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Research Article

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Comparative Quality Evaluation of Ibuprofen in Tablets

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Abstract Ibuprofen is a nonsteroidal anti-inflammatory inflammatory drug (NSAID) which is used in reducing inflammation and pain associated with many diseases like rheumatoid arthritis, osteoarthritis etc. It acts by inhibiting the cycloxygenase enzyme and thereby reducing the synthesis of prostaglandins. It is a racemic mixture of [+] S and [-]R-enantiomers. Ibuprofen is the most commonly used and most frequently prescribed NSAID. Although its anti-inflammatory properties may be weaker than those of some other NSAIDs, it has a prominent analgesic and antipyretic role. Ibuprofen is given as a tablet with a potency of 200 to 800 mg. The usual dose is 400 to 800 mg three times a day. It is almost insoluble in water with a pH of 5.3. Recemic ibuprofen and the S (+) enantiomer are mainly used in the treatment of mild to moderate pain associated with dysmenorrhea, headache, migraines, postoperative toothache, treatment of spondylitis, osteoarthritis, rheumatoid arthritis, soft tissue disorder. The aim of the study is to compare the different physical parameters including appearance, uniformity of mass, uniformity content (mass variation) and spectrophotometric assay for quality evaluation and characterization of tablets of six different brands. All six brands of ibuprofen tested meet the specification of the EP, BP and USP for content uniformity, weight variation and assay content.

Keywords Ibuprofen, Method development, Spectrophotometry

Introduction

Nonsteroidal anti-inflammatory drugs (NSAIDs) are one of the most commonly prescribed drugs, which are widely used in the treatment of various conditions accompanied by pain and inflammation. They are used to treat both acute (injuries of various nature, headaches, toothaches, dysmenorrhea) and chronic conditions (osteoarthritis, rheumatoid arthritis). Although they effectively reduce pain and inflammation, the effect of these drugs is limited in time, and due to the need for repeated dosing, they are not suitable for long-term therapy of chronic conditions [1]. Ibuprofen is one of the most potent orally active antipyretic, analgesic and non-steroidal anti-inflammatory drug (NSAID) used extensively in the treatment of acute and chronic pain, osteoarthritis, rheumatoid arthritis and related conditions [2]. Ibuprofen is the most commonly used and is the most commonly prescribed NSAID. It is a non-selective inhibitor of cyclooxygenase-1 (COX-1) and cyclooxygenase-2 (COX-2). Although its anti-inflammatory properties may be weaker than some other nonsteroidal drugs, its effects are due to their inhibitory action on cyclooxygenases involved in prostaglandin synthesis [3]. The aim of the study is to compare the different physical parameters including appearance, average tablet weight, uniformity content (mass variation) and spectrophotometric assay for quality evaluation and characterization of tablets of six different brands. All six brands of ibuprofen tested meet the specification of the EP, BP and USP for content uniformity, weight variation and assay content [4 - 10].

Materials and Methods

Materials and Equipment

Six brands of Ibuprofen tablets were commercial products from Bosnian market, with labelled contents of 200 mg, 400 mg and 600 mg. The following reagent (sodium hydroxide) was from Sigma-Aldrich, Germany. Pure Ibuprofen reference powder was obtained from USP. All the chemicals and reagents used were of analytical grade. The aqueous solutions, 0.1 mol/L sodium hydroxide was freshly prepared with distilled water. A Shimadzu UV-Visible double beam spectrophotometer (Shimadzu, Japan) with matched 1 cm quartz cells was used for the measurements at 220 nm.

Appearance

Their visual properties were analyzed on the samples: color, shape, surface shape, presence of the described grooves and monograms.

Uniformity of mass

According to the European Pharmacopoeia (EP) for the mass uniformity parameter Ph. Eur. 2.9.5., Under the category of film-coated tablets, the acceptability criterion is set based on the average tablet weight. By definition, all film tablet samples have an average film tablet weight of more than 250 mg, which means that all tested samples have a criterion for individual film tablet weights (PMT) min 18/20 PMT ± 5% and max 2/20 PMT ± 10% [5, 7].

Uniformity content (mass variation)

To ensure the consistency of dosage units, each unit in a batch should have an active substance content within a narrow range around the label claim. Calculation of acceptable value is according to European Pharmacopoeia 9.0. Uniformity of dosage units, 2.9.40.[6].

Assay determination

Preparation of 0.1 mol/L sodium hydroxide solution

A 4 g mass of sodium hydroxide was weighed in a 1 L volumetric flask and the volume made up to mark with distilled water.

Preparation of Ibuprofen stock solution

A 25 mg mass of the pure reference material was weighed and dissolved in 0.1 mol / L sodium hydroxide in a 100 mL volumetric flask and the volume made up to mark with same solvent (0.25 mg / mL). Working solutions were prepared by making appropriate dilutions of this standard Ibuprofen stock solution from 75% - 110% in regards to 100% (0.027 mg / mL).

