Asian J. Exp. Sci., Vol. 20, No. 1, 2006, 97-100

In Vitro Comparative Evaluation of Different Brands of Nifedipine Capsules

Deepak Sharma* and Rakesh Gupta
Lal Bahadur Shastri College of Pharmacy,
Tilak Nagar, Jaipur, India

Abstract : Five leading brands of Nifedipine soft gelatin capsules A, B, C, D and E were subjected to *in vitro* comparative evaluation with respect to compliance with prescribed standards of Indian Pharmacopoeia. All the brands complied with respect to physical appearance and disintegration time. One of the brand failed to meet the requirements of uniformity of content and content of active ingredient (assay). The results of study revealed that manufacturers need to be highly research based and need strict adherence with current good manufacturing practices (cGMP) and current good laboratory practices (cGLP) to maintain proper quality of medicine as pharmaceuticals are life saving drugs, quality is an imperative for growth and key tool to make a smooth entry into competitive world market.

Key words : Nifedipine, Indian Pharmacopoeia, Disintegration time, Uniformity of content, Assay, Quality.

Introduction :

Nifedipine is a potent calcium channel blocker, a life saving drug for hypertension, angina pectoris and Raynaud's syndrome (Braunwald, 1982). It inhibits cellular influx of calcium ions, which are responsible for maintenance of plateau phase of action potential of cardiac muscle. It is used for treatment of elevated blood pressure and in treatment and prophylaxis of angina pectoris (Sorkin, 1985). The stability study of nifedipine in an electrolyte solution used to induce cardioplegia suggests that it degraded more rapidly at 25^0C than at 4^0C. However, even when protected from light and refrigerated, nifedipine concentration declined to approximately 90% of its original value within 6 hours of preparation (Bottorff, 1984). Therefore, uniformity of content and assay are important parameters for evaluation of nifedipine capsules. In India, every pharmaceutical organization follows variable manufacturing techniques under different conditions, which may result in variation on quality of products. Quality and efficiency are the hallmark of pharmaceutical industry (Tripathi, 1997).

It is a fact that quality building exercise cannot be achieved without an adequate research base in the country. Quality is essential for growth and main tool to make a smooth entry into competitive world market (Singh, 1994). Each batch of finished goods is required to comply with the prescribed standards of Indian Pharmacopoeia, British Pharmacopoeia or United States Pharmacopoeia. In the present work, an attempt has been made to evaluate and compare some marketed brands of nifedipine soft gelatin capsules as per the prescribed standards of Indian Pharmacopoeia. The capsules of 10 mg were chosen for the study.

* **Corresponding author :** E-mail : deepak_sharma3@rediffmail.com

Material and Methods :

Five commercially available brands of nifedipine soft gelatin capsules – 10 mg were procured from market. All chemicals used were of analytical reagent grade and obtained commercially and used as such without further purification. All brands had same manufacturing year. The products were coded as A, B, C, D, and E.

General Characteristics : Soft gelatin capsules of nifedipine were subjected to visible examination and observed for any leakage of contents.

Disintegration time : One capsule was placed in each of six tubes of assembly and assembly was suspended in water. Discs were added to each tube, temperature was maintained at 37 $\pm$ 2^{o}C and assembly was operated for 60 min. (Indian Pharmacopoeia vol. II, 1996).

Content of active ingredient (Assay) : The content of 5 capsules equivalent to 50 mg of nifedipine was transferred to 200 ml volumetric flask with the aid of small quantity of methanol and volume was made up with methanol and mixed. 20 ml of this solution was diluted to 100 ml with methanol and mixed properly. Absorbance of this resulting solution was measured at 350 nm, spectrophotometrically (Indian Pharmacopoeia, 1996), results are shown in Table 1.

Uniformity of content : This test is applicable to products that contain 10mg or less than 10% w/w of active ingredient of dosage form unit. Content of active ingredient in each of 10 capsule was determined by using method of assay for nifedipine capsule (Indian Pharmacopoeia vol. I, 1996), the results are shown in Table 2.

Results :

All the brands A, B, C, D and E of nifedipine capsule complied with the prescribed standards for general characteristics and disintegration time. The soft gelatin capsules complied the test for disintegration and all six capsules disintegrated within 60 min (Table 1). All the brands exhibited assay profile within the prescribed limit (Table 1) except capsules of brand C, which showed assay value of 86.66% (Fig. 1). Pharmacopeial standards require that nifedipine capsules contain not less than 90% and not more than 110% of the stated amount of nifedipine. The capsules of brand C did not comply the pharmacopeial standards for uniformity of content (Table 2). Pharmacopeial standards require that not more than one of individual assay value obtained (Fig. 2) is outside the limit of 85 to 110% of the average value; none is outside the limit of 75 to 125% of the average value.

Discussion :

The results of present study revealed that manufacturers must take every possible care to ensure that any batch produced must

Table 1 : Disintegration time and assay of different brands of nifedipine capsule – 10 mg.

