Advancement of RP-HPLC technique for Pregabalin

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Editorial Note

Pregabalin is an antiepileptic medication and belives to block pain by interfering with pain signals travelling through the damaged nerves and the brain. Etoricoxib is a non-steroidal anti-inflammatory drug (NSAID) called COX-2 inhibitors. It works by blocking the release of certain chemical messengers that are responsible for pain and inflammation (redness and swelling). As there is no HPLC method reported for this combination.Etoshine NP Tablet PR is a combination of two medicines. It is used in the treatment of pain caused due to nerve damage (neuropathic pain). Pregabalin (75 mg) +Etoricoxib (60 mg) is used in the treatment of Neuropathic pain. Novel RP-HPLC Method was developed using Gemini, C18, 150 × 4.6 mm, 5 µ and Mobile Phase composition was [Methanol: Acetonitrile (70:30): 20 mM Ammonium Formate] (50:50 v/v), the flow rate was kept 1.0 ml/min.The retention time was found to be 2.415 and 9.992 for Pregabalin and Etoricoxib respectively. Better Chromatography and resolution were obtained for both the drugs.

High performance liquid chromatography (HPLC) is an essential analytical tool in assessing drug products. HPLC methods should be able to separate, detect, and quantify the various drugs and drug-related degradants that can form on storage or manufacturing, detect and quantify any drugs and drug-related impurities that may be introduced during synthesis. Validation is the process of establishing the performance characteristics and limitations of a method and identification of the influences which may change these characteristics and to what extent.

Novel marketed combination by Sun Pharma company recently. There is no HPLC method reported for this combination. Etoshine NP Tablet PR is a combination of two medicines. It is used in the treatment of pain caused due to nerve damage (neuropathic pain). Pregabalin (75 mg)+Etoricoxib (60 mg) is used in the treatment of Neuropathic pain. Pregabalin is an antiepileptic medication and belives to block pain by interfering with pain signals travelling through the damaged nerves and the brain. Etoricoxib is a non-steroidal anti-inflammatory drug (NSAID) called COX-2 inhibitors. It works by blocking the release of certain chemical messengers that are responsible for pain and inflammation (redness and swelling). As there is no HPLC method reported for this combination. This novel combination was recently launched by sun pharma company 2020.

Analytical method validation ensures that various HPLC analytical techniques shall give reliable and repeatable results; it is a crucial step in developing new dosage forms as it provides information about accuracy, linearity, precision, detection, and quantitation limits. According to the ICH guideline, "the objective of validation of an analytical procedure is to demonstrate that it is suitable for its intended purpose. Solution A Preparation: Use a 1000-mL graduated cylinder to measure 900 mL of filtered MS-grade water. Use a pipette to add 13.9 mL of the Sigma (28%) ammonium hydroxide solution to the 900 mL of filtered MS-grade water. Mix well. Using a pipette, carefully add 1.62 mL of formic acid to the cylinder. Mix well. Check the pH of the solution. Take 50 ml from the above mixture. After this Prepare Solution B which contained Acetonitrile + Methanol mixture (30 + 70 ml). Take 50 ml from this mixture B.Before using the mobile phase was filtered through 0.45 μm membrane filters and degassed by sonication for 10 min. The analysis was carried out on a Shimadzu 8030 series HPLC system. The analyses were conducted on an analytical column Gemini, C_{18}, 150 × 4.6 mm, 5 µ with a detection wavelength of 210 nm. The operating temperature of the column was set at 30°C. The injection volume was 10 μL, and the flow rate was maintained at 1.0 mL/min. The run time was 10 minutes. A standard solution of Pregabalin and Etoricoxib was prepared by dissolving an accurately weighed amount of Pregabalin (50 mg) and Etoricoxib (40 mg) in 50 ml of the mobile phase, and then 5 ml of the resulting solution was diluted to 25 mL by the same solvent to obtain a standard solution of Pregabalin

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