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Pharmaceutical Equivalent Dissertation of Fexofenadine Hydrochloride Brands

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ABSTRACT
Fexofenadine Hydrochloride is a piperidine derivative. It is indicated to relieve signs and symptoms that are related with seasonal allergic rhinitis, such as rhinorrhea, sneezing nose, throat and itchy eyes. The aim of study is to establish pharmaceutical equivalence of different brands of Fexofenadine HCl 60 mg film coated tablets available in Karachi, Pakistan. The quality control parameters which are studied are weight variation test, diameter, thickness, disintegration, dissolution and assay specified by British and United State Pharmacopoeia. One-Way ANOVA was applied and results were assessed. Weight variation, Diameter, Thickness and Dissolution results was found to be highly significant among different brands of Fexofenadine Hydrochloride. Weight variation and hardness value requirement was complied by all brands. Disintegration time for all brands was within range i.e. 30 minutes and also complies with the BP/USP recommendation. All brands showed more than 90 % drug release within 45 minutes. The present conclusion suggests that almost all the brands of Fexofenadine Hydrochloride that are available in Karachi meet the specification for quality control analysis. The results of dissolution and assay performed by UV-Spectrophotometer are within specifications and a linear relationship was found between different brands.
Key words: *Fexofenadine Hydrochloride, Quality Control Evaluation, Assay, UV-Spectrophotometer.*

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INTRODUCTION

Molecular Formula: $C_{32}H_{39}NO_4$

Molecular Weight: **501.65636 g/mol**

Fexofenadine hydrochloride (FEX) (Figure 1) (RS)-2-[4- [1-Hydroxy-4-[4-(hydroxy-diphenyl-methyl)-1-piperidyl] butyl]phenyl]-2-methyl-propanoic acid is used to relieve the allergy symptoms of seasonal allergic rhinitis (hay fever), including runny nose; sneezing; and red, itchy, or watery eyes; or itching of the nose, throat, or roof of the mouth in adults [1, 2]. It is carboxylic acid metabolite of terfenadine, a nonsedating selective histamine H1 receptor antagonist. This drug contains an asymmetric carbon in its chemical structure and is administered clinically or is used as a P-glycoprotein probe as a racemic mixture of R- and S-enantiomers [3, 4].

Fexofenadine is a second-generation, long lasting H1-receptor antagonist (antihistamine) which has a selective and peripheral H1-antagonist action. Histamine is a chemical that causes many of the signs that are part of allergic reactions, such as the swelling of tissues. Histamine is released from histamine-storing cells (mast cells) and attaches to other cells that have receptors for histamine. The attachment of the histamine to the receptors causes the cell to be "activated," releasing other chemicals which produce the effects that we associate with allergy. Fexofenadine blocks one type of receptor for histamine (the H1 receptor) and thus prevents activation of cells by histamine. Unlike most other antihistamines, Fexofenadine does not enter the brain from the blood and, therefore, does not cause drowsiness. Fexofenadine lacks the cardiotoxic potential of terfenadine, since it does not block the potassium channel involved in repolarization of cardiac cells [4].

Fexofenadine HCl is biopharmaceutical classification system type II as it possesses low solubility and high permeability.

Fexofenadine HCl is a non-sedating anti- histamine drug indicated for the symptomatic relief of symptoms associated with rhinitis, urticarial and allergic skin conditions [5]. Fexofenadine is used as hydrochloride

salt and the probability that cardio toxic effects occur in connection with Fexofenadine is assessed as being extremely low when compare to other anti-histamines. Besides, Fexofenadine may improve a safer alternative in the treatment of asthma and atopic dermatitis and is rapidly absorbed with a long duration of action, making it suitable for once daily administration as its half life is about 14 hrs.[6]
Literature survey reveals that fexofenadine hydrochloride is estimated individually or in combination with other drugs by UV spectrophotometry [7-9], RP-HPLC [10–12], HPTLC [13, 14], in biological fluid by RP-HPLC [15–17], LC/MS [18], LC/MS/MS [19, 20], and stability indicating method [21].

