



## Development and Validation of Novel Stability-Indicating LC Method to Determine Sitagliptin and Metformin in Presence of Degraded Products

Sachin B. GURAV\* & Neela M. BHATIA

Bharati Vidyapeeth College of Pharmacy,  
Kolhapur, MS, India.

**SUMMARY.** A novel, precise, selective and sensitive stability indicating RP-HPLC method has been developed and validated for sitagliptin phosphate monohydrate (SIT) and metformin HCl (MET) in presence of two degradation products of SIT. Degradation products formed by alkaline degradation and has been separated and characterized as triazole and acid impurity of SIT. The separation was carried out on a Waters Spherisorb SCX column (250 × 4.6 mm, 10 μm) using a mobile phase of ammonium dihydrogen phosphate buffer pH 3.00: acetonitrile (55:45 % v/v). Quantitation was achieved using UV detection at 210 nm. Peak purity of MET and SIT established in presence of all major degradation product in stressed samples. The proposed method of analysis has been validated as per ICH guidelines and proved to be specific, precise, linear, rugged and robust. The effectiveness of the method was demonstrated with marketed pharmaceutical preparation of SIT and MET.

**RESUMEN.** Se ha desarrollado y validado un método de RP-HPLC novedoso, preciso, selectivo y sensible para sitagliptina fosfato monohidratado (SIT) y metformina HCl (MET) en presencia de dos productos de degradación de SIT. Los productos de degradación formados por degradación alcalina se han separado y caracterizado como triazol y la impureza ácida de SIT. La separación se llevó a cabo en una columna Waters Spherisorb SCX (250 × 4,6 mm, 10 μm) usando una fase móvil de tampón de dihidrógeno fosfato de amonio de pH 3:acetonitrilo (55:45% v/v). La cuantificación se logró usando detección UV a 210 nm. Se estableció la pureza máxima de MET y SIT en presencia de los principales productos de degradación en muestras estresadas. El método de análisis propuesto ha sido validado según las directrices ICH y ha demostrado ser específico, preciso, lineal, resistente y robusto. La efectividad del método se demostró con la preparación farmacéutica comercializada de SIT y MET.

**KEY WORDS:** forced degradation, metformin, pharmaceutical preparation, sitagliptin, stability indicating.

\* Author to whom correspondence should be addressed. *E-mails:* gurav.sachintm@gmail.com, sachinnew2018@gmail.com