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Research Article

In vitro Comparative Study of Different Brands of Dexamethasone Tablet Available in Bangladesh

Jakaria M*, Mousa A Y, Parvez M, Zaman R, Arifujjaman, Sayeed M A, Ali M H

Department of Pharmacy, International Islamic University Chittagong (IIUC), Chittagong 4203, Bangladesh

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ABSTRACT

Dexamethasone, a steroidal drug belongs to synthetic member of the glucocorticoid class that produced anti-inflammatory as well as immunosuppressant effects. The aim of the present study was to comparative study of quality parameters such as weight variation test, hardness test, friability test, disintegration test, assay and acid-base degradation studies among the different brands of dexamethasone tablet available in Bangladesh. The *in vitro* study was done by performing various test procedures associated to assess the quality of tablets. The brands had been passed for the weight variation tests, because no tablets cross the ± 10 % weight variation. According to the test procedure by using Monsanto hardness tester, no brands of dexamethasone tablets were within the specified limit. Percentage friability of the six brands was not more than 1% and thus they met the specifications. The entire brand disintegrated within 5 minutes and thus they complied with the specifications. Except brand Dexameson, percent of assay for all brands were between ranges 90-110%. In degradation study, no brands comply with the USP specified limit that means desxamethasone was not stable in the forced degradation study. In conclusion, in the quality control parameters studies, all brands of dexamethasone tablet (except. Dexameson in assay), had shown satisfactory results.

Keywords: Dexamethasone, quality, weight variation, hardness, friability, disintegration, assay and degradation study.

INTRODUCTION

Dexamethasone (9α-fluoro-16α-methyl-11β, 17α, 21-trihydroxy-1, 4-pregnadiene-3, 20-dione) known as a synthetic member of the glucocorticoid class of steroid drugs that produced anti-inflammatory and immunosuppressant effects (Fig. 1). It is more potent than cortisol in its glucocorticoid effect, whereas having minimal mineralocorticoid effect. Regarding the WHO's list of Essential Medicines, it is one of the most important medications needed in a basic health system and used to treat many inflammatory and autoimmune conditions, such as rheumatoid arthritis and bronchospasm. Additionally, it is given in small amount before and/or after some forms of dental surgery and useful to counteract allergic anaphylactic shock, if given in high doses. It is available in certain eye drops and as a nasal spray and certain ear drops. With respect to the widespread use of the drug, developing the rapid, low cost, and reliable procedure for quantitation of it in real samples with different matrices is necessary[1,2]. The quality of pharmaceuticals is a global concern; counterfeit medicines are increasingly detected worldwide. Quality of pharmaceutical product is the most essential for efficacy and safety of product. Quality of product defines to its confining to the standards pre-set to assure the desired purpose[3,4]. Pre requirement of drug products that should be chemically and pharmaceutically equivalent, must be identical in strength, quality, purity, active ingredient release profile and also in the same dosage form, for the same route of administration. In order to ensure the requisite quality, drug manufacturers are required to test their products during and after manufacturing and at various intervals during the shelf life of the product[5,6]. It is needed to ensure that the generic and branded drugs products are pharmaceutically equivalent moreover, it also necessity to choose one product from several generic drug products of the same active ingredients[7,8]. The aim of the present study was to comparison the quality parameters such as weight variation, hardness, friability, disintegration, assay and acid-base degradation among the different brands of dexamethasone tablet available in Bangladesh.

