



## Thermal Analysis Used to Assess Pharmaceutical Preparations Containing Theophylline

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### DESCRIPTION

The confirmation of medicinal product composition is a critical pharmaceutical concern. The purity and identity of Active Pharmaceutical Ingredients (API) in finished drugs have an impact on the efficacy and safety of pharmacotherapy. The advanced analytical approaches that are now in use are tedious and time-consuming. Less sophisticated methods, such as UV-Vis spectrophotometry, are less specific. Theophylline and aminophylline pharmaceutical formulations were evaluated using Thermogravimetry Analysis (TGA) and computed Differential Thermal Analysis (c-DTA) in the current investigation. Because of its benefits, the TGA technique can be utilized as an alternative for screening the composition of pharmaceutical products. The results suggest that TGA with c-DTA support is a good screening approach for determining the composition of medicinal formulations containing theophylline and aminophylline. Both thermal approaches work in tandem to produce consistent results. TGA, unlike the pharmacopoeial UV-Vis technique, enables unambiguous identification and differentiation of one and two component pharmaceutical formulations. Moreover, TGA and c-DTA were utilized to identify the excipient used in the formulation of a commercial medicine as well as discover significant levels of lactose in the experimentally created counterfeit formulation. The findings show that TGA and c-DTA have a wide range of applications and are beneficial in pharmacology.

A variety of analytical procedures are used to confirm the qualitative and quantitative makeup of a medication. These procedures are used in medication quality control, appraising generic pharmaceuticals, and recognizing counterfeit drugs. High-Performance Liquid Chromatography (HPLC) with UV-Vis detection and IR spectroscopy are favored approaches. Advanced analytical techniques, such as NMR spectroscopy, can be utilized to discover active medicinal compounds. Differential Scanning Calorimetry (DSC) is one of the thermal methods that may be used. The procedures specified individually for API in pharmacopoeia monographs can also be used to determine the identity and identification of active pharmaceutical ingredients. These approaches are based on chemical compound reactions and the assessment of its physicochemical properties, such as

solubility, melting point, optical rotation, and refractive index. Among the methods for validating a compound's chemical structure, such as mass spectrometry, infrared spectroscopy, or nuclear magnetic resonance spectroscopy, Pharmacopoeia offers UV-Vis absorption spectrophotometry. The UV-Vis technique is limited in that the test material must be dissolved in a solvent, often alcohol or water. As a result, this approach cannot be utilized to test for insoluble compounds. Specificity, accuracy, precision, repeatability, detection limit, linearity, and range should be the primary characteristics of drug testing procedures. This study employed commercially available pharmaceutical formulations to demonstrate the feasibility of detecting one and two-component medicines containing theophylline using TGA and c-DTA methodologies. Preparations comprising theophylline and aminophylline, i.e. a 2:1 mixture of theophylline and ethylenediamine, were utilized. Both medications investigated are methylxanthines, which are used to treat and prevent dyspnea in patients with bronchial asthma and chronic obstructive pulmonary disease. Theophylline works by relaxing bronchial smooth muscle, blood vessels in the lungs, and peripheral arteries. This is accomplished by blocking the phosphodiesterase that degrades cAMP. Theophylline enhances respiratory rate via raising the respiratory center's sensitivity to the stimulating effects of CO<sub>2</sub>. Theophylline also enhances heart muscle and diaphragm contractility, stomach acid production, and diuresis. It also activates the Central Nervous System (CNS). Theophylline is mostly available as sustained-release pills. When theophylline's serum concentration surpasses 20 mg/ml, it causes side effects. Nausea, vomiting, restlessness, sleeplessness, increased respiration and heart rate, reduced blood pressure, muscular tremors, and convulsions are all possible side effects.

### CONCLUSION

Theophylline ethylenediamine is aminophylline. The inclusion of ethylenediamine improves theophylline solubility, allowing the medicine to be administered as an injectable. Aminophylline's mode of action is similar to that of theophylline. Several nations have pulled aminophylline pills from the market due to their narrow therapeutic index and multiple adverse consequences. Nonetheless, aminophylline is still available in tablet form, for example, in the United States, Canada, Portugal, or Germany, as a powder for the creation of prescription pharmaceuticals in a pharmacy (Poland), or as an injection, which is the most popular form.