MATERIALS AND METHOD

The increasing level of use of Fexofenadine Hydrochloride develops a need to monitor the quality for the assessment of its quality control parameters of the various brands of Fexofenadine Hydrochloride tablets that are available in the market. The objective of this study was to determine the physical and chemical properties of four different Fexofenadine Hydrochloride tablets brands marketed in Karachi. These tablets were evaluated by official and non-official standards like weight variation, the thickness, the diameter, the disintegration with the specifications of British Pharmacopoeia while dissolution and Assay with the specifications of United State Pharmacopoeia.
Fexofenadine Hydrochloride, the film coated tablets, having a label strength of 60mg. Different brands were purchased from market in Karachi and the study was performed within product expiration dates.
The SPSS one-way Anova was applied on the data that we obtained from these parameters and assessed.

1. ***UNIFORMITY OF WEIGHT***:

The sample of the tablets of each brand were weighed together and by using weighing balance (Electronic Balance,Model No.FX-400), average weight was determined. The weight variation of the 20 tablets was conducted from each brand as per specification and the results were recorded.

2. ***THICKNESS***:

The thickness from individual brand on 10 tablets was measured and also average thickness of tablets of each brand by using vernier caliper and the results were recorded.

3. ***DIAMETER***:

Diameter was determined of 10 tablets of each brand by using vernier caliper and also the results of average diameter of tablets of each brand was recorded.

4. ***DISINTEGRATION TEST***:

The disintegration test was performed on 6 tablets from individual brand as per procedure and specification. The disintegration time of 6 tablets of individual brand was determined at 37^{o}C in distilled water using Tablet Disintegrator of Curio Apparatus. The time of disintegration was taken to be the time when any of the granule of tablet was left on the mesh.

5. ***DISSOLUTION TEST***:

The dissolution test was conducted by the use of basket apparatus as per procedure specified in United State Pharmacopoeia on tablets from individual brand. This was determined by using a Tablet Dissolution Apparatus II i.e. Paddle Type (GDT-7L from Galvano Scientific) containing 900 ml of 0.001N HCl maintained at 37^{o}C with a speed of 50rpm. All tablets were put from each brand in each of the compartments and the machine was fixed operated at the intervals of 5, 10, 15, 30 and 45 minutes. In all the experiments, at specified intervals, 10ml of the sample was taken. Absorbance of each of the withdrawn sample at 220nm was determined by using UV-visible spectrophotometer. The concentration of Fexofenadine Hydrochloride tablets present in the samples were determined according to the specified monograph of Fexofenadine Hydrochloride in the USP.

6. Assay by UV-Spectrophotometer:

The UV-Spectrophotometer was used for Assay analysis. As Fexofenadine Hydrochloride is freely soluble in methanol and ethanol therefore for determining the content uniformity, ten tablets were weighed and powdered. The powder equivalent to 10 mg of FXD was extracted into methanol and liquid was filtered (Whatman No. 1 filter paper) and solutions of different concentrations were prepared i.e. 200ppm, 100ppm, 50ppm, 25ppm, 12.5ppm, 6.25ppm, 3.125ppm and 1.5625ppm and the solutions were analysed at the absorbance of 219nm.

RESULTS AND DISCUSSIONS

Fexofenadine Hydrochloride is a piperidine derivative. It relieves the signs and symptoms which include the seasonal recurrent rhinitis, for instance rhinorrhea, sneezing, nose. Throat and itchy eyes. The present research is specifically based on developing a liquid chromatographic method to determine the Fexofenadine in tablets and the dissolution method by UV/VIS spectrophotometer was also developed. Lichrosper 10µm (C18) column was used for the development and the mobile phase is composed of acetonitrile-5mM ammonium acetate buffer (50:50, v/v) pumped at a flow rate of 1ml/min.The UV

detector was operated at 254nm. This method was suitable for the sustainability of system, its accuracy/retrieval, system precision, method precision, its ruggedness and sturdiness, detection limit and quantitation limit. In the same way, different concentrations of standard and sample solutions were prepared which are i.e. 65µg/ml, 35µg/ml, 17.5µg/ml, 8.75µg/ml and 4.375µg/ml for the dissolution method. Consequently, it was concluded that the proposed HPLC method was easy, specific but detailed and less time consuming. In addition, the linearity of the dissolution was found to be suitable and acceptable as well. The correlation coefficient of standard solutions was 0.9979 similarly the correlation coefficient of model solutions was 0.9963 [22].