Brand	Disintegration time (min.)	Nifedipine content (% Assay)
A	35	97.65
B	40	97.05
C	30	86.66
D	28	103.42
E	34	105.18

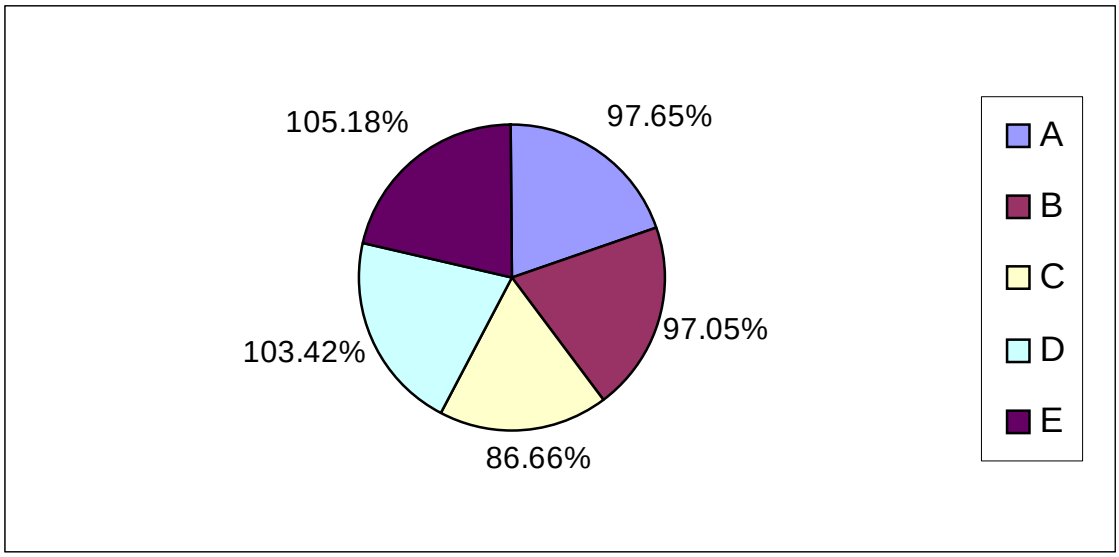

Fig. 1 : Comparative nifedipine content for different brands A, B, C, D and E of nifedipine capsule.

Table 2 : Uniformity of content of nifedipine capsule (% content) of different brands A, B, C, D, and E.

Unit	A	B	C	D	E
1	99.85	104.31	88.47	104.73	106.72
2	94.64	98.46	70.68	99.91	104.81
3	85.32	88.73	101.41	112.73	101.76
4	80.14	90.48	74.32	97.76	115.65
5	98.53	105.86	76.48	108.79	97.64
6	105.83	109.72	100.09	105.76	105.89
7	108.46	94.72	68.16	99.16	108.76
8	96.99	85.64	80.89	89.76	101.78
9	99.18	97.86	102.48	100.95	98.99
10	107.08	95.81	99.90	103.68	108.07

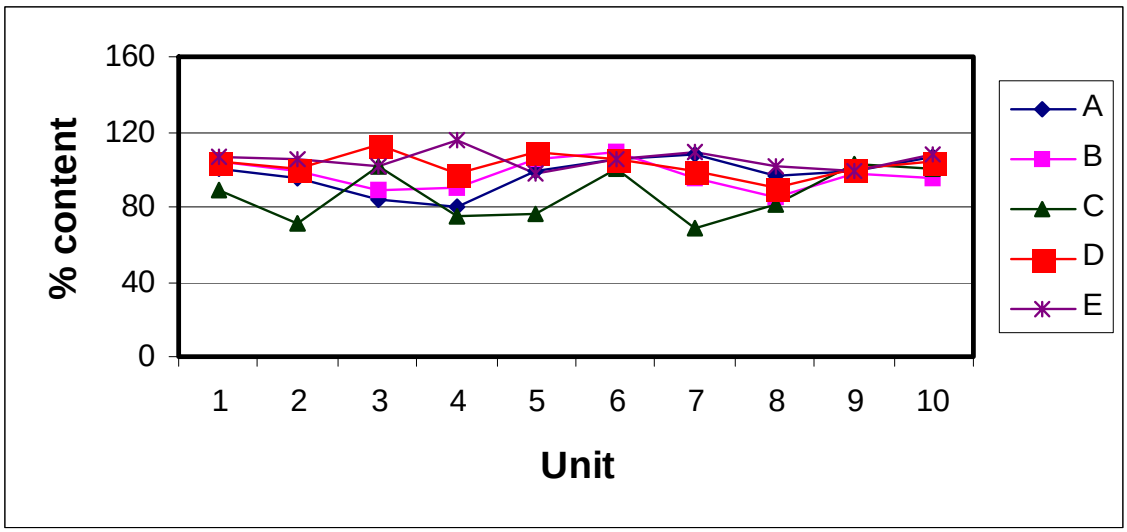

Fig. 2 : Comparative uniformity of content profile for different brands A, B, C, D and E of nifedipine capsule.

comply with the prescribed standards not only at the time of manufacture but also during its shelf life. Quality medicine is to be delivered to consumer; loss of quality means, loss of customer satisfaction and loss of organization's resources. Hence, it can be recommended that, to meet the requirement of quality, the industries need to be highly research based and must give more emphasis on the total quality management by following the framed "quality-policy".

Acknowledgement :

The authors are thankful to Emeritus Prof. (Dr.) V.N. Sharma, SMS Medical College, Jaipur, for his valuable guidance.

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