MATERIALS AND METOHDS

Study design

Comparative *in vitro* quality control parameters between the commercially available tablet brands of dexamethasone in Bangladesh were studied through the

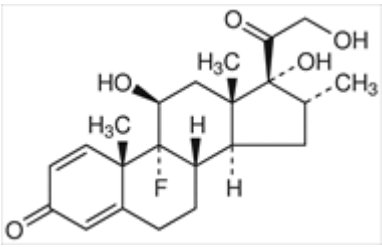

Figure 1: Chemical structure of dexamethasone

*Author for Correspondence

Table 1: Label information about sample

S. No	Brand Name	Batch No.	Mfg. Date	Exp. Date	Mfg. Lic. No	DAR No	Manufactured by
1.	Dexonex	405001	May,2014	April, 2016	33&114	012-947-50	Square pharma ltd.
2.	Steron	T0514048	June, 2014	Oct, 2016	250&115	036-162-50	ACME
3.	D-Cort	39	Apr, 2014	Aug, 2016	50 & 182	083-229-50	Globe Pharma ltd
4.	Decason	Tcj002	Oct,2014	Oct, 2017	12 & 80	025-041-50	Opsonin
5.	Dexamethason	05J13	Oct,13	Oct, 16	109 &191	096-279-50	ALBION
6.	Dexameson	06	Aug,2014	Aug, 2016	324 &153	152-61-50	Innova Pharma ltd.

Table 2: Physical appearance of different brands

S. No	Brand Name	Color	Shape and others
1.	Dexonex	White	Round, uncoated
2.	Steron	White	Round, uncoated
3.	D-Cort	White	Round, uncoated
4.	Decason	White	Round, uncoated
5.	Dexamethason	White	Round, uncoated
6.	Dexonex	White	Round, uncoated

Table 3: The weight variation limit of different brand

S. No	Brands	Average wt.	Weight variation limit
1.	Dexonex	0.08010	-3.24 to +4.49%
2.	Steron	0.1409	-3.90 to +5.03%
3.	D-Cort	0.14713	-3.01 to +4.60%
4.	Decason	0.0599	-4.50 to +2.83%
5.	Dexamethason	0.0956	-2.09 to +3.87%
6.	Dexameson	0.0878	-5.58 to +8.79%

Table 4: Average Hardness of different brand

S. No	Brands	Average Hardness (kg/f)
1.	Dexonex	2 kg/f
2.	Steron	2 kg/f
3.	D-Cort	2 kg/f
4.	Decason	2 kg/f
5.	Dexamethason	2 kg/f
6.	Dexameson	1 kg/f

Table 5: Average % of friability of different brand

S. No	Brands	Average % of friability
1.	Dexonex	0.513%
2.	Steron	0.312%
3.	D-Cort	0%
4.	Decason	0.33%
5.	Dexamethason	0%
6.	Dexameson	0.513%

evaluation of weight variation, hardness, friability, disintegration time, assay and acid-base degradation study. The study was done by performing various test procedures associated to assess the quality of the tablets.

Sample collection

Six different brands of dexamethasone produced in Bangladesh were collected from different local drug shop located in Bayezid Bostami thana in Chittagong district. All brands of dexamethasone contain 0.5 mg per tablet.

Label information about sample shown in table 1.

Instruments and Equipment

These includes

- Test-tube, Beaker, Funnel, Pipette
- Balance: Electronic precision balance, LF224DR, Shinko Denshi Co. ltd
- Friability Tester (Pharma Source)
- Hardness Tester: Monsanto
- Disintegration Tester: Digital disintegration tester (Phrama Source)
- Spectrophotometer : UV-Vis Spectrophotometer, UV mini-1240, SHIMADZU

Methodology

Weight Variation Test

Twenty tablets from each brands of dexamethasone were weighted individually with the mentioned analytical balance and average weight and the percent deviation was determined for each brand[9]. The equation for calculation of percentage weight variation is given below:

Percentage weight variation= (average weight - individual weight)/ individual weight x 100 %

Hardness Test

Tablet hardness is typically expressed as the load necessary to crushing a tablet placed on its edge and hardness is sometimes termed the tablet crushing strength. The suitability of the tablet in considers to mechanical stability during packaging and shipment can usually be predicted on the basis of hardness. The crushing strength was determined with a tablet hardness tester (Monsanto). Four tablets were randomly selected from each brand for this test[10,11].

