

## Formulation Development of Betahistine Dihydrochloride by using Co-processed QuickTab™ : A Strategy to Shelf Stable Tablets of Hygroscopic Drug

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**SUMMARY.** The objective of this investigation was to developed a stable betahistine dihydrochloride tablets by direct compression method. Six formulations were designed by using excipients HPMC 15, Aerosil 200, Lactose DC, Povidon K30, Avicel pH 102, Magnesium stearate and Quick Tab™ (Tricalcium phosphate, Microcrystalline cellulose, Povidon and Cross povidone). Pre and post formulation testing were evaluated before and after stability studies. Similarity factor of dissolution profiles of test formulations were calculated by comparing with innovator brand. Among six formulations, formulation F was optimized and stable. The physico-chemical parameters of formulation A to E after stability studies were changed due to moisture uptake with increased mean weight and hardness, although formulation F remains unchanged. The dissolution profile comparisons of formulation A to E were failed i.e., less than 50, except formulation F. The study concluded that Quick Tab™ is better aid for stable betahistine dihydrochloride tablets by direct compression method.

**RESUMEN.** El objetivo de esta investigación fue desarrollar una tableta estable de diclorhidrato de betahistina por método de compresión directa. Se diseñaron seis formulaciones utilizando excipientes HPMC 15, Aerosil 200, Lactosa DC, Povidon K30, Avicel pH 102, estearato de magnesio y Quick Tab™ (fosfato tricálcico, celulosa microcristalina, povidona y povidona cruzada). Las pruebas previas y posteriores a la formulación se evaluaron antes y después de los estudios de estabilidad. Los perfiles de factor de similitud de disolución de las formulaciones de prueba se calcularon comparándolos con la marca innovadora. Entre seis formulaciones, la formulación F fue optimizada y estable. Los parámetros fisicoquímicos de las formulaciones A a E después de los estudios de estabilidad cambiaron debido a la absorción de humedad con un aumento del peso medio y la dureza, aunque la formulación F permanece sin cambios. Las comparaciones del perfil de disolución de la formulación A a E fallaron, es decir, menos de 50, excepto la formulación F. El estudio concluyó que Quick Tab™ es una mejor ayuda para las tabletas estables de diclorhidrato de betahistina por el método de compresión directa.

**KEY WORDS:** betahistine dihydrochloride, direct compression, Quick Tab™, shelf stable, hygroscopicity

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