CLAIMS

1. A process for preparing a drug delivery composition comprising at least a drug, comprising the steps of

a) preparing a masterbatch comprising a drug and a first polymer by

(i) heating the first polymer, wherein said first polymer has a melting temperature below 140°C; and

(ii) introducing the drug during heating of the first polymer, with a drug content between 0.1% and 90%, based on the total weight of the masterbatch; and

b) introducing the masterbatch in a polymer-based matrix during production of the drug delivery composition,

wherein step a) is performed at a temperature at which the first polymer is in a partially or totally molten state, preferably below 140°C, preferably by extrusion and step b) is performed at a temperature at which both the first polymer and the polymer of the polymer-based matrix are in a partially or totally molten state, and wherein the drug has a molecular mass above 10 kDa, preferably above 14 kDa, more preferably above 15 kDa.

2. The process of claim 1, wherein the drug is deprived of any polymer-degrading activity.

3. The process of anyone of the previous claims, wherein the drug is selected from proteins, particularly enzymes, antibodies and hormones.

4. The process of anyone of the previous claims, wherein the drug represents between 0.1% and 80%, based on the total weight of the masterbatch, preferably between 0.1% and 70%, more preferably between 0.1% and 60%.

5. The process of anyone of the previous claims, wherein the masterbatch comprises, based on the total weight of the masterbatch, 50% +/-10% by weight of a first polymer and 50% +/-10% by weight of drug.

6. The process of anyone of the previous claims, wherein the drug represents between 0.01 and 49% by weight of the drug delivery composition, based on the total weight of the drug delivery composition.

7. The process of anyone of the previous claims, wherein the first polymer is a polyester and/or polyether, preferably a polyester preferably selected from polycaprolactone (PCL), poly butylene succinate adipate (PBSA), polybutylene adipate terephthalate (PBAT), polyhdroxyalkanoate (PHA), polylactic acid (PLA), polyglycolic acid (PGA) or copolymers.

8. The process of anyone of the previous claims, wherein step b) is performed at a temperature T between 50°C and 200°C.

9. The process of anyone of the previous claims, wherein step b) is performed by extrusion, internal mixing, co-kneading, extrusion-compounding, extrusion blow-molding, cast film extrusion, calendaring, thermoforming, injection-molding, compression molding, extrusion-swelling, rotary molding, ironing, coating, stratification, expansion, pultrusion, compression-granulation and 3D printing.

10. The process of anyone of claims 1-9, wherein the masterbatch is introduced in the polymer-based matrix at a temperature T between the glass transition temperature (Tg) and the melting temperature of at least one polymer of the polymer-based matrix.

11. The process of anyone of claims 1-9, wherein the masterbatch is introduced in the polymer-based matrix at a temperature T which is above the glass transition temperature (Tg) of at least one polymer of the polymer-based matrix, preferably at or above the melting temperature of said polymer.

12. The process of anyone of the previous claims, wherein the polymer-based matrix comprises a polyester, preferably selected from PLA, PCL, polybutylene adipate terephthalate (PBAT), polyhydroxyalkanoate (PHA), polyglycolic acid (PGA), polybutylene succinate (PBS), poly(ethylene adipate) (PEA), and copolymers or blends/mixtures thereof.

13. The process of anyone of the previous claims, wherein the polymer-based matrix contains PLA, preferably PLLA and/or PDLA, preferably as the only polymer.

14. The process of anyone of the previous claims, wherein the polymer-based matrix contains copolymer PLGA, preferably as the only polymer.

15. The process of anyone of the previous claims, wherein the masterbatch comprises PCL and the polymer-based matrix comprises at least a polymer selected from PLA, PLGA and PGA.

16. The process of anyone of the previous claims, wherein the masterbatch comprises PLGA and the polymer-based matrix comprises at least a polymer selected from PLA, PLGA and PGA.

17. The process of anyone of the previous claims, wherein the drug delivery composition further contains a polymer-degrading enzyme suitable for degrading at least one polymer of the polymer-based matrix, preferably selected from proteases, esterase, cutinases, or lipases.

18. The process of claim 17, wherein the polymer-degrading enzyme is introduced in the masterbatch during step a) and/or wherein the polymer-degrading enzyme is introduced in the polymer-based matrix during step b), simultaneously or sequentially with the masterbatch.

19. The process of anyone of the previous claims, wherein the drug delivery composition is a pharmaceutical composition, preferably selected from tablet, gel, coating, particles and microbeads.

20. The process of anyone of claims 1 to 18, wherein the drug delivery composition is shaped to form a drug delivery device, preferably a medical device, more preferably selected from implant, film, stent, leaflet, valve, coil, scaffold, dressing, rod, patch, fibers, suture fibers, screw, bone plate or implant, bone cement, and prostheses.

21. A drug-delivery device obtainable by the process of anyone of claims 1 to 20.