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A Comparative Developed Method for Visible (VIS) Spectrophotometric Determination and Statistical Analysis of Ibuprofen in Two Pharmaceuticals

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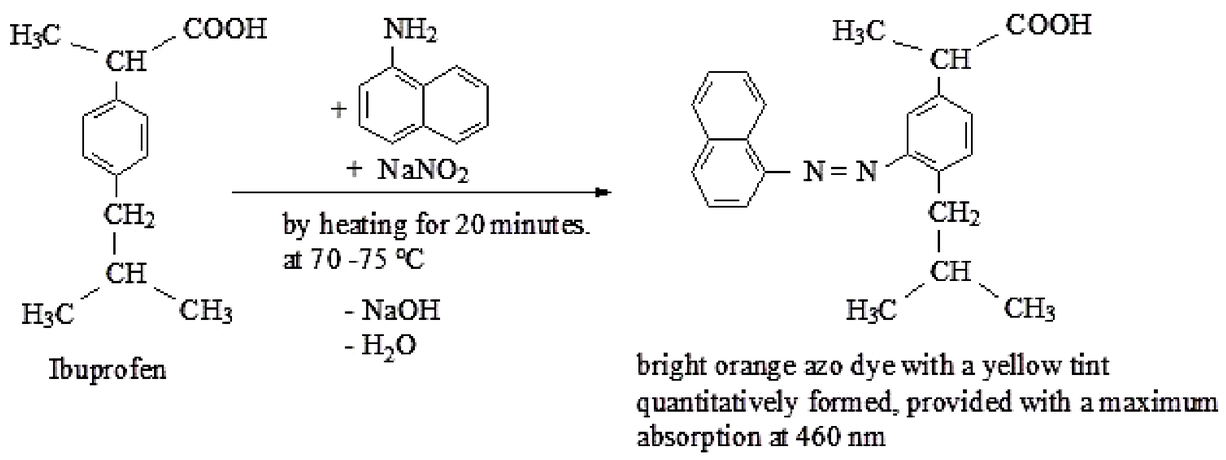
INTRODUCTION & AIM

Ibuprofen is a propionic acid derivative, a non-steroidal anti-inflammatory drug with a very effective anti-inflammatory and analgesic action and an significant antipyretic effect. It is a non-selective strong inhibitor of both Cyclooxygenase isoforms, Cyclo-oxygenase-1 (COX-1) and Cyclooxygenase-2 (COX-2). **The main purpose of this research was to establish the accuracy of the official Ibuprofen amount calculated on the pharmaceutical tablet, according to the Rules of Good Pharmaceutical Practice provided by the European and Romanian Pharmacopoeias. Ibuprofen real concentrations can also be exactly found from various unknown pharmaceutical samples, according to the Official Pharmacopoeias Rules**. Color reaction occurred quantitatively between Ibuprofen with alpha-naphthylamine ethanolic solution 0.1% , sodium nitrite $NaNO_2$ aqueous solution 4-5% , by heating at a high temperature of 70-75ºC , which led to the quantitative synthesis of an intense orange-yellowish azo dye that was spectrophotometrically analyzed at its maximum assigned absorption wavelength, **λ = 460 nm**. The pure Ibuprofen amount on the pharmaceutical tablet was calculated at **λ.=460 nm** for both pharmaceuticals and was found to be **611,750 mg,** assigned to a mean percentage content of **101,958% active substance** for the first pharmaceutical product**,** very close to the officially declared amount **(600 mg)**, with a average percentage error of only **1,958** % in addition to the stated active substance content. For the second pharmaceutical product, pure Ibuprofen content was calculated and assigned to **394,774 mg for a** mean percentage content of **98,694% , close enough** to the official declared amount **(400 mg)**. The average percentage error was only **1,307** % less than the officially declared active substance content. The Ibuprofen amounts found in both pharmaceuticals were within the normal range of values, located below ± **5%**, which is the official maximum percentage deviation mentioned in European and Romanian Pharmacopoeias. Ultimately, both spectrophotometric methods were statistically validated. A fundamental objective was to develop a new spectrophotometric method for dosing Ibuprofen in pharmaceutical samples, to statistically validate and for its application in laboratory practice and in pharmaceutical research

METHOD

Ibuprofen, 2 - (4-isobutylphenyl) propanoic acid, a non-steroidal anti-inflammatory derived from propionic acid, present as an active substance in two pharmaceutical products, reacted completely with an alcoholic α-naphthylamine solution, 0.1%, in the presence of an aqueous solution of NaNO2, 4%, by heating for 20 minutes at the constant temperature of 70 - 75°C, which led to the quantitative formation of a compound colored in intense orange yellow (azo dye) which showed an absorption maximum at of wave **λ. = 460 nm**. The dye was obtained in an amount perfectly equivalent to pure Ibuprofen present in both initial samples taken into study. By spectrophotometric dosing of the intense orange azo dye with a yellowish tint formed, at λ = 460 nm, compared to absolute ethyl alcohol as a control, Ibuprofen from the two analyzed pharmaceutical samples could be directly analyzed.



