Conflict of interest No conflict of interest

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NP-015 QUALITY ASSESSMENT OF 3D PRINTED SILDENAFIL AND Furosemide Tablets for the Paediatric Population Using an Innovative Extrusion-Based Technique

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Background and importance Commercially available tablets often don’t meet patients’ needs, as is the case for children. Three-dimensional (3D) printing can possibly achieve this. However, most investigated 3D printing techniques for production of pharmaceutical preparations may not be suitable for chemically unstable drugs. In addition, quality requirements are not well established.

Aim and objectives A proof-of-principle study was conducted using a low heat, solvent-free extrusion-based 3D printing technique. Furosemide and sildenaﬁl immediate release tablets containing paediatric appropriate dosages were the model products. The quality requirements as stated by the European Pharmacopoeia (EP) were evaluated.

Materials and methods Formulations containing furosemide, 2 mg or 10 mg per tablet, or sildenaﬁl, 4 mg per tablet, were slightly heated to a semi-solid to allow printing. The tablets were analysed for weight distribution (EP 2.9.5.), content uniformity (EP 2.9.40.) and dissolution profile (EP 2.9.3.), using an analytical balance, high-performance liquid chromatography ultraviolet and UV/VIS spectrophotometry, respectively. Content uniformity and dissolution analyses were performed in triplicate. Linear regression analysis was performed to assess tablet mass and content.

Results The weight distribution met the requirements of EP 2.9.5 with a relative standard deviation of 1.26%. The acceptance values of the content uniformity of furosemide 2 mg, 10 mg and sildenaﬁl 4 mg ranged between 4.2–10.6, 4.8–8.9 and 6.6–9.2, respectively, where a maximum value of 15 was accepted. A linear correlation between tablet mass and content was found. Furosemide 10 mg and sildenaﬁl 4 mg showed a dissolved content of >80% after 45 minutes, indicating an immediate release proﬁle. For furosemide 2 mg batches, the second testing level had to be used. This preparation also met the requirement of an immediate release proﬁle. Additionally, the tablets should also have sufﬁcient microbiological stability (EP 5.4.1) and mechanical strength (EP 2.9.7 and 2.9.8), though an adjusted test for mechanical strength is necessary for applicability to 3D printed tablets.

Conclusion and relevance This proof-of-principle study shows lower temperature 3D printing can be useful in enabling production of personalised tablets. Further investigation of suitable quality tests for 3D printed tablets will be performed in further studies.