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Research Article

COMPARATIVE EVALUATION OF FEW MARKETED PRODUCTS OF AMOXICILLIN TRIHYDRATE DISPERSIBLE TABLETS IP

VAMSHI KRISHNA T, GIRISH PAI K*, MOHAN SINGH, LALIT KUMAR , M SREENIVASA REDDY

Department of Pharmaceutics, Manipal College of Pharmaceutical Sciences, Manipal University, Manipal, Karnataka, 576104, India.

Email: girish.pai@manipal.edu

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ABSTRACT

Objective: The objective of the study was to carry out the disintegration test and test for uniformity of dispersion for few marketed brands of Amoxicillin Trihydrate 250 mg dispersible tablets IP.

Methods: Five different brands were randomly selected for this study, which were coded as brands A, brand B, brand C, brand D and brand E. The tests for disintegration time and uniformity of dispersion were performed as per procedure stated in British Pharmacopoeia (BP 2011) and Indian Pharmacopoeia (IP 2007).

Results: The important criteria for dispersible tablet to comply with regulatory requirements are to pass in the disintegration test and test for uniformity of dispersion. Based on the study, all the selected brands passed the disintegration test. However among the five brands only brands B & D passed for test for uniformity of dispersion, whereas rest of brands i.e., A, C & E did not comply as per pharmacopoeial specifications.

Conclusion: Based on the supporting data, brand D was found to be the best and superior among the selected brands of Amoxicillin Trihydrate 250 mg dispersible tablets.

Keywords: Dispersible Tablets, Amoxicillin Trihydrate, Disintegration Test and Uniformity of Dispersion.

INTRODUCTION

Amoxicillin Trihydrate (4- hydroxy analogue of ampicillin) is a beta-lactum antibiotic used to treat infections such as Bronchitis, Urinary tract infection, Gonorrhea, gastro-enteritis, endocarditis etc [1].

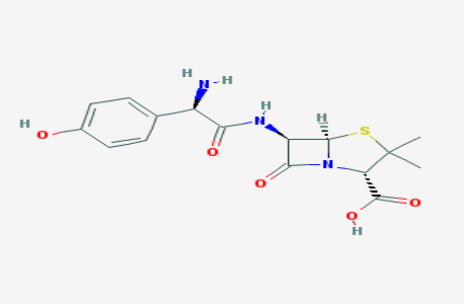

Fig. 1: Chemical structure of amoxicillin [2]

Dispersible tablets disintegrate rapidly and act fast to elicit pharmacological action. Dispersible tablets are either uncoated or film coated tablets that produce a uniform dispersion in purified water and may contain permitted flavoring and sweetening agents [3]. They are mainly intended for fast action, increased bioavailability and for those patients who cannot swallow the conventional tablets covering target patient groups like pediatric, geriatric, dysphasic, coughing and non-co-operating patients.

Choice of excipients especially disintegrants can phenomenally affect the tablet's quality attributes like disintegration time. The type of fillers or diluents and lubricants may also affect tablet disintegration time [4]. Manufacturing environmental conditions and process parameters need to be optimized as they have significant effect on disintegration of tablet. Important examples are the method of granulation (which will affect the physical properties of granules), mixing condition during addition of lubricants & anti-adherents, the applied punch force during tableting and punch force time relationship [4]. Although hardness of the tablet increases with increase in compaction force but it may either increase or decrease disintegration time or give complex relationship with maximum and minimum disintegration time. Superdisintegrants are prerequisite in dispersible tablets to ensure that these tablets are rapidly broken down into the primary particles to facilitate the dissolution or release of the active ingredients within specified time. Superdisintegrants improve disintegration efficiency resulting in decreased their use levels in formulation when compared to traditional disintegrants.

MATERIALS AND METHODS

Materials

Five different brands of Amoxicillin Trihydrate IP 250 mg dispersible tablets purchased from pharmacy shops, disintegration test apparatus, sieve no. 22, Monsanto Hardness tester, purified water (Millipore) and 100 mL beaker.