Friability Test

The experiment was started by weighing 10 tablets altogether which is considered as the initial weight, W1. All the tablets placed in the drum of friability tester and the equipment was rotated 100 rpm for 4 min (i.e. = 25 rpm for 1 min). Then the tablets were taken out, deducted, and reweighed (only the intact ones). This is considered as the final weight, W2. Then the percentage loss of weight of the tablets was calculated by using following equation[10].

Percentage friability= {(Initial weight- Final weight)/ Initial weight} x100

Disintegration Test

Tablet disintegration was determined in the tablet disintegration tester. Six tablets from each brand were

Table 6: Disintegration time of dexamethasone tablet

S. No	Brands	Average disintegration test
1.	Dexonex	3 min
2.	Steron	3 min 1 sec
3.	D-Cort	3 min 8 sec
4.	Decason	3 min
5.	Dexamethason	48 sec
6.	Dexameson	36 sec

Table 7: Percent of the assay of brand with standard dexamethasone

S. No	Brands	% of assay with standard
1.	Dexonex	93.68%
2.	Steron	97.78%
3.	D-Cort	100%
4.	Decason	93.68%
5.	Dexamethason	95.73%
6.	Dexameson	82.59%

Table 8: Effect of acidic pH

S. No	Brands	% Assay
1.	Dexonex	21.24%
2.	Steron	59.04%
3.	D-Cort	27.68%
4.	Decason	31.96%
5.	Dexamethason	21.69%
6.	Dexameson	18.40%

Table 9: Effect of basic pH

S. No	Brands	% Assay
1.	Dexonex	22.27%
2.	Steron	24.69%
3.	D-Cort	33.19%
4.	Decason	34.70%
5.	Dexamethason	33.19%
6.	Dexameson	24.51%

employed for the test in distilled water at 37°C using disintegration Apparatus. The disintegration time was taken to be the time no particle remained on the basket of the system[11].

Assay

The weight of ten (10) tablets from each sample brand was taken singly and then the average weight determined. Each of the samples was crushed using the mortar and pestle, the required amount of the sample needed was weighed. Methanol (MeOH) was prepared and poured into a 500 ml volumetric flask. 50 ml volumetric flasks were used to put the different samples and each flask was labelled appropriately. Small amount of the prepared methanol was then added and made up to the 50 ml mark in each flask. The solutions were sonicated for 15min using a sonicator and then filtered to get a clear solution. 2.5 ml of the filtrate was withdrawn from each volumetric flask using a 5ml pipette, poured into a new 50 ml conical flask and made up to the 50ml mark. Small amount was taken from each flask and put into a cuvette. The same procedure was then repeated for the standard dexamethasone. The absorbance was taken using the UV-spectrophotometer at a wave length of 238 nm^2. The percentage content and milligram content of each of the samples was then determined and compared with the standard. The % of the assay calculated by following formula,

% of the assay= (Absorbance of Brand/Absorbance of Standard) x100

Acid-base degradation study

For Acid: To study the effect of acid, 5 ml of 10 ppm solution of each brand was taken in four separated test tubes, then 5ml of 0.1N HCl was added in each test tube. They were then left for a period of 30 minutes. Upon completion of the time period, solutions were transferred to a cuvette separately and then absorbance of the solutions was recorded at the wavelength of 238 nm[12-15].

For Base

To study the effect of base, 5 ml of 10 ppm solution of each brand was taken in four separated test tubes, then 5 ml of 0.1N NaOH was added in each test tube. The samples were then left for a period of 30 minutes. Upon completion of the time period, solutions were transferred to a cuvette separately and then absorbance of the solutions was recorded at the wavelength of 238 nm[12-15].

RESULTS AND DISCUSSION

The physical appearance of different brands of dexamethasone shown in table 2.

