

CHROMATOGRAPHIC SPECTROPHOTOMETRIC DETERMINATION USING REVERSE PHASE HPLC TECHNIQUE FOR MESALAZINE OR MESALAMINE (MESA)

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Abstract.

Aim: The aim of this paper is to estimate Mesalazine or Mesalamine (MESA) in pharmaceuticals.

Methodologies: The reversed-phase HPLC (RP-HPLC) results were used to evaluate the type of Mesalazine. Chromatographic analysis was carried out using an HPLC-UV method along with an Ion Pac column (Arcus EP-C18; 5 m, 4.6 mm, 250 mm) and a mobile phase of acetonitrile: acetic acid: water, 40:40:20 (v/v/v) + 0.5 M potassium dihydrogen orthophosphate buffer at pH 3.3, at a flow rate of 1.0 ml/min. At 260 nm, UV detection was employed in the HPLC method. Exactness, precision, particularly, linearity, and affectability were all accepted for the technique. The (MESA) had a maintenance time of (3.17) minutes. The (MESA) alignment plots were over the target ranges of 1–5 g/L, R^2 0.9998. The quantitation limit was 0.3613 g/ml, with a detection limit of 1.636 g/ml. The precision of the proposed procedure, which ranged from 98.0 percent to 100 percent, was determined through recovery experiments.

Conclusion: The modern HPLC-UV approach was used to analyze generic drug products, and the planned technique's efficiency was confirmed. The study's findings show that precision, accuracy, and efficiency are all within reasonable limits, so there is no substantial difference between the values obtained using the proposed methodology and those obtained using the traditional method.

Key words. Mesalazine (MESA) chromatographic, mesalamine degradation, mesalamine crud.

Introduction.

Mesalazine (MESA), also named mesalamine, its chemical name is 5-amino-2-hydroxy benzoic acid. The powder or crystals of MESA has a white or light grey or light pink color (Britishpharmacopia, 2013). It is soluble in oil, acidic and alkaline medium, fairly insoluble in chloroform, ether, ethyl acetate, and n-hexane [1].

Mesalamine (Figure 1) also known as Mesalazine or 5-amino salicylic acid (5-ASA), is an anti-inflammatory drug used to treat inflammatory bowel diseases, such as ulcerative colitis

and mild-to-moderate Crohn's disease. Mesalamine is a bowel-specific aminosalicylate drug that acts locally in the gut and has its predominant actions, thereby having few systemic side effects. As a derivative of salicylic acid, Mesalamine is also thought to be an antioxidant that traps free radicals, which are potentially damaging byproducts of metabolism. Mesalamine is considered the active moiety of Sulfasalazine, which is metabolized to Sulfapyridine and Mesalamine. A literature survey revealed that a few analytical methods have been reported for the determination of Mesalamine in pure drug, pharmaceutical dosage forms, and biological samples using spectrophotometry, HPLC, UPLC, and LC-MS either in single or in combined forms. The aim of the present work is to develop and validate a simple, fast, and reliable isocratic RP-HPLC method with UV detection for the determination of Mesalamine in bulk and in tablet dosage forms. Confirmation of the applicability of the developed method was validated according to the International Conference on Harmonization (ICH) for the determination of Mesalamine in bulk and tablet dosage forms [2-9].

Synthesis of Mesalamine.

The synthetic step in the synthesis disclosed therein is the reaction of a cyano group on the biphenyl ring with an azide, such as tributyl tin azide, as follows:

Synthesis of Mesalazine

The current study's aim was to establish and validate an RP-HPLC system with an ultraviolet (UV) detector for quantitative Mesalazine determination in pharmaceuticals.

Experiment.

Tools:

Completely automatic digital computer control is standard on the LC-100 series S-HPLC. Its electronic circuit design, internal mechanical construction techniques, processing technology, cinematography workstation functions, and technical requirements make it one of the most stable and reliable instruments available double-beam optical spectrometer (Angstrom Advanced Inc. USA), a sort UV-100 PC with a 1 cm light frequency quartz cell, and an IBM compatible PC make up the LC100-style HPLC-UV. The replica was made out of UPVC. PLS Toolbox for Matlab R2003b, VP pumps, and a UV indicator with variable frequency programming, as well as PLS Toolbox for Matlab R2003b, chemometric techniques, and the halfway least squares process, were all great (PLS). An Angstrom Developed Inc. LCsolution programming tool was used to coordinate peakareas. An Ion Pac segment and an ArcusEP-C18 analyticalcolumn were used to conduct the chromatographic separation and measurement at room temperature (250 mm 4.6 mm; molecule size 5 m). Before

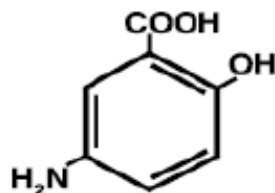


Figure 1. Passive external rotation of the shoulder while lying on the back.