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In-vitro evaluation of two marketed brands of dexamethasone tablets IP as per Indian pharmacopoeia

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Abstract
The ability of a dosage form to deliver the medicament at the site of action is the most important parameter in order for a drug to show the desired action. The quality of a dosage form is quite important as it determines the safety and efficacy of the active constituent present in it. The method of preparation of a dosage form varies from manufacturer to manufacturer hence it can be assumed that their efficacy is likely to be varied. The present study was carried out in order to evaluate the quality of two brands of Dexamethasone Tablets IP 0.5 mg available commercially whether they qualify the entire test as mentioned in Indian Pharmacopoeia which there by suggests their quality and efficacy for use among the population. The study was exclusively experimental that used Indian Pharmacopoeia 2014 to check the *in vitro* quality of Dexamethasone Tablets IP using different analytical techniques and procedure. All the two brands under the study were within the specification for weight variation test for tablet. The test for Assay and uniformity of content carried out by High Performance Liquid Chromatography using U-HPLC System (Thermo- Dionex) equipped with an UV detector and stainless steel column (20cm × 5mm) packed with octadecylsilane chemically bonded to porous silica. Identification test was done by infrared absorption spectrophotometry, by comparing the spectrum with that obtained with Dexamethasone RS. The present research work indicated that two different brands which were examined did not show much difference in their results and they were found to be within the acceptance limits.

Keywords: dexamethasone, Indian pharmacopoeia, quality control

Introduction
The importance of good manufacturing practices (cGMP) for establishing the quality of pharmaceutical products has emerged as a very significant issue. In the manufacturing process of a pharmaceutical product quality control test plays a very significant role, it includes various parameters for eliminating or preventing every possible error for maintaining the quality of finished product. Quality as per ISO 8402-1986 is best defined as "the totality of features and characteristics of a product or service that bears its ability to satisfy as stated or implied needs [1]". In process and Finished product quality control tests are done to measure the efficiency of the product before they get released commercially. On completion of the manufacturing process of finished product, quality control tests are done with reference to qualitative and quantitative characteristics. The compliance of the approval limits of the finished product during its entire shelf life is studied. Pharmacopoeias are standard monograph for all drugs. There are various official pharmacopoeias in which includes the Indian Pharmacopoeia (IP), United States Pharmacopoeia (USP), British Pharmacopoeia(BP), European Pharmacopoeia (EP), wherein they have laid down specified limits within which the product should fall to fulfill the requirements in order to be compliant as per the standards [2].

Dexamethasone is a synthetic adrenocortical steroid and is chemically designated as 9-fluoro-11β, 17, 21-trihydroxy-16α-methylpregna-1, 4-diene, 3, 20- dione. The drug is 25 times more potent than cortisol in its glucocorticoid effect, while having minimal mineralocorticoid effect. It has anti-inflammatory and immunosuppressant effects and is used for the treatment of many conditions including rheumatologic problems, a number of skin diseases such as erythema multiforme, severe allergies, asthma, chronic obstructive lung disease, croup, cerebral edema, in addition to other medications in tuberculosis and a number of other infectious diseases. However, it is characterized by a low water solubility (0.08 mg/ml at 25°C) and consequently low and irregular bioavailability. Also the therapeutic efficacy has been questioned with regard to its short half-life, potential toxicity at high doses (Foster *et al*., 2006). Therefore, some advanced delivery systems of drug need to be developed [3, 4, 5].

The main objective of this research work is to evaluate the quality of two brands of Dexamethasone Tablets I.P 0.5 mg marketed in North East region of India, in order to verify whether these products complies with the standard or not. The Indian Pharmacopoeia is an official document meant for overall Quality Control and Assurance of Pharmaceutical products marketed in India published by the Indian Pharmacopoeia Commission (IPC) on behalf of the Ministry of Health & Family Welfare, Government of India. The Indian Pharmacopoeia provides standards for drugs manufactured/ marketed in India to control as well as assure the quality of medicines.

Table 1: List of Commercial Brands of Dexamethasone Tablets IP 0.5 mg

Product code	Batch No.	Manufacturer	Mfd date	Exp date
A	BET1225	Cadila Health Care Limited	06/2017	05/2020
B	31Q0041	Wockhardt Limited	04/2016	03/2019

Materials and methods

In this study the active pharmaceutical ingredient (API), Dexamethasone was obtained from M/S Regent Biotech. We have procured two commercial brands of Dexamethasone Tablets IP 0.5 mg from retail pharmacies located in Guwahati and they are listed in table 1.