An effective spectrophotometric method was developed which authenticated the quantitation of antihistamine fexofenadine in capsules and coated tablets. The solvent which was used was Ethanol and the wavelength of absorbance was at 220nm which was employed to the quantitation of the drug. The evaluation of the analytical parameters of linearity, precision, accuracy, limits of detection, and quantitation and specificity fulfilled the method authentication. The method was found to be linear (r=0.9999) at concentrations ranging from 8.0 to 20.0 µg ml ^{1}, precise (RSD intra-day=0.29; 0.18; 0.39; RSD inter-day=0.12 for capsules and RSD intra-day=0.13; 0.16; 0.13; RSD inter-day=0.13 for coated tablets), accurate (percentage recovery=99.97% for capsules and 100.51% for tablets), sensitive (limits of detection and quantitation of 0.10 and 0.29 µg ml ^{1}, respectively) and specific. Moreover, the method was also compared with the high performance liquid chromatography, the method previously developed for the same drug. However, the results showed no substantial differences between the methods in quantitation [23].

A simple RP-HPLC method was developed using a PDA detector which was used to validate the analysis and dissolution of (FEX) in dosage forms. Mobile phase: triethylamine phosphate 1%, pH 3.2: acetonitrile (ACN): methanol (50: 30: 20), 210 nm detection, C_{18} Phenomenex® column. The validation of the method was based on the parameters including regarding accuracy/precision (RSD < 1%), linearity (r^2 = 0.9999), and robustness. Moreover, the method was found to be suitably applied to the determination of the drug in commercial tablet preparation and was found to be fast and consistently reliable for quantification and it was also compared with the dissolution profiles of FEX tablets. When using f_2 factor as a comparisons parameter no any medium showed any difference in formulation other than HCL 0.1 formulation which exhibited similar results for the parameters f_1/f_2 and DE allowing to affirm that the two formulations are similar and with the same performance *in vivo* [24].

The research study is based on the formation and authentication of dissolution test for capsules and coated tablets and the method used for it was HPLC. The suitable conditions were determinate after testing sink conditions, dissolution medium and agitation intensity. The apparatus which were applied to tablets and capsules were paddle and basket. capsules, products A and B, and coated tablets, products A, B and C were evaluated.The best dissolution conditions tested, for the products in each respective pharmaceutical dosage form were applied to evaluate the dissolution profiles. Different and similar factors and dissolution efficacy were the parameters which were employed. The optimal conditions to carry out the dissolution tests were 900 ml of 0.01 M hydrochloric acid as dissolution medium, basket at 100 rotation per minute (rpm) stirring speed for capsules and paddle at 75 rpm for tablets.However, the dissolution profiles for tablets products A, B, c and for capsules product were different. It was shown that the developed and validated dissolution tests satisfactorily describes the time-course of the drug release. The results that were achieved showed adequate dissolution profiles and proved that the HPLC method was validated [25].

An easy and simple high-performance thin layer chromatographic method was developed to determine the Fexofenadine Hydrochloride (FEX) and montelukast sodium (MTKT) at the same time in dosage form. . The separation was carried out on Merck HPTLC aluminum plates of silica gel G60 F254, (20×10 cm) with 250 µm thickness using toluene: ethyl acetate: methanol: ammonia (30%) (0.5: 7: 2: 0.5, v/v/v/v) as mobile phase. Moreover, at the absorbance mode of 220nm, HPLTC separation of the two drugs were carried out which were followed by densitometric measurement. The drugs were resolved satisfactorily with Rf values of 0.21±0.01 and 0.59±0.01 for FEX and MTKT, respectively.. The linear regression analysis data for the calibration plots showed good linear relationship with r2 = 0.9996 and 0.9998 for FEX and MTKT, respectively, in the concentration range of 2400–10800 ng spot 1 for FEX and 200–900 ng spot 1 for MTKT. The method was validated for precision, robustness, specificity, and accuracy. However, the limitations of quantitation and detection were 100 100 and 300 ng spot 1, respectively, for FEX and 50 and 100 ng spot 1, respectively, for MTKT. Consequently, this developed HPLC method can be applied for identification and quantitative determination of FEX and MTKT in bulk drug and drug formulation [26].

