

Design of Orodispersible Mini Tablets of Sodium Levothyroxine (Lt4 odmts) †

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Abstract: Hypothyroidism is one of the most common endocrine diseases; in which the thyroid gland does not produce enough thyroid hormones. Hypothyroidism is treated with levothyroxine sodium (LT4), and the tablet is the most widely used LT4 formulation for treatment. However, an age-appropriate pediatric formulation of LT4 is not yet commercially available. The aim of this work was to design Levothyroxine orodispersible mini tablets (ODMT) for pediatric patients. Two pharmaceutical formulations were designed with three different dosages of LT4 (5,10, and 15 µg). The effect of two excipients (StarLac[®] and Croscarmellose sodium) and the LT4 were evaluated. Rheological studies of powder mixtures were carried out (Hausner index and Carr index), and process controls were evaluated (organoleptic characteristics, weight uniformity, hardness, friability) and finished product according to official specifications (disintegration, dissolution, wetting time, and content uniformity). The addition of a super disintegrant such as Croscarmellose sodium gives the best results of hardness, flowability, and fast disintegration. These OMDTs, with 5 to 15 µg of LT4, showed the best results for parameters of hardness from 3.133 to 3.233 kp, friability 0,2008 to 0,2017 %, disintegration time 10 seconds, weight variation and content uniformity were acceptable. The results obtained were within the acceptance range, so these LT4 OMDTs can be an alternative for the development of a safe and effective pediatric.

Keywords: Levothyroxine; orodispersible mini tablets; Starlac; Croscarmellose sodium; pediatric patients.

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Conflicts of Interest

The authors declare no conflict of interest. The funders had no role in the design of the study; in the collection, analysis, or interpretation of data; in the writing of the manuscript; or in the decision to publish the results.