 wherein said fenugreek fiber has a ratio of insoluble to soluble dietary fibers of between 0.2 to 5.~~

76) The composition of claim 61 wherein said fenugreek fiber has a ratio of insoluble to soluble dietary fibers of between 0.8 to 3.

87) The composition of claim 61 wherein said fenugreek fiber has a ratio of insoluble to soluble dietary fibers of between 1 to 3.

98) The composition of claim 1 wherein said active agent is a pharmaceutically active agent having an absorption window in the gastrointestinal tract, having non-uniform absorption characteristics throughout the gastrointestinal tract, having low solubility at high pH values, having local action in the gastrointestinal tract, having instability in lower gastrointestinal tract or requiring longer duration in intestine.

109) The composition of claim 98 wherein said active agent is levodopa, methyldopa, carvedilol, hydrochlorothiazide, captopril, orlistat, valsartan, candesartan, eprosartan, irbesartan, losartan, olmesartan, telmisartan, valsartan, pratosartan, acyclovir, metformin, AZT, didanosine, gabapentin, levodopa, oc-methyldopa, baclofen, valacyclovir, nitrofurantoin, ciprofloxacin, amoxicillin, pentoxifylline, prazosin, acyclovir, nifedipine, diltiazem, naproxen, flurbiprofen, ketoprofen, fenoprofen, fentiazac, oestradiol valerate, sulpiride, captopril, cimetidine, zidovudine, nicardipine, terfenadine, salbutamol, carbamazepine, ranitidine, enalapril, simvastatin, fluoxetine, famotidine, ganciclovir, famiciclovir, pentazocine,, saquinavir, ritonavir, nelfinavir, thiamphenicol, clarithromycin, azithromycin, ceftazidime, cyclosporine, digoxin, paclitaxel, iron salts, cephalexin, lithium carbonate or citrate, calcium carbonate or citrate, riboflavin, ascorbic acid, folic acid, vitamin E pravastatin, captopril, benazepril, enalapril, cilazapril, fosinopril, ramipril, albuterol, pirbuterol, furosemide, allopurinol, atenolol, ranitidine, cimetidine, famotidine, nizatidine, omeprazole, ampicillin, amoxicillin, benzylpenicillin, phenoxymethylpenicillin, bacampicillin, pivampicillin, carbenicillin, cloxacillin, cyclacillin, dicloxacillin, methicillin, oxacillin, piperacillin, ticarcillin,flucloxacillin, cefuroxime, cefetamet, cefetrame, cefixime, cefoxitin, ceftazidime, ceftizoxime, latamoxef, cefoperazone, ceftriaxone, cefsulodin, cefotaxime, cephalexin, cefaclor, cefadroxil. cefalothin, cefazolin, cefpodoxime, ceftibuten, aztreonam, tigemonam, erythromycin, dirithromycin, roxithromycin,

azithromycin, clarithromycin, clindamycin, paldimycin, lincomycin, vancomycin, spectinomycin, tobramycin, paromomycin, metronidazole, tinidazole, itraconazole, ornidazole, amifloxacin, cinoxacin, ciprofloxacin, difloxacin, enoxacin, fleroxacin, norfloxacin, ofloxacin, temafloxacin, doxycycline, minocycline, tetracycline, chlortetracycline, oxytetracycline, methacycline, rolitetracyclin, nitrofurantoin, nalidixic acid, gentamicin, rifampicin, amikacin, netilmicin, imipenem, cilastatin, chloramphenicol, furazolidone, nifuroxazide, sulfadiazin, sulfametoxazol, bismuth subsalicylate, colloidal bismuth subcitrate, gramicidin, mecillinam, cloxiquine, chlorhexidine, dichlorobenzylalcohol, methyl-2-pentylphenol, or metoprolol.

~~11~~10) The composition of claim 1 wherein said excipient is a polymer, effervescent couple, superdisintegrant, diluent, release retardant, lubricant, granulating aid, colorant, flavorant, surfactant, pH adjuster, solubilizer, preservative, stabilizer, anti-adherent or gildant.