The results of the physicochemical parameters of four brands of Fexofenadine Hydrochloride film coated 60mg tablets were discussed. The three brands i.e. FEX-02, FEX-03 and FEX-04 compared with the multi-

national brand used as standard i.e. FEX-01*. The assessments involved evaluation of weight variation, thickness, diameter, disintegration, dissolution studies Assay evaluation.

Table 1 of weight variation shows the different brands averages and standard deviation. We use standard deviation against average weight of tablets for comparison and more accuracy. The tablets of brand 3 i.e. FEX-03 have high values of standard deviation while the tablets of brand 2 i.e.FEX-02 have low values of standard deviation. The results of weight variation for all the brands gave values which complied with B.P. Specifications for weight uniformity as none of the brands deviated from the mean value by up to ±10%.

Diameter and Thickness was measured and evaluated of 10 tablets of each brand and the average diameter and thickness with their standard deviation values were recorded in Table 2 of diameter and table 3 of thickness that shows that the brand that is used as a standard i.e. FEX-01* have lower standard deviation values of thickness and brand 3 i.e. FEX-03 have lower values of standard deviation of diameter while brand 3 i.e. FEX-03 have high values of standard deviation of thickness and brand 2 i.e. FEX-02 have high values of standard deviation of diameter. The disintegration results of Table 4 showed that all the brands passed the disintegration test as per British Pharmacopeia (BP 2007) that specifies 30 minutes for film coated tablets. According to the monographs of B.P. for each of the tablets tested for dissolution, the active ingredient amount in solution is not less than 80% of the stated amount. Disintegration test is an important step in drugs release from immediate release dosage forms. The rate of disintegration is directly related to the rate of dissolution. The results obtained from the dissolution studies stated in Table 5 of Dissolution revealed that all the brands passed with the standards of B.P. for conventional release tablets.

Therefore it can be evaluated that all of the four brands determined in this study have shown good results and in range in all of the physicochemical comparison and assay of different brands of the generic i.e. Fexofenadine HCl.

Table 1: **Weight variation of different Brands**

SERIAL No.	Average Weight	S.D
FEX-01*	203.10	2.644
FEX-02	211.50	2.635
FEX-03	167.20	3.458
FEX-04	306.30	3.164

Table 2: **Diameter of different Brands**

SERIAL No.	Average Diameter	S.D
FEX-01*	5.230	0.1567
FEX-02	5.520	0.2150
FEX-03	5.300	0.1054
FEX-04	9.33	0.1947

Table 3: **Thickness of different Brands**

SERIAL No.	Average Thickness	S.D
FEX-01*	3.3	0.1247
FEX-02	3.59	0.1370
FEX-03	3.05	0.527
FEX-04	3.34	0.1174

Table 4: **Disintegration of different Brands**

SERIAL No.	Code No.	Batch No.	Disintegration Time	Official Limits	Comments
FEX-01*	025526	29046XV	2.23	Not more than 30min	Within specified limit
FEX-02	021783	WL165	3.96	Not more than 30min	Within specified limit
FEX-03	000552	4206	3.17	Not more than 30min	Within specified limit
FEX-04	005310	BF573	7.48	Not more than 30min	Within specified limit

Table 5 : ***Dissolution*** **of different Brands**

Serial No.	5min	10min	20min	30min	45min	% Dissolution of 45min at 220nm
FEX-01*	1.658	1.868	1.977	2.078	2.220	100%
FEX-02	1.444	1.729	1.952	2.064	2.125	95.72%
FEX-03	1.652	1.866	1.972	2.075	2.118	95.40%
FEX-04	.944	1.476	1.868	1.953	2.061	92.83%

Table 6 : Assay Of Different Brands

Serial No.	200ppm	100ppm	50ppm	25ppm	12.5ppm	6.25ppm	3.125ppm	1.5625ppm	% Assay of 200ppm at 219nm
FEX-01*	3.16	2.86	2.11	1.47	.58	.27	.12	.04	100%
FEX-02	3.02	2.61	2.00	.94	.46	.21	.09	.02	95.56%
FEX-03	3.15	2.82	2.07	1.42	.58	.29	.12	.02	99.68%
FEX-04	3.11	2.78	2.10	1.21	.49	.29	.15	.06	98.41%

