CLAIMS

1. A polymer-based ocular insert for drug delivery by noninvasive insertion into the upper or lower fornix conjunctiva of the eye characterized in that the ocular insert has a spherical shape, comprises at least one polymeric layer with a drug core and allows the sustained release of at least one drug up to 300 days of release time, and wherein
the drug core comprises a first drug and is configured to release such first drug at a first rate and the at least one polymeric layer comprises a second drug and is configured to release such second drug at a second rate, wherein the drug core and the at least one polymeric layer are configured to completely release the first and second drugs such that the first and second release rates are different, and wherein the first and second release rates are linear or Fickian.

2. The ocular insert according to claim 1 characterized in that the polymeric layer comprises a polyester, such as polycaprolactone, poly(lactic acid), poly (glycolic acid) or their copolymers, and a polyol, such as polyethylene glycol, castor oil or poly (vinyl alcohol), the polyol content in the final mixture varying from 0% to 50%.

3. The ocular insert according to claim 2 characterized in that the polymeric layer comprises polycaprolactone (PCL) and polyethylene glycol (PEG) or copolymers of polycaprolactone (PCL) and polyethylene glycol (PEG), the molecular weight of PCL varying from 500 up to 30, 000 and the molecular weight of PEG varying from 200 up to 40,000.

4. The ocular insert according to claim 3 characterized in that the polymeric layer preferably comprises a copolymer of PCL-PEG in which the content of PEG varies from 10% to 30%.

5. The ocular insert according to claims 1 to 4 characterized in that the polymeric layer further contains crosslinkers , such as acrylates or cyanates , and plasticizers , such as adipates, phthalates, polymers or solvents .

6. The ocular insert according to any of the claims 1 to 5 characterized in that the ocular insert further comprises:

at least one layer of a polymer-based matrix where at least one drug is dispersed;

a central core of at least one drug surrounded by a polymeric layer; or

combinations of layers thereof.

7. The ocular insert according to claim 1 characterized in that it has a diameter from 2 mm to 8 mm.

8.The ocular insert according to claim 7 characterized in that it is a sphere of 8.0 mm diameter.

9. The ocular insert according to any of the claims 1 to 8 characterized in that the drug release mechanism is diffusion, osmosis, bioerosion or any combination thereof.

10. The ocular insert according to any of the claims 1 to 9 characterized in that the at least one drug is chosen from antibiotics, such as tetracycline, chlortetracycline, bacitracin, neomycin, polymyxin, gramicidin, cephalexin, oxytetracycline , chloramphenicol kanamycin, rifampicin, gentamycin, erythromycin, penicillin and fluoroquinolones; antibacterials such as sulfonamides, sulfadiazine, sulfacetamide, sulfamethiazole and sulfisoxazole, nitrofurazone and sodium propionate; antivirals including idoxuridine, trifluorothymidine, acyclovir, ganciclovir and interferon; anti-allergenics such as sodium cromoglycate , antazoline, methapyriline , chlorpheniramine, cetirizine and prophenpyridadine ; anti-inflammatories such as hydrocortisone, hydrocortisone acetate, dexamethasone, dexamethasone 21-phosphate, fluocinolone, medrysone, prednisolone acetate, fluoromethalone , betamethasone, triamcinolone, flurbiprofen and other non-steroidal anti-inflammatory drugs; decongestants such as phenylephrine, naphazoline and tetrahydrozoline : miotics and anticholinesterase such as pilocarpine, acetylcholine chloride, physostigmine , eserine, carbachol, di-isopropyl fluorophosphate, phospholine iodine, and demecarium bromide; mydriatics such as atropine sulfate, cyclopentolate, homatropine, scopolamine, tropicamide, eucatropine, and hydroxyamphetamine ; sympathomimetics such as epinephrine; immunological drugs such as vaccines and immune stimulants; hormonal agents such as estrogens,

estradiol, progestational, progesterone, insulin, calcitonin, parathyroid hormone and peptide, vasopressin, hypothalamus releasing factor; beta adrenergic blockers such as timolol maleate, levobunolol HC1 and betaxolol HC1; growth factors such as epidermal growth factor and fibronectin; carbonic anhydrase inhibitors such as dichlorphenamide, acetazolamide and methazolamide and other drugs such as prostaglandins, antiprostaglandins , and prostaglandin precursors or analogues and mixtures thereof.

11. Process of manufacturing the ocular insert according to any of the claims 1 to 10 characterized by customizing the desired releasing rate by defining the drug concentrations, the polymeric layer, the thickness of each layer and the thickness of the entire device.

12. Process according to claim 11 characterized by further comprising the steps of

I) obtaining a central core of at least one drug surrounded by a polymeric layer:

a - compressing the drug either alone or with a small amount of polymer or aggregator to form a mini tablet;

b - generating each layer by covering the previous (inner) layer of the insert with a mixture of melted polymer and drug; this mixture is adjusted according to the required release profile; the layer thickness is defined by the amount of the mixture and the radius of the insert already formed;

c - mixing the drug or drugs with the melted polymer by stirring, and controlling the cooling and the stirring of the mixture until a homogenous solid or gel-like compound is obtained;

or

II) obtaining a monolithic polymer-based matrix where the at least one drug is dispersed by molding or hot-melt extrusion.