Quality control parameters

Identification Test

Reversed phase High Performance Liquid Chromatography (HPLC) was used for carrying out the identification test on U-HPLC System (Thermo- Dionex) autosampler integrated with UV detector. The software employed was Chromeleon chromatography data system [9].

Assay

The assay was also carried out by HPLC. This test was done to determine the actual amount of active ingredient present in the tablet and its compliance with the labeled amount. The chromatographic conditions maintained throughout the procedure were a stainless steel column (20cm × 5mm) packed with octadecylsilane chemically bonded to porous silica (5µm). The mobile phase is a mixture of 53 volumes of HPLC grade water and in the other channel 47 volumes Methanol (Fischer Scientific) is used. The mobile phase was pumped into the system at a flow rate of 1.4ml per minute with Spectrophotometer wavelength set at 238nm and injection volume of 20µl. The mobile phase prior to use was degassed under vacuum by filtration through 0.2µ nylon membrane [6].

Preparation of Reference solution

Dexamethasone working standard (WS) equal to 10.5 mg was accurately weighed and dissolved in 50ml of methanol (50 percent) further 5ml was diluted to 10ml with the same solvent to get a final concentration of 105 µg/ml. The prepared solution was sonicated for 10 minutes making final concentration equivalent to 105mcg and filtered through 0.45µm filter [6].

Preparation of Test solution

Of all the two batches 20 tablets of each batch were weighed separately and powdered. An accurately weighed powder containing 2.5 mg of Dexamethasone was transferred to 20ml volumetric flask with addition of mobile phase as diluent. The prepared solution was sonicated until complete mixing and filtered through 0.45µm filter [6].

Uniformity of Content

This test is done on tablets containing 10mg or less or in the case of tablet having enteric coated as described under assay following the same chromatographic conditions. Amongst the two batches ten tablets of each batch were checked for uniformity of content [6].

Preparation of Reference solution:

dexamethasone working standard (WS) equal to 12.5 mg was accurately weighed and dissolved in dissolved in 50ml of methanol (50 percent) further 5 ml was diluted to 50ml with the same solvent. The prepared solution was sonicated for 10 minutes making final concentration equivalent to 25mcg and filtered through 0.45µm filter [6].

Preparation of Test solution

Test solution was prepared by dispersing 1 tablet in 25 ml of methanol (50 percent) [6].

Results and discussion

Identification Test

This test was found to be in compliance with the criteria mentioned in I.P. which was determined by infrared absorption spectrophotometry, by comparing the spectrum with that obtained with Dexamethasone RS.

Assay

In this test the determination of actual amount of active ingredient present in the formulation was found to be within the acceptance limit of (90-110) % in all the two different brands of Dexamethasone tablets IP under study and are listed in Table 2. Figures 1, 2 and 3 show the chromatograms of standard Dexamethasone and tested Dexamethasone tablets obtained from HPLC.

Uniformity of Content

The test for uniformity of content carried out for two different brands were in compliant with the I.P. limit of (85-115) % of average weight and listed in Table 3.

Table 2: Results of Assay of the two brands of Dexamethasone Tablets IP 0.5 mg

Product code	Batch No.	Identification (HPLC)	Assay (HPLC)
A	BET1225	Complies	94 (90-110) %.
B	31Q0041	Complies	105.80 (90-110) %.

Table 3: Results of Content Uniformity of the two brands of Dexamethasone Tablets IP 0.5 mg

Sl. No.	BET1225	Sl. No.	31Q0041
Tablet 1	98.4	Tablet 1	97.00
Tablet 2	92.08	Tablet 2	96.40
Tablet 3	98.27	Tablet 3	92.19
Tablet 4	96.65	Tablet 4	100.39
Tablet 5	97.31	Tablet 5	94.46
Tablet 6	88.46	Tablet 6	99.47
Tablet 7	101.98	Tablet 7	96.25
Tablet 8	91.82	Tablet 8	93.95
Tablet 9	100.50	Tablet 9	90.24
Tablet 10	93.95	Tablet 10	99.77
Average-95.94% Limit-(81.55-110.33) %		Average-96.01% Limit-(81.60-110.41)%	