~~12~~11) The composition of claim ~~11~~10 wherein said polymer is a hydrophilic polymer selected from the group consisting of polyalkylene oxide; cellulosic polymer; acrylic acid and methacrylic acid polymer, and ester thereof, maleic anhydride polymer; polymaleic acid; poly(acrylamide); poly(olefinic alcohol); poly(N-vinyl lactam); polyol; polyoxyethylated saccharide; polyoxazoline; polyvinylamine; polyvinylacetate; polyimine; starch and starch-based polymer; polyurethane hydrogel; chitosan; polysaccharide gum; zein; shellac-based polymer; polyethylene oxide, hydroxypropyl cellulose, hydroxypropyl methyl cellulose, hydroxyethyl cellulose, sodium carboxy methylcellulose, calcium carboxymethyl cellulose, methyl cellulose, polyacrylic acid, maltodextrin, pre-gelatinized starch or polyvinyl alcohol, or a combination thereof.

~~13) The composition of claim 1 wherein said composition is in the form of a gastroretentive dosage form.~~

~~14~~12) The composition of claim ~~13~~1 wherein said gastroretentive dosage form is a monolithic tablet, a bilayer tablet, a multilayer tablet or an inlay tablet.

~~15) The composition of claim 13 wherein at least two dimensions of said gastroretentive dosage form are greater than 10 mm after swelling within one hour in media simulating a typical gastric environment.~~

~~16) The composition of claim 13 wherein said gastroretentive dosage form is retained in the stomach for at least 2 hours.~~

~~17~~13) The composition of claim ~~13~~1 wherein said gastroretentive dosage form is retained in the stomach for 2 to 12 hours.

~~18~~14) The composition of claim 1 wherein said composition exhibits controlled release of said active agent over a period of up to 24 hours.

~~19~~15) Use of fenugreek fiber according to claim 1 for the preparation of a medicament that exhibits delayed transit through the gastrointestinal tract.

~~20~~16) Use of fenugreek fiber according to claim 1 for the preparation of a medicament for gastroretention of said one or more active agents.

~~21~~17) A process for preparing ~~a~~ oral pharmaceutical composition ~~in the form of a monolithic gastroretentive dosage form exhibiting delayed transit through the gastrointestinal tract~~ comprising the steps of:

(a) blending (i) an active agent, (ii) fenugreek fibers comprising soluble and insoluble dietary fibers in a ratio of insoluble to soluble fibers of 0.2 to 5 and protein content of less than 10% by weight of the fiber and having viscosity greater than 10,000 cps at 2%w/v at 25°C and (iii) at least one pharmaceutically acceptable excipient to form a blend; and

(b) compressing said blend to form matrix tablets;

wherein ~~said fenugreek fiber comprises of soluble and insoluble dietary fibers and has viscosity greater than 10,000 cps at 2%w/v at 25°C and protein content of less than 10% by weight of the fiber~~(i) the composition is in the form of gastroretentive dosage form, (ii) the dosage form swells such that at least two dimensions of the dosage form are greater than 10 mm within one hour in 0.1N

HCl, and (iii) the dosage form, after swelling, maintains integrity and remains in the gastric cavity for at least 2 hours.

~~22~~18) A process for preparing ~~a~~ oral pharmaceutical composition ~~in the form of a bilayered gastroretentive dosage form exhibiting delayed transit through gastrointestinal tract~~ comprising the steps of:

(a) blending an active agent, at least one release retardant and a lubricant to form a drug layer;

(b) blending (i) fenugreek fibers comprising soluble and insoluble dietary fibers in a ratio of insoluble to soluble fibers of 0.2 to 5 and protein content of less than 10% by weight of the fiber and having viscosity greater than 10,000 cps at 2%w/v at 25°C, (ii) at least one lubricant and (iii) at least one pharmaceutically acceptable excipient to form a gastrorententive layer; and

(c) compressing said drug layer and said gastroretentive layer into a bilayer tablet;

wherein ~~said fenugreek fiber comprises of soluble and insoluble dietary fibers and has viscosity greater than 10,000 cps at 2%w/v at 25°C and protein content of less than 10% by weight of the fiber~~(i) the composition is in the form of gastroretentive dosage form, (ii) the dosage form swells such that at least two dimensions of the dosage form are greater than 10 mm within one hour in 0.1N HCl, and (iii) the dosage form, after swelling, maintains integrity and remains in the gastric cavity for at least 2 hours.