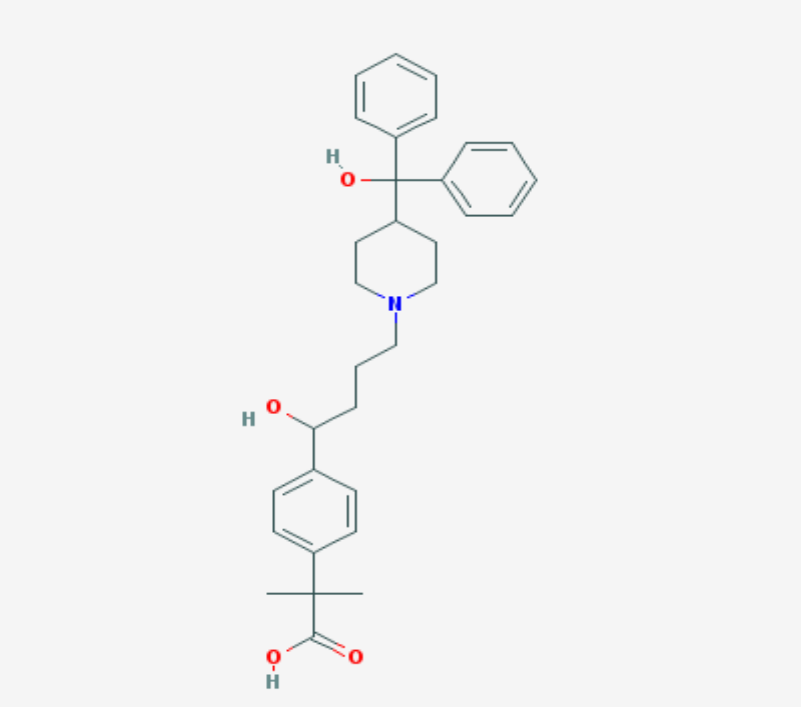

Figure 1: STRUCTURE OF FEXOFENADINE[1]

