

Formulation Characterization Of Parathyroid Hormone PTH(1-34) Coated On A Novel Transdermal Microprojection Delivery System- Water Determination

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This study assessed the feasibility of determining the water content of the PTH (1-34) formulation coated on a novel transdermal microprojection delivery system, ZP-PTH. Thermogravimetric analysis (TGA) and Karl Fischer (KF) titration were used for water analysis. Headspace moisture was determined by internal vapor analysis and a hand-held moisture sensor. The moisture sorption isotherm was established by moisture sorption analyzer. PTH(1-34) API and formulation showed several weight-loss phases in TGA thermograms. Water loss is not a single-phase event, occurring over a wide temperature range. The typical water amount in a single ZP-PTH coated array is below the sensitivity of TGA and KF titration. Combining 20 coated array samples together in a single extract made KF analysis is possible but impractical due to strenuous sample preparation requirements and controls. The moisture sorption isotherm allowed accurate prediction of water content when the headspace moisture level is known. We demonstrated that TGA and KF titration are not practically possible for determining the water content in ZP-PTH. Simple alternative approaches can ensure that the desired water content in the ZP-PTH coating is achieved without direct water measurement. This study provides scientific rationales to justify the application of unconventional approaches.