Methods

Disintegration Test

Temperature of the disintegration apparatus was adjusted to 26ºC. One tablet was introduced into each of 6 tubes of disintegration apparatus assembly without placing disc. Assembly was then suspended into the beaker containing 900 ml purified water and the apparatus was operated for 3 minutes. The assembly was then removed and checked visually for presence of any retained particles [3, 5, 6].

Test for Uniformity of Dispersion

2 tablets were placed in 100 ml of purified water and stirred gently until both the tablets are completely dispersed. A smooth dispersion

was obtained which was passed through sieve screen with a nominal mesh aperture of 710 µm (sieve number 22). There shall not be any retention of particles on sieve number 22 to comply the test [3, 5, 6].

Hardness Test

Hardness test was performed using Monsanto Hardness tester on 5 tablets of each brand. The tablet was placed in the instrument and the pressure required to completely break the tablet was noted. The average hardness of the 5 tablets was calculated. Hardness was performed for informative purpose.

Results and Discussion:

We assumed that hardness was going to have an impact on either disintegration time or uniformity of dispersion, but to our surprise in the study conducted, hardness had nothing to do with both of these parameters. For example, even though brand E had least hardness, still it failed for uniformity of dispersion. The results are shown in Table 1.

Table 1: Data for Hardness

Hardness Kg / cm²					
Brand A	7.5	8.0	7.5	7.3	7.8
Brand B	5.5	6.0	5.0	5.8	5.4
Brand C	4.0	4.4	4.5	4.9	5.0
Brand D	5.8	5.5	6.0	6.0	6.2
Brand E	3.1	2.9	3.0	3.0	3.5

Table 2: Data for Disintegration time and Uniformity of dispersion

Name of the official test/parameter	Brand A	Brand B	Brand C	Brand D	Brand E
Disintegration time	1 minute 35 seconds	1 minute 56 seconds	28 seconds	59 seconds	20 seconds
Test for uniformity of dispersion	Fail	Pass	Fail	Pass	Fail

From the above data shown in table 2, it was observed that all brands complied for disintegration test as per limit prescribed in BP 2011 (3 minutes) and IP 2007 (3 minutes). Only two brands i.e., Brands B and D passed the test for uniformity of dispersion as per specifications given in BP 2011 and IP 2007. Brands A, C & E failed test for uniformity of dispersion as few particles were observed to be retained on 22 mesh as depicted in figures 3, 4 & 5 respectively.

Fig. 2: Sieve No. 22 (Before study)

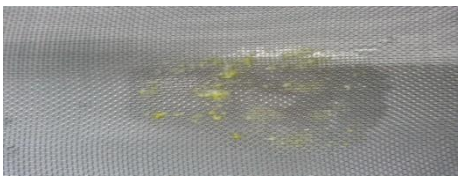

Fig. 3: Sieve No. 22 Brand A

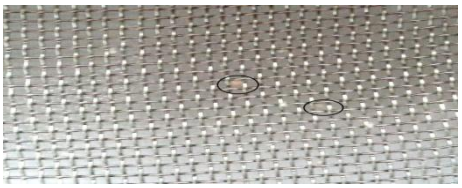

Fig. 4: Sieve No 22 (enlarged view), Brand C

Fig. 5: Sieve No. 22 (enlarged view), Brand E

The failures of brand A, C and E with respect to test for uniformity of dispersion may be due to one of the following reasons,

- Poor choice or selection of super disintegrant
- Higher concentration of binder
- Tablet hardness

CONCLUSION

All the brands selected for study, passed the test for disintegration as per BP and IP. Brand E was found to be the best with respect to its disintegration time as it disintegrated by 20 seconds, but failed for uniformity of dispersion. Only two brands i.e., B and D passed the test for uniformity of dispersion and disintegration time. Among the brand B and D, brand D was found to be superior with respect to disintegration test and test for uniformity of dispersion. To sum up, disintegration time and uniformity of dispersion of dispersible tablets depends mainly on the careful selection of super disintegrant in the formulation, proper addition of suitable binder and maintaining optimum hardness during compression process.

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