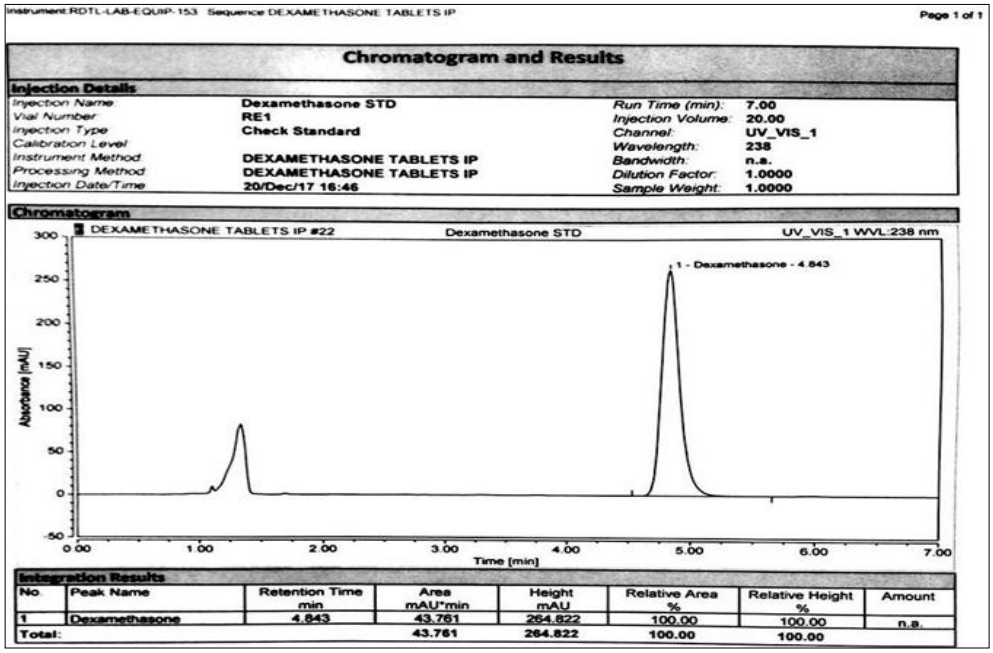

Fig 1: Chromatogram of Dexamethasone RS

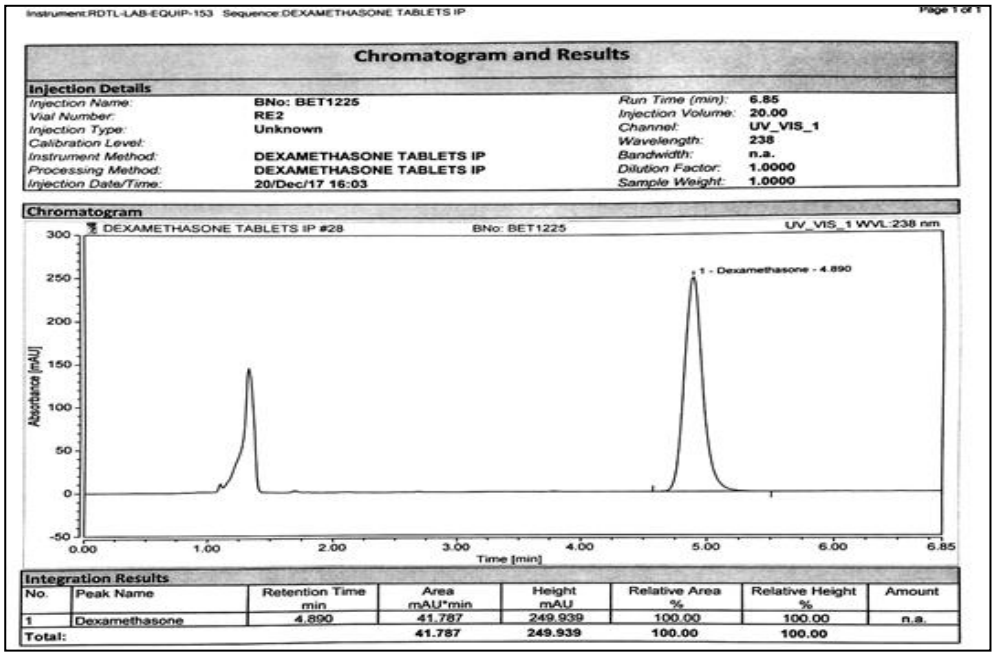

Fig 2: Chromatogram of Dexamethasone Tablets IP 0.5 mg

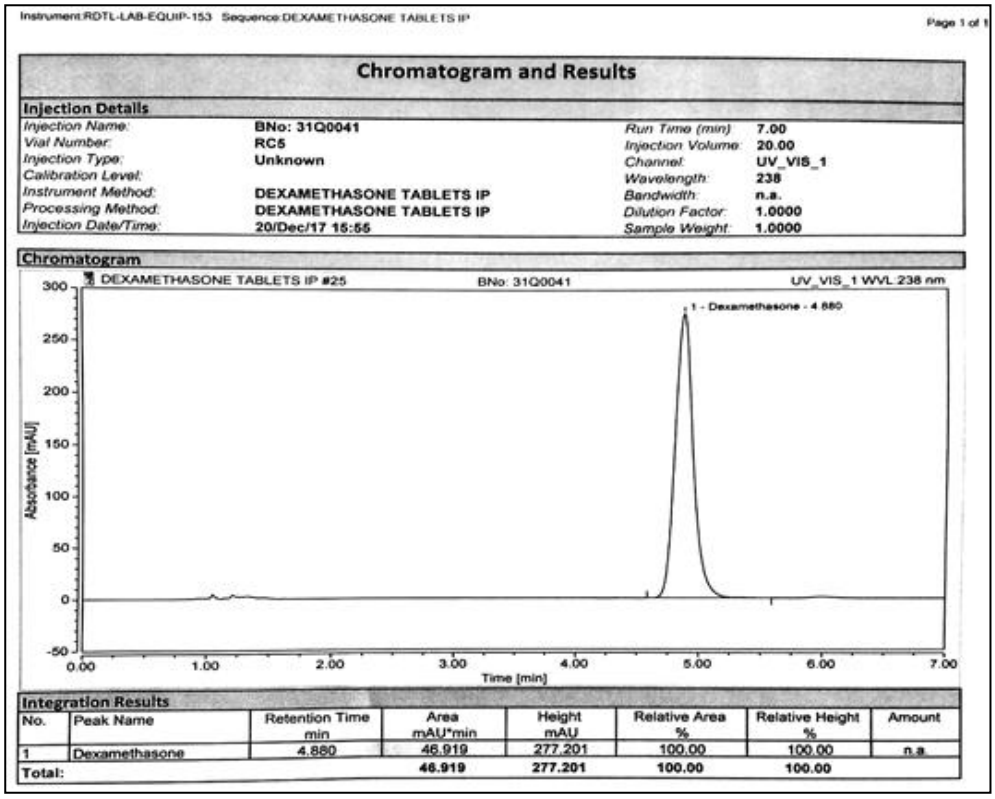

Fig 3: Chromatogram of Dexamethasone Tablets IP 0.5 mg

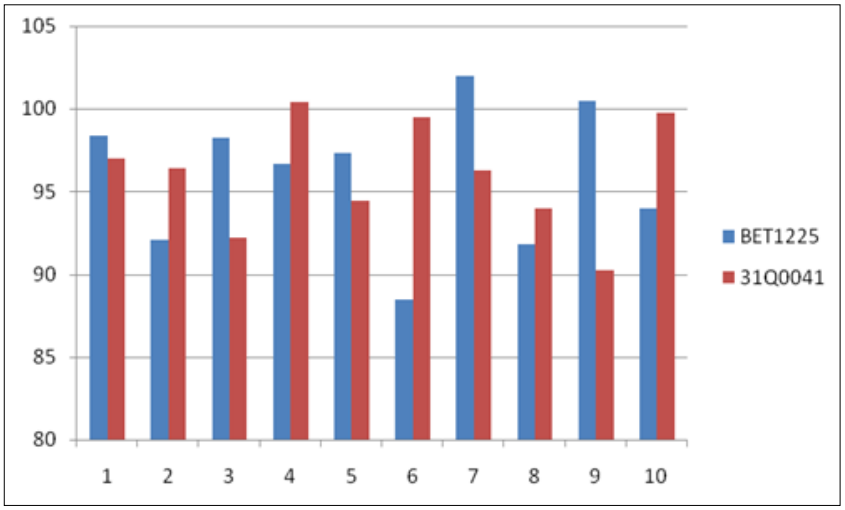

Fig 3: Comparative results of Content Uniformity of the two brands of Dexamethasone Tablets IP 0.5 mg

Conclusion

The qualitative analysis as given in the monograph of Dexamethasone tablets IP in Indian Pharmacopoeia were performed using different analytical methods and were found to meet the requirements in all respects All the brands have passed all the official tests prescribed by Indian Pharmacopoeia (IP). Formulation additives in the tablet, physical form of the drug used in the tablet and manufacturing processes vary from manufacturer to manufacturer which is responsible for the variation in the observed dissolution profiles. All two brands under study were evaluated for test of identification, assay, content uniformity and dissolution and their comparative results in the entire test conform with the limits as given under acceptance criteria. Hence it is concluded that the main aim behind this research work was to check that whether various brands of different pharmaceutical companies available in Northeast region of Indian market align with the acceptance criteria and also that two brands can be substituted for one another in terms of quality depending upon their availability.

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