



## Determination of Ergotamine Tartrate and Caffeine Simultaneously in their Formulation

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### Article History:

Received on: 05 Oct 2022

Revised on: 28 Oct 2022

Accepted on: 29 Oct 2022

### Keywords:

Ergotamine Tartrate,  
Caffeine

### ABSTRACT

There are numerous additional benefits of caffeine, and the most popular one is to increase mental alertness. For the treatment of migraine headaches, caffeine is taken orally or injected together with ergotamine and medicines such as aspirin and acetaminophen. A group of drugs known as ergot alkaloids includes ergotamine. It acts in conjunction with coffee by inhibiting the enlargement of blood vessels in the head that cause headaches. Specific forms of headaches are treated or prevented with this combination of medications (vascular headaches, including migraine and cluster headaches). The UV-Visible Spectrophotometric technique for simultaneous assessment of caffeine and ergotamine in the tablet dosage form in the solvent system of methanol and distilled water in a 1:1 ratio provides an accurate estimate of the % label claim of a marketed product (Cafergot).



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eISSN: 2583-116X

pISSN:

DOI: <https://doi.org/10.26452/fjphs.v3i1.333>



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### INTRODUCTION

Although it has numerous additional purposes, caffeine is most frequently used to increase mental alertness. For migraine headaches, caffeine is administered orally or rectally, with medicines (such as aspirin and acetaminophen) and a substance called ergotamine [1, 2]. Additionally, it is used with opioids to treat and prevent migraines following epidural anesthesia and primary headaches.

One of the most popular stimulants among athletes is caffeine. The National Collegiate Athletic Association permits the use of caffeine within specific parameters (NCAA). Urine with a concentration of more than 15 mg/mL is forbidden. The average person needs roughly 8 cups of coffee with 100 mg of caffeine each to obtain this urine content. In the form of a tablet under the trade name CAFERGOT, ergotamine tartrate and caffeine are used to prevent and cure migraine headaches. The drug ergotamine tartrate belongs to the group of drugs known as ergot alkaloids. Together with coffee, it prevents headaches by limiting the growth of blood vessels in the head. This combo drug treats or contains specific forms of headaches (vascular headaches, including migraines and cluster headaches). Sometimes, enlarged blood vessels in the brain might produce headache discomfort. To operate, these enlarged blood arteries are constricted by ergotamine tartrate [3, 4].

### Reagents

Along with triple-distilled water, all the components

used in this experiment were of analytical quality. Both caffeine and ergotamine tartrate were purchased from S.D. Fine Chem Ltd.

### Apparatus

A Jasco Spectrophotometer, Model-V-630 (Japan), with a spectral bandwidth of 1 nm and wavelength precision of  $\pm 0.3$  nm with automated wavelength

correction, was used for the spectral analysis. Glassware used in each step was thoroughly cleaned with double-distilled water before being dried in a hot air oven after being soaked overnight in a solution of chromic acid and sulphuric acid.

## METHODOLOGY

### Linearity

Working standard solutions of caffeine and ergotamine tartrate were taken in various 10-ml volumetric flasks and diluted with distilled water up to the mark to produce concentrations of 2, 4, 6, 8, and  $10\mu\text{g/ml}$  caffeine and 50, 60, 70, 80, and  $90\mu\text{g/ml}$  ergotamine. A calibration curve was created by graphing concentration vs absorbance, and line equations were computed for both medications [5].

### Preparation of Stock Solution

Ergotamine tartrate (10 mg) and caffeine (10 mg) were accurately weighed and transferred to two separate 100 ml volumetric flasks, where they were dissolved in 50 ml of methanol to reach the desired volume. Ergotamine and caffeine were  $100\mu\text{g/ml}$  in a stock solution [6].

### Preparation of Working Standard

Wavelength selection for detection Drug solution scans were performed between 200 and 400 nm. Ergotamine tartrate and caffeine both had significant absorption at 277 and 281 nanometers, respectively, hence those wavelengths were chosen for detection. To produce the working standard for both solutions, dilute the needed amount of the 100 g/ml stock solutions of caffeine and ergotamine tartrate.

### Precision

The ergotamine tartrate ( $60\mu\text{g/ml}$ ) and caffeine ( $4\mu\text{g/ml}$ ) responses were estimated five times for the repeatability investigations, and the data are shown as the relative standard deviation. By calculating the equivalent answers three times on the same day and three separate days for three different concentrations of ergotamine ( $50, 60, 70\mu\text{g/ml}$ ) and caffeine ( $4, 6, 8\mu\text{g/ml}$ ), the intermediate precision was performed. The findings are provided in terms of relative standard deviation [7].