General Procedure

A blank solution was prepared in the same way but excluding the analyte (Ibuprofen). The above solutions were all prepared in triplicates. The absorbance of each solution was measured at 220 nm against a blank **(**0.1 mol / L sodium hydroxide)**.**

Validation of the proposed method

The calibration curve for the drug was constructed in selected solvents. Regression equation for the data was derived with the aid of Microsoft Excel software program. Each concentration of standard solution was assayed in triplicates and the mean absorbance obtained was then plotted versus concentration [9].

Determination of accuracy and precision of the proposed method

The precision and accuracy of the method were investigated based on inter-day variation (repeatability) assessment by analyzing Ibuprofen using six replicates. The precision and accuracy of the method were expressed as % RSD and recovery of the measured concentration, respectively.

Determination of Ibuprofen content in capsules, hard formulation using the proposed method

Six different brands of Ibuprofen tablets formulation were assayed using the developed method. For each brand, the contents of 20 tablets were weighed, ground into a fine powder. An accurately weighed portion of the powder equivalent to 25 mg Ibuprofen was transferred into a 100 mL volumetric flask. Samples were dissolved in of 0.1 mol / L sodium hydroxide. After filtration, all samples diluted to final target concentration 0.027 mg / mL. The content of each label claim was verified by comparing the concentrations obtained from the validated curves with the actual concentrations of the drug taken.

Results & Discussion

All the brands used in this investigation sere within their shelf life.

Appearance

From these visual observations, we can say that all samples are of adequate appearance, without any flaws and damage (Figure 1). Detailed observations of the appearance of the tested samples are in Table 1.

Figure 1: Appearance of tested samples

Table 1: Detailed observations of the appearance

Parameter	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Sample 6
Shape and colour	Round, red	Round, red	Round, white	Oblong, white	Oblong, white	Oblong, white
Surfaces	Biconvex	Biconvex	Biconvex	Biconvex	Biconvex	Biconvex, with brake line on one side
Engraving	/	/	/	/	/	/
Damage	/	/	/	/	/	/

Uniformity of mass

From the below results, all tested samples satisfy criteria defined by European Pharmacopoeia Requirement 2.9.5.

Table 2: Uniformity of mass for tested samples

Sample No	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Sample 6
m1	359.51	704.97	770.30	523.78	782.73	805.36
m2	358.84	718.63	769.25	521.92	788.13	814.13
m3	358.69	713.44	772.39	534.56	790.85	810.32
m4	360.83	714.50	768.98	528.07	794.42	800.57
m5	357.15	726.88	765.01	519.41	814.66	809.13
m6	359.49	705.01	770.31	523.81	782.75	805.35
m7	358.85	718.64	769.23	521.96	788.14	814.12
m8	358.67	713.46	772.40	534.59	790.85	810.36
m9	360.82	714.91	768.95	528.04	794.40	800.61
m10	357.17	726.92	765.03	519.40	814.63	809.13
m11	359.50	705.02	770.33	523.83	782.74	805.39
m12	358.86	718.64	769.27	521.95	788.14	814.17
m13	358.68	713.46	772.38	534.53	790.91	810.37
m14	360.83	714.91	768.91	528.06	794.43	800.62
m15	357.18	726.92	765.06	519.43	814.70	809.13
m16	359.54	705.02	770.30	523.80	782.64	805.15
m17	358.90	718.64	769.28	521.86	788.00	813.91
m18	358.73	713.46	772.39	534.48	790.74	810.07
m19	360.83	714.92	768.95	527.97	794.24	800.27
m20	357.21	726.91	765.03	519.33	814.48	808.81
PMT	**359.01**	**715.76**	**769.19**	**525.54**	**794.13**	**807.85**
MIN (mg)	**357.15**	**704.97**	**765.01**	**519.33**	**782.64**	**800.27**
MAX (mg)	**360.83**	**726.92**	**772.40**	**534.59**	**814.70**	**814.17**
%	**99.48**	**98.49**	**99.46**	**98.82**	**98.55**	**99.06**
%	**100.51**	**101.56**	**100.42**	**101.72**	**102.59**	**100.78**

Uniformity of dosage units (by mass variation)

From the below results, all tested samples meet criteria defined by the European Pharmacopoeia 2.9.40. Acceptable values of parameter L are less than 15.