Sample concentrations and amounts of pure Ibuprofen **calculated** on solid film-coated tablets of the two pharmaceutical products

Sample	$A_{P\,1}$	Cp_1 (µg/mL)	µg Ibuprofen /film-coated tablet	mg Ibuprofen / film-coated tablet
Ibuprofen® solution	0,.446	4,1374	611749,640	611,749640

Sample	A_P	Cp (µg/mL)	µg Ibuprofen / solid tablet	mg Ibuprofen / solid tablet
Nurofen ®solution	0,.251	2,07611	394774, 106	394,774106

RESULTS & DISCUSSION

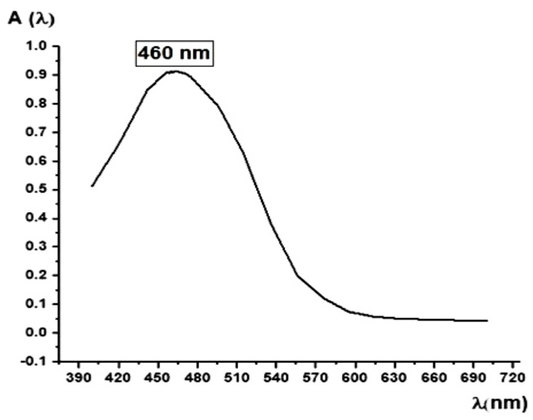


Fig. 1 Absorption Spectrum of Ibuprofen in Visible (Vis} range , according to the quantitative reaction with alpha-naphthylamine

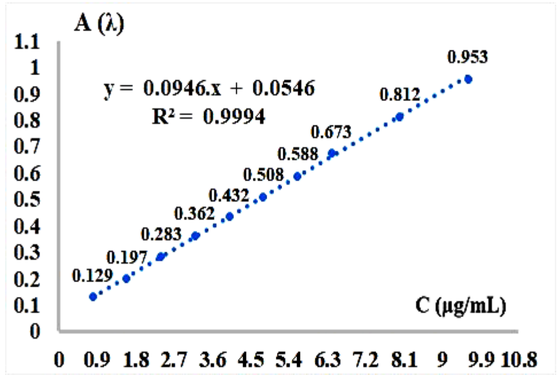


Fig. 2 Calibration Graph for ten Ibuprofen standard solutions (0.80 µg/mL – 9.60 µg/mL)

Table 1. Measured mean absorbances values depending on standard concentrations of Ibuprofen solutions (0.80 µg/mL - 9.60 µg/mL)

Nr. Det.	mL standard solution of Ibuprofen , 200 µg/mL	mL solution $NaNO_2$, 4 %	mL alcoholic solution of α-naftilamine, 0,1%	C (µg/mL)	A (λ)
1.	0,1	0,2	0,2	0,80	0,129
2.	0,2	0,4	0,4	1,60	1,197
3.	0,3	0,6	0,6	2,40	0.283
4.	0,4	0,8	0,8	3,20	0,362
5.	0,5	1,0	1,0	4,00	0,432
6.	0,6	1,2	1,2	4,80	0,508
7.	0,7	1,4	1,4	5,60	0,588
8.	0,8	1,6	1,6	6,40	0,673
9.	1,0	2,0	2,0	8,00	0,812
10.	1,2	2,4	2,4	9,60	0,953

Table 2. Regression Statistics

Regression Statistics	
Multiple R (correlation coefficient)	0,9997003
R Square, R^2 (linear regression coefficient)	0,9994007
Adjusted R Square, R^2	0,9993258
Standard Error of the Regression Line (SE)	0,0069247
Observations	10

CONCLUSION

The amount of Ibuprofen in the two analyzed pharmaceutical samples was determined exactly by the new method. As a result of this experiment, for the first pharmaceutical product an amount of **611,750 mg** of pure Ibuprofen /solid capsule of pharmaceutical product were obtained, which corresponded to a percentage content of **101,958% active substance** determined by pure Ibuprofen acetate. This amount was very close to the reference value, officially indicated amount by the manufacturer, which was **600 mg pure Ibuprofen on tablet**. The relative percentage deviation (relative procedural error) compared to the official allowed value (500 mg)was **only 1,958 %** and it fell perfectly within the official normal and admitted percentage error values indicated by the Romanian and European Pharmacopoeias X Th Edition **(± 5 %).** In case of the second pharmaceutical product studied, pure Ibuprofen content was calculated and assigned to **394,774 mg for a** mean percentage content of **98,694% , close enough** to the official declared amount **(400 mg)**. The average percentage error (deviation) in the case of second product was only **1,307** % less than the officially declared active substance content of **400 mg**.. in European and Romanian Pharmacopoeias.). The average percentage (deviation in this second case was below the maximum official percentage deviation of **± 5 % imposed by** Romanian and European Pharmacopoeias X Th Edition

FUTURE WORK / REFERENCES

1. https://go.drugbank.com/drugs/DB01050 accessed Wednesday, 02/10/2024, at 6.00 p.m.

2. Zawada ET Jr: Renal consequences of nonsteroidal anti inflammatory drugs. Postgrad Med. 1982 May;71(5):223-30.

3. Townsend KP, Pratico D: Novel therapeutic opportunities for Alzheimer's disease: focus on nonsteroidal anti-inflammatory drugs. FASEB J. 2005 Oct;19(12):1592-601