### Accuracy

To assess the method's accuracy, recovery experiments of caffeine and ergotamine tartrate were conducted at three distinct levels (80%, 100%, and 120%). The average recovery % was calculated. Table 1 displays the calculated recovery values.

### Assay of Drug Formulation

The Weight Variation Test was carried out following I.P. using tablets containing 500mg of caffeine hydrochloride and 5 mg of ergotamine tartrate. These 20 pills were precisely measured and pulverized. A 100ml volumetric flask was filled with a combination of 50ml methanol and 50ml distilled water, along with tablet powder containing 10mg of ergotamine and caffeine. After 30 minutes of sonication, filter the solution. The percentage content of the medicines has been determined from this solution, and a functional solution has been prepared [8, 9].

### Detection Limit

The lowest quantity of analytical in a sample that can be identified is not necessarily quantitative, as an exact number is the detection limit of a particular analytical process.  $\text{LOD} = 3.3\sigma/S$ , Where S is the calibration curve's slope and the response's relative standard deviation.

### Quantitative Limit

The quantitation limit of an analytical process is the lowest amount of analyte in a sample that can be quantitatively determined with enough precision and accuracy.  $\text{LOQ} = 10\sigma/S$ , Where S is the calibration curve's slope and the response's relative standard deviation.

## RESULTS AND DISCUSSION

According to ICH criteria, the UV-Visible Spectrophotometric technique for simultaneous quantifying caffeine and ergotamine tartrate was straightforward and practical with reasonable accuracy, precision, LOD, and LOQ [Table 2].

The method worked well for identifying medicines in their pharmaceutical formulation. The sample recoveries in all formulations utilising the aforementioned approach were in good agreement with the corresponding label claim or theoretical drug content, indicating the validity of the method and the absence of excipient interference in the estimation.

Drugs remained stable in the chosen solvent system of methanol and distilled water for more than 48 hours, indicating that samples do not need to be estimated right away [Table 1].

**Table 1: Recovery and Assay Analysis**

	Ergotamine Tartarate	Caffeine
Amount used	50 $\mu$ g	5 $\mu$ g
Amount recovered	49.58 $\mu$ g	4.97 $\mu$ g
Percentage recovered	99.16%	99.4%
Label Claim	500mg	50mg
Estimated	495.93mg	49.21mg
Percentage	99.18%	98.42%

**Table 2: LOD and LOQ Analysis**

S. no.	Parameters	Ergotamine Tartarate	Caffeine
1	Max(nm)	277nm	281nm
2	Linearity range	16-40 $\mu$ g/ml	17-42 $\mu$ g/ml
3	Regression equation	Y=0.0512x - 0.1095	Y=0.0232x - 0.0013
4	Correlation coefficient	0.9827	0.9594
5	Limit of detection	10.5187 $\mu$ g/ml	10.46 $\mu$ g/ml
6	Limit of quantification	31.8750 $\mu$ g/ml	31.6810 $\mu$ g/ml
7	Intra day	0.8788 $\pm$ 0.0409	0.9119 $\pm$ 0.0518
8	Interday	0.8428 $\pm$ 0.0089	0.8720 $\pm$ 0.0161

## CONCLUSION

The proposed UV-Visible Spectrophotometric technique accurately calculates the % label claim for the marketed product Cafergot while simultaneously measuring ergotamine tartrate and caffeine in the tablet dosage form in the methanol solvent system distilled water.

## ACKNOWLEDGEMENT

I want to thank my esteemed Principal (Dr. Venkata Gopala Krishna Sunku) at Vasavi Institute of Pharmaceutical Sciences, Vasavi Nagar, Peddapalli (V), Sidhout (M), Kadapa (Dist), Andhra Pradesh, 516247, India.

## Conflict of Interest

The authors declare no conflict of interest, financial or otherwise.

## Funding Support

The authors declare that they have no funding for this study.

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**Cite this article:** Srikanth A, Bhavanasi Mounika, Venteru Muni Sekhar. **Determination of Ergotamine Tartrate and Caffeine Simultaneously in their Formulation.** Future J. Pharm. Health. Sci. 2023; 3(1): 1-4.



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