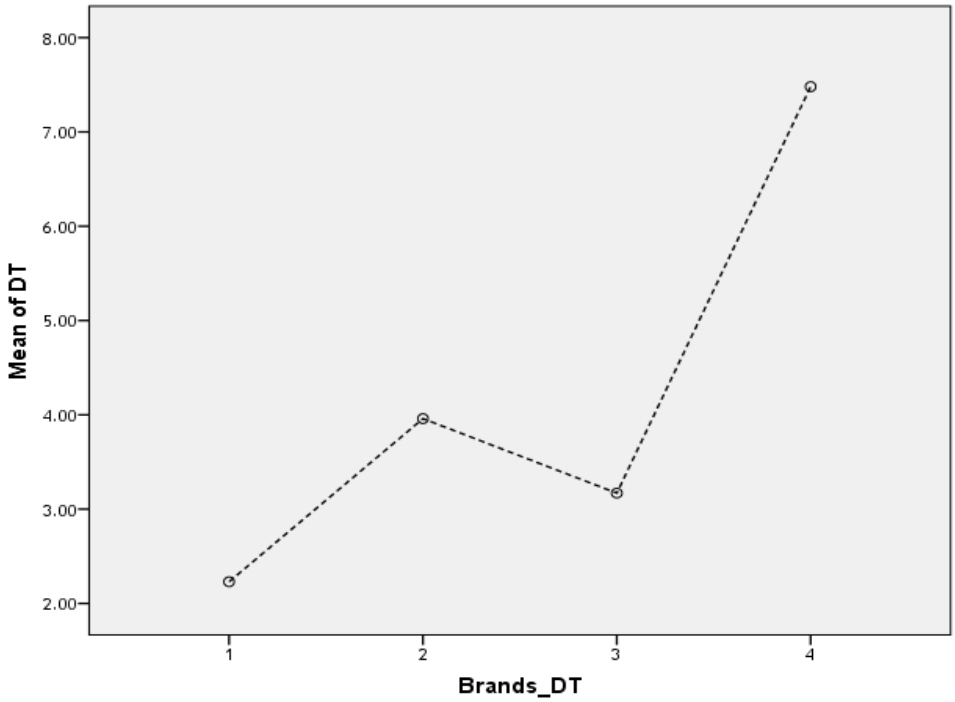

Figure 2: MEAN PLOTS OF DISINTEGRATION OF DIFFERENT BRANDS

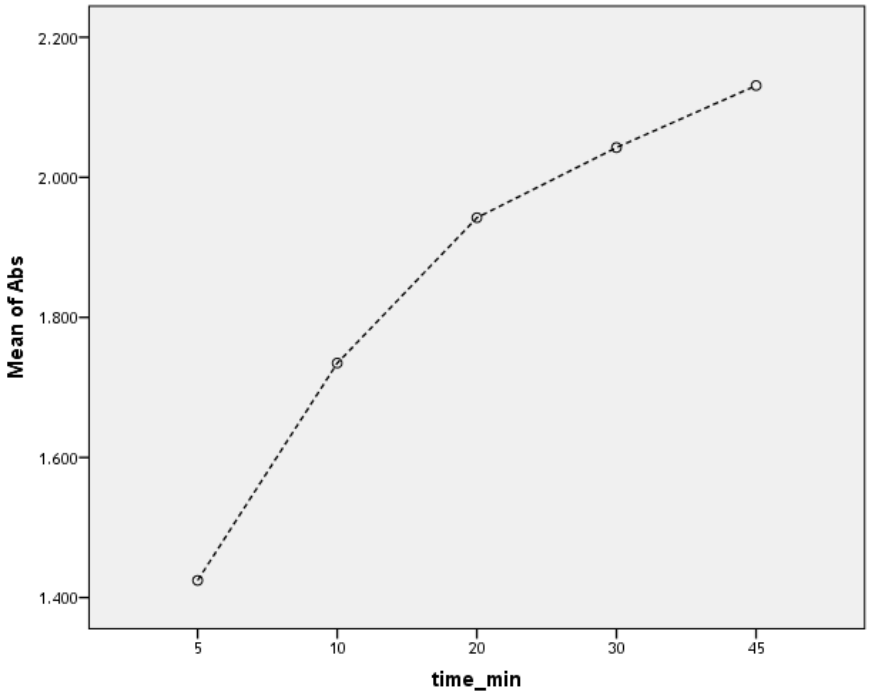

Figure 3: MEAN PLOTS OF DISSOLUTION OF DIFFERENT BRANDS

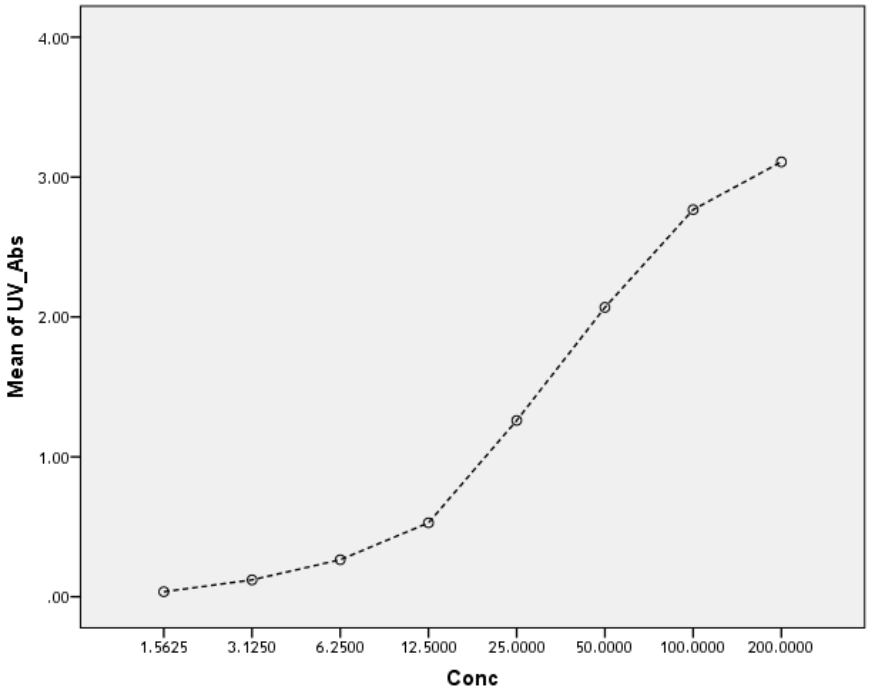

Figure 4: MEAN PLOTS OF ASSAY OF DIFFERENT BRANDS

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