Weight Variation Test

Weight variation of tablets is an important in-process control evaluation. The specification of this test is given in different pharmacopeias. The weight of a tablet being compressed is determined by the amount of granulation in the die prior to compression. For that reason, anything that can alter the die filling process can alter the tablet weight and weight variation. Result of weight variation shown in table 3. According to the BP, the limit of weight variation test were, the average weight 130 mg or less the percentage difference should be ±10, more than 130 percentage differences should be ±7.5 and 324 mg and above percentage difference should be ±5. Regarding to the experimental result, average weight of all brands were less than 130 mg along with the percentage of differences comply with the limit ±10.

Hardness Test

Hardness denotes the capability of a tablet to withstand mechanical shocks during handling in manufacturing, packaging and shipping. Tablet hardness, in turn, influences tablet density and porosity. It may affect tablet friability and disintegration time. It usually affects the drug dissolution and release and it may affect bio-availability. The acceptable range of hardness or crushing strength of tablet is 4 to 7 kgf (kilogram of force)[14]. For both of the formulations, five tablets of each brand were taken and hardness of the tablets was determined. Regarding the results, average hardness for each brand was between 1 and 2 kg/f (Table 4). According to the limit for Monosanto hardness tester, no brands of dexamethasone comply with the specified limit.

Friability Test

Friability is a tendency of the tablet to crumble. It is important for the tablet to resist attrition. For the duration of manufacturing and handling, tablets are subjected to stresses from collision and tablet sliding towards one another and other solid surfaces, which can result in the removal of small fragments and particles from the tablet surface. Usally, friability test is performed to evaluate the ability of the tablets to withstand abrasion in packing, handling and transporting. In this friability test, all brands showed impressive friability values. The friability values for dexamethasone tablet brands were ranged from 0 to 0.64%. For all brands, the percent (%) friability was less than 1% which ensures that all the tablets of each brand were mechanically stable (Table 5)[10].

Disintegration Test

A drug to be absorbed from a solid dosage form after oral administration, it must be in solution, and the first important step towards this condition is usually the break-up of the tablet, it is well-known as disintegration. Simply, disintegration is the break down process of tablet into smaller particles and is the first step towards dissolution. The disintegration test is a measure of the time required under specific conditions for a group of tablets to disintegrate into particles which will pass through a 10 mesh screen. In general, the test is useful as a quality assurance tool for conventional dosage forms. The rate of drug absorption as well as the therapeutic efficacy of the drug is dependent upon the disintegration time. If the disintegration time is not perfect we cannot state that effectiveness of the drug is good. The standard disintegration time for USP uncoated tablet must be as low as 5 minutes but majority of the tablets have a maximum disintegration time of 30 minutes. All brands comply with this limit (Table 6).

Assay

This study was carried out to quantify the various brands of dexamethasone tablets marketed in Bangladesh and to ascertain whether they are of the standard specified in the official compendiums. According to BP it should be 90-100%. From our evaluation except Dexameson, all brands of dexamethasone comply with this limit (Table 7)[2].

Acid-base Degradation Studies

The purpose of degradation studies is to investigate those changes, to get a shelf life of the drug product and to recommend storage conditions, which will be applicable to all future batches of the tested drug product manufactured and packaged under similar circumstances. In our study, we used UV spectrometry to investigate the degradation of dexamethasone and the limit of the assay by USP specified that the content should not be less than 95% and not more than 105% of labeled amount. According to USP specified limit, no brand of dexamethasone comply with this USP specified limit (Table 8 & 9)[12-15]. In this study, it was observed that in most case the all brands had been passed. For example, in weight variation test all the tablets have passed. Because of Monsanto hardness suitable for large size tablet but dexamethasone was a smaller in size. So, no brands had been passed in hardness test due to experimental procedure. All brands also passed for friability tests. Disintegration time of the tablets was under acceptable range. The percentage of assay also accepted for all brands (except Dexameson) but acid-base degradation studies all brands were mostly degraded. As all drugs substances are life saving so both overdose and sub therapeutic dose of the drug is risky for the patients. As a result, more care should be given by the pharmaceutical company during the production along with marketing of pharmaceutical products because pharmaceutical companies are dealing with the life of human. This study might helpful to the further research of dexamethasone.

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