

STANDARDIZATION AND STUDIES ON COMMERCIAL TABLETS OF VALDECOXIB

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ABSTRACT

Different brands of Valdecoxib were evaluated for their tablet characteristics and *in vitro* dissolution profiles. The obtained data will be useful in formulation and in maintaining the manufacturing processes, which affect the dissolution characteristics and ultimate bioavailability.

Keywords: Valdecoxib, Tablet, Dissolution Profile, Disintegration Time.

INTRODUCTION

Evaluation of tablet is important to ensure the purity, quality and efficacy of products¹. Drug absorption and physiological availability are largely dependent upon having the drug in dissolved state, therefore suitable dissolution characteristics are an important property of a satisfactory drug product^{2,3,4,5}.

Only a few reports have appeared in literature on the quality of drug formulation available in India. With this view point, to assess the *in vitro* availability of different brands of Valdecoxib [non-steroidal anti-inflammatory drug (NSAID) selective cyclooxygenase II (COX-2) inhibitor]⁶, at the time of study, tablets of current manufacturing batches were procured from the market.

MATERIALS AND METHODS

Four brands of Valdecoxib tablet (10mg) designated as Test Product A-D were procured from the open market. The chemicals and reagents used were of AR/LR grade. Monsanto type tablet hardness tester were used for hardness measurement, friability was done by the use of Roche Friabilator. For disintegration, disintegration apparatus IP

standard- Indian equipment corpn. was used. UV-VIS spectrophotometer, Shimadzu was used for assay. For dissolution, dissolution tester TDT 08L Electrolab was used.

Evaluation of Valdecoxib Tablets

As Valdecoxib is a new non-steroidal anti-inflammatory drug recently introduced in Indian market, it is not official in USP, IP and BP. That is why a general procedure for evaluation of tablet listed in Indian Pharmacopoeia was followed¹. The evaluation parameters are described below.

Uniformity of weight

Twenty tablets were selected at random from each of the test products and weighed individually and altogether. Percent deviation was found and documented.

Hardness

The hardness was determined for six randomly selected tablets by measuring the pressure required to break the tablet with its diametrical axis using a Monsanto type tablet hardness tester (Campbell Electronics,

Mumbai). The result was expressed as an average of six readings in terms of kg/cm².

Friability

10 tablets were selected at random from each test product. Initial weight was determined. Tablets were put in Roche friabilator and friabilator was run for four minutes for 100 revolutions. Final weight was determined after dusting and % loss was calculated and documented.

Disintegration Time (D.T.)

D.T. studies were carried out on disintegration test apparatus machine IP standard (Campbell Electronics, Mumbai). The test was carried out at 37 ± 2 °C in a suitable medium (distilled water). The time for disintegration was noted in each test product for 6 tablets.

Assay

Twenty tablets were selected at random from each of the test products and were powdered and sample equivalent to 10 mg of Valdecoxib was dissolved in 100 ml of 0.1N NaOH. 1ml of this solution was taken and diluted to 10.0 ml with 0.1N NaOH solution. The absorbance was measured spectrophotometrically at λ_{max} of 244.6 nm. The content was calculated using standard curve of Valdecoxib reference sample in 0.1N NaOH solution.

Dissolution rate studies

In vitro dissolution profile of test products was determined on a dissolution tester TDT 08L Electrolab apparatus. The dissolution vessel contained 1000 ml of suitable media maintained at 37 ± 0.5 °C and basket speed was set at 50 rpm. 10 ml sample was withdrawn at 5, 10, 15, 20, 30, 40, 50, 60, 70 minutes intervals. The sample so withdrawn were replenished with fresh media. The withdrawn samples were filtered and absorbance was determined using UV-VIS spectrophotometer at 244.4 nm.

The amount dissolved was calculated using standard curve of Valdecoxib in water-methanol (5% v/v).

a) Dissolution medium: Water-methanol (5% v/v) was used as dissolution medium.

b) Data treatment: The *in vitro* dissolution profile namely, cumulative drug release, A₁₅, A₃₀ (% amount of drug dissolved in 15, 30 minutes), T₅₀, T₈₀ (time taken for 50% and 80% dissolution) were determined.

RESULTS and DISCUSSION

The uniformity of weight of four brands of Valdecoxib was within limits as prescribed in IP as shown in Table 1. The data of hardness and DT as given in Table 1 revealed that DT increased with increase in hardness. Friability data were within the limits (Table 1). Drug content determined from assay studies indicated that there is slight variation among those four brands.

On the basis of dissolution data as depicted in Table 2, it was apparent that the different brands of drug manufactured by different manufacturers differed hence it might be inferred that the different brands were not same but were different in their formulation. Variations in brands may be attributed by one or more than one sources for quality variation i.e. men, money, machine, materials, methods and management.

CONCLUSION

In conclusion, obtained data will be useful in formulation and in maintaining the manufacturing processes which affect the dissolution characteristics and ultimate bioavailability. Further, it may be concluded that owing to the variations, the marketed formulations require stringent in house quality control and check by the regulatory authorities.

It may also be concluded from the obtained data that these test products are not pharmaceutically equivalent but all of them are quality products.

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Table 1: Data for Uniformity of Weight, Hardness, Friability, DT, and Assay Studies

Product Code	Uniformity of weight* (gm)	Hardness** (kg/cm ²)	Friability (% loss)	DT** (min)	% Active Ingreient***
A	0.18 (0.0049)	4.75 (0.42)	0.074	9.2 (1.22)	104.5 (1.5)
B	0.22 (0.0039)	2.25 (0.27)	0.0605	0.24 (0.06)	102.7 (0.46)
C	0.11 (0.0025)	3.2 (0.26)	0.311	1.62 (0.18)	103.5 (1.14)
D	0.14 (0.0036)	3.0 (0.0)	0.317	0.48 (0.05)	103.4 (1.03)

* Mean of 20 readings ** Mean of 6 readings *** Mean of 3 readings

Table 2: Dissolution Data for Different brands of Valdecoxib Tablets

Product Code	% drug dissolved (in 70 min)	A ₁₅ *	A ₃₀ *	T ₅₀ *	T ₈₀ *
A	100.54 (0.553)	53.46 (1.95)	72.44 (1.46)	12.98 (1.140)	39.22 (1.975)
B	97.9 (1.36)	43.02 (6.37)	72.67 (4.17)	18.07 (0.47)	36.85 (4.86)
C	101.7 (0.089)	73.43 (1.188)	89.36 (2.65)	4.636 (1.75)	19.916 (1.730)
D	98.8 (3.72)	59.79 (2.348)	77.763 (2.57)	10.075 (1.263)	32.98 (3.47)

* Mean of 6 reading

A₁₅ Percent drug dissolved in 15 min

A₃₀ Percent drug dissolved in 30 min

T₅₀ Time taken in minutes for 50% dissolution

T₈₀ Time taken in minutes for 80% dissolution

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