Formulation and characterisation of 3D-printed tablets of Metformin hydrochloride.

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Background: Metformin hydrochloride is an antidiabetic agent used in the management of type 2 diabetes to control the amount of sugar in the blood. It is a hydrophilic drug that has a biological half-life of 1.5-4.5 hours. The aim of the work was to prepare 3D printed metformin tablets using locally fabricated filaments made from the thermoplastic polymer, Eudragit RSPO. Eudragit is a brand name used to refer to a wide range of copolymers that are based on polymethacrylates. It appears as a white powder and has a faint amine-like odour. It is reported to be insoluble with low permeability, have a molecular weight of 32000g/mol and a glass transition temperature of 64ºC. Eudragit RSPO with the aid of hot melt extrusion has been used to prepare formulations such as solid dispersions, transdermal films, pellets, extrudates, tubes and compressed tablets. 3D printed formulations that have incorporated Eudragit RSPO as the polymer matrix include floating tablets, patches, capsule, expandable gastroretentive device and 3D tablets.

Methods: To prepare drug loaded filaments, 0.25g of Metformin Hcl was mixed with 9.75g of Eudragit RSPO and 0.76ml of Triethyl citrate using a mortar and pestle. The mixture was placed in a hot melt extruder and cylindrical filaments were extruded at 120ºC. Filaments of approximately 1.7mm were selected and printed at 180ºC using a 3D printer The generated tablets were then characterised in terms of morphology, thermal stability, weight uniformity, friability, hardness, disintegration, drug loading and dissolution.

Results: The prepared tablets had an average height, diameter and weight of 5.01mm (±0.18), 13.58mm (± 0.19) and 0.734g(±0.01) respectively. The friability test resulted in a 0.8% weight loss and the hardness test showed an average crushing strength of 458N± 40. An 88% drug loading was generated and based on the dissolution test; a 100% drug release was achieved after 10 hours. Thermal analysis of metformin powder showed that it had a melting temperature of 240ºC and began degradation at 270ºC. Thermogravimetric analysis of the tablets presented no sign of degradation at temperatures below 200ºC. Scanning electron microscopy showed that there were some deposits on the surface of the tablets. The tablets did not disintegrate after 90 minutes of the disintegration test run.

Conclusions: Drug loaded tablets were formulated using the fused deposition modeling method of 3D printing. Characterisation of tablets showed that they met the standard of the British Pharmacopeia in terms of uniformity of weight and dimensions as well as friability. Although tablet disintegration did not occur, Eudragit RSPO extended drug release for up 10 hours and achieved a complete drug release.