Development and Optimization of Taste-Masked Orally Disintegrating Tablets (ODTs) of Clindamycin Hydrochloride
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Purpose
The purpose of this research was to develop an Orally Disintegrating Tablet (ODT) dosage form containing taste-masked beads of clindamycin HCl.

Methods
Several formulation strategies were evaluated and a taste-masked ODT of clindamycin was prepared without the use of a waxy cushioning agent. Clindamycin HCl (ca. 46% w/w) was coated onto microcrystalline cellulose beads (Cellets® 200) followed by an application of a taste-masking layer of an Amino Methacrylate Copolymer, NF [Eudragit EPO® (EPO)] coating suspension. The efficiency of both the drug coating and the taste-masking EPO polymer coating processes as well as the taste-masked ODTs was determined using potency and drug release analysis.

Results
Magnesium stearate was found to be advantageous over talc in improving the efficiency of the EPO coating suspension. A response surface methodology using a Box-Behnken design for the tablets revealed compression force and levels of both disintegrant and talc to be the main factors influencing the ODT properties, with the addition of talc to the EPO coated beads before tableting being the most critical in ensuring ODTs disintegrate within 30 seconds. The optimized ODT formulation also showed negligible (<0.5%) drug release in phosphate buffer (pH 6.8) after 1 min. of shaking, which is analogous to the residence time in the oral cavity.

Conclusion
By carefully adjusting the levels of the coating polymers, the amounts of disintegrant and talc, as well as the compression force, robust ODTs can be obtained to improve pediatric and geriatric patient compliance for clindamycin oral dosage forms.