



Formulation and *In Vitro* Evaluation of Taste-Masked Fast Disintegrating Tablets of Prednisolone

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SUMMARY. Prednisolone is a widely used glucocorticoid in most inflammatory situations such as respiratory, rheumatoid and cancer disorders. The bitter taste of this drug is the major problem limiting its use especially in children. The present study deals with the formulation and evaluation of taste masked oral disintegrating tablets (ODTs) of prednisolone, which are rapidly disintegrated in mouth upon contact with saliva. Two different methods of taste masking, wet granulation and encapsulation, were employed and their taste masking efficiency were compared. Eudragit E, a pH sensitive polymer, was used as taste masking agent and tablets were formulated using different combinations of superdisintegrants with other excipients. Results of tasting tablets by healthy volunteers indicated almost similar taste masking efficiency for both methods. The optimized formulations with proper amounts of crospovidone (11% w/w), Ac-Di-Sol (11% w/w) and Avicel (13% w/w) as disintegrants showed a rapid disintegration time (< 45 sec), proper hardness (~3.5) and friability less than 1%. It seems that Eudragit E could be an efficient polymer for masking the bitter taste of prednisolone and fast disintegrating tablets can be suggested as a promising choice for use in patients who have problems with swallowing bitter taste drugs.

RESUMEN. La prednisolona es un glucocorticoide ampliamente utilizado en la mayoría de las situaciones inflamatorias tales como trastornos respiratorios, reumatoides y de cáncer. El sabor amargo de esta droga es el problema principal que limita su uso especialmente en niños. El presente estudio se ocupa de la formulación y evaluación de tabletas desintegrantes orales (ODTs) de prednisolona enmascaradas con sabor, que se desintegran rápidamente en la boca al contacto con la saliva. Se emplearon dos métodos diferentes de enmascaramiento del sabor, granulación en húmedo y encapsulación, y se comparó su eficacia de enmascaramiento del sabor. Se usó Eudragit E, un polímero sensible al pH, como agente de enmascaramiento del sabor y se formularon comprimidos usando diferentes combinaciones de superdesintegrantes con otros excipientes. Los resultados de las tabletas con sabor por voluntarios sanos indicaron una eficiencia de enmascaramiento del sabor casi similar para ambos métodos. Las formulaciones optimizadas con cantidades adecuadas de crospovidona (11% p/p), Ac-Di-Sol (11% p/p) y Avicel (13% p/p) como desintegrantes mostraron un tiempo de desintegración rápido (< 45 s), dureza adecuada (~ 3.5) y friabilidad inferior al 1%. Eudragit E podría ser un polímero eficiente para enmascarar el sabor amargo de la prednisolona y los comprimidos de desintegración rápida puede sugerirse como una opción prometedora para su uso en pacientes que tienen problemas con la ingestión de drogas de sabor amargo.

KEY WORDS: Eudragit E, microencapsulation, oral disintegrating tablets (ODTs), prednisolone, wet granulation.

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