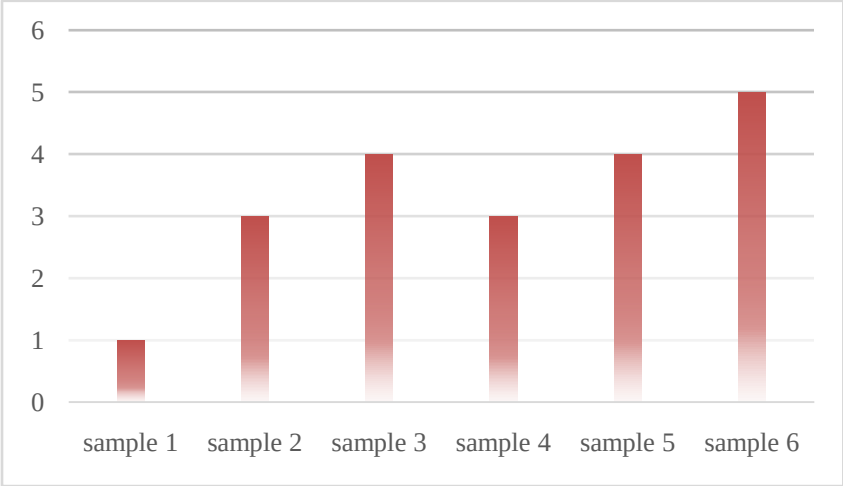

Figure 2: Uniformity of dosage units for tested samples

Spectrophotometric assay determination

The content of ibuprofen in the tested samples was determined by spectrophotometric method using 0.1 mol / L sodium hydroxide as solvent. For the purpose of method verification, the linearity of the standard solution was

doneby preparing solutions in concentrations of 0.021 mg / mL - 0.031 mg / mL in relation to the working concentration of the standard solution 0.027 mg / mL (Figure 3).

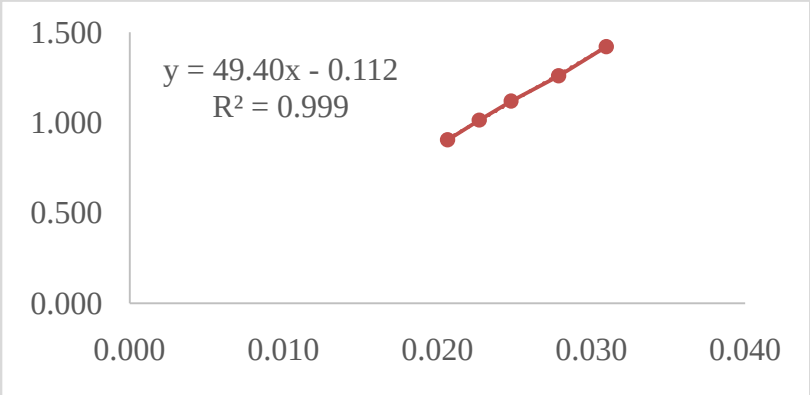

Figure 3: Linearity for Ibuprofen

Table 3 shows all validation results.

Table 3: Validation results

Results	**0.1 mol / L sodium hydroxide**
Correlation coefficient (r^2)	0.9993
Accuracy, RSD	100.0%; 0.51%
Precision (n=6)	0.45

Table 4 obtained for the analysis of six brands of Ibuprofen tablets using the developed method (Figure 4).

Table 4: Content of Ibuprofen using proposed method

Samples	**% of content Ibuprofen**	**mg of content Ibuprofen**
Sample 1- 200 mg tablets	100.6	201.2
Sample 2- 400 mg tablets	100.7	402.9
Sample 3- 600 mg tablets	105.0	629.7
Sample 4- 400 mg tablets	100.3	401.0
Sample 5- 600 mg tablets	101.2	607.0
Sample 6- 400 mg tablets	104.9	419.7

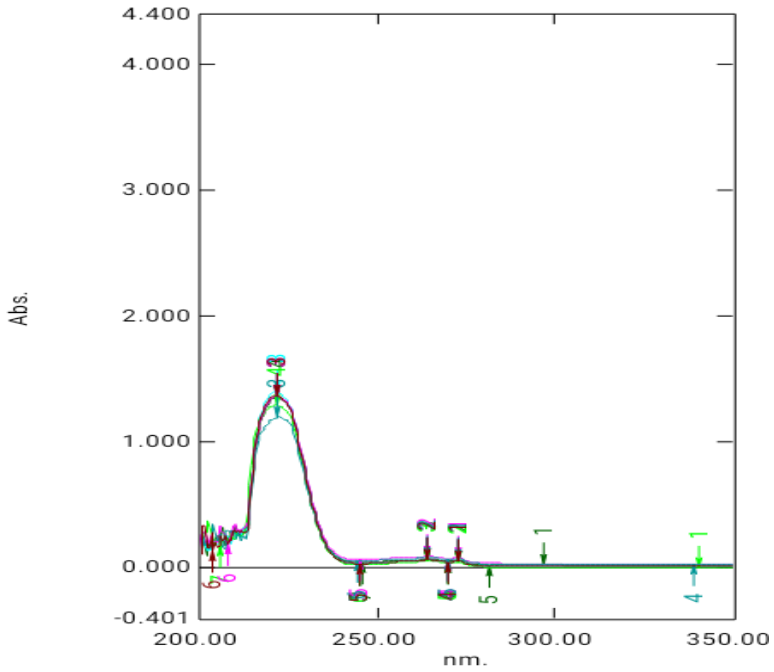

Figure 4: Spectrograms of standard and sample solutions

Conclusion

According to the present study, it was clearly demonstrated that all six brands of the ibuprofen tablets (film coated) comply with EP, BP and USP specifications for quality control tests of uniformity of weight, uniformity of content and assay content. The method has the advantage of being simple, accurate, precise and suitable for routine quality control of Ibuprofen in dosage form without any interference from excipients.

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