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Development and Validation of Stability Indicating UV Spectrophotometric Method for Simultaneous Estimation of Indacaterol and Momestasone Furoate in Pharmaceutical Dosage Form

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Abstract: *A simple, accurateand precise stability indicating UV spectrophotometric method has been developed for simultaneous estimation of Indacaterol and Momestasone Furoate in pharmaceutical dosage form. The absorbance of Indacaterol and Momestasone Furoate was measured at two different wavelength 260 nm and 224 nm. It shows linear response between the concentration ranges 12-18 µg/ml and 25.6-38.4 µg/ml of regression coefficient r^2 being 0.9994 and 0.9994 of Indacaterol and Momestasone Furoate, respectively. A recovery study was carried out to confirm the methods accuracy. In the recovery study, the % RSD was less than 2. The % degradation by acidic, basic, oxidation, thermal and photolytic degradation of Indacaterol was found to be 5.39, 2.37,3.46, 2.43 and 1.64%, while of Momestasone Furoate it was 2.37, 11.44, 1.18, 9.88 and 2.35%.The method for estimation of Indacaterol and Momestasone Furoate was found to be precise, specific, reproducible & economical, as per ICH guideline the results of analysis were validated and found to be satisfactory.*

Keywords: Indacaterol, Momestasone Furoate, UV spectrophotometer, simultaneous estimation, Validation, Force degradation

I. INTRODUCTION

Indacaterol Acetate chemical name is (R)-5-(2-((5,6-Diethyl-2,3-dihydro-1H-inden-2-yl)amino)-1-hydroxyethyl)-8-hydroxyquinolin-2(1H)-one acetate. It is a longacting beta2-adrenergic agonist, which attributes to stimulate intracellular adenyl cyclase, the enzyme that catalyses the conversion of adenosine triphosphate (ATP) to cyclic-3', 5'-adenosine monophosphate (cyclic AMP). Increased cyclic AMP levels cause relaxation of bronchial smooth muscle. When inhaled, indacaterol acts locally in the lung as a bronchodilator, it has a rapid onset of action and a long duration of action.[1-3]

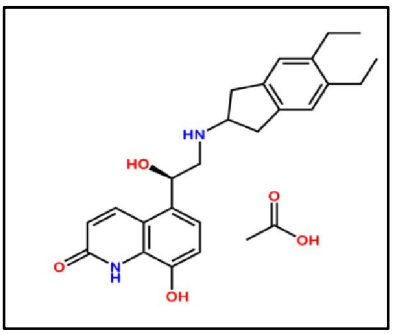

Figure 1: Structure of Indacaterol Acetate

Mometasone furoate is (11β,16α)-9,21-dichloro-11-hydroxy-16- methyl-3, 20-dioxopregna-1, 4-dien-17-yl 2-furoate. It is a synthetic corticosteroid with high affinity for glucocorticoid receptors and local anti-inflammatory properties.

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Studies in asthmatic patients have demonstrated that inhaled mometasone furoate provides a favourable ratio of pulmonary to systemic activity. It is likely that much of the mechanism for the effects of mometasone furoate lies in its ability to inhibit the release of mediators of the inflammatory response.[4-5]

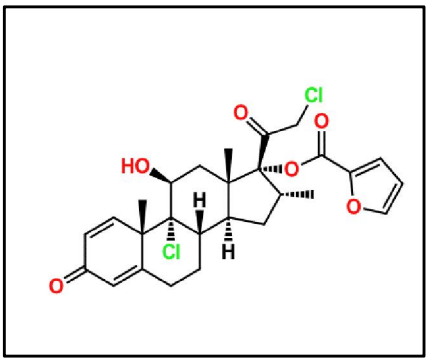

Figure 2: Structure of Momestasone Furoate

Literature review declares that no any UV spectrophotometric Method has been reported in order to estimate indacaterol and Momestasone Furoate respectively. In this research work a simple, precise and accurate UV method for simultaneous estimation of Indacaterol and Momestasone Furoate was developed and validated as per ICH guidelines.

II. MATERIALS AND METHODS

Instrumentation

A Shimadzu 1800 UV/VIS spectrophotometer with 1 cm matched quartz cells were used for all spectral measurements.[6-7]

For weighing, a calibrated weighing balance was used.

All the glassware's which was used were made up of Borosilicate and they were calibrated.

Chemicals and reagents –

Analytical pure sample of Indacaterol Acetate and Momestasone Furoate were received as gift sample from Anant Pharmaceuticals Pvt. Ltd. And Vamsi Labs Ltd. Solapur respectively. A Pharmaceutical dosage form used in this study was purchased from market labelled as INDAMET 320 contains Indacaterol Acetate Equivalent to Indacaterol of 150 µg and Momestasone Furoate of 320 µg.

The solvents used were Acetonitrile (AR grade) and distilled water to prepare mobile phase.

III. METHOD DEVELOPMENT

Selection of Wavelength

The sample was scanned from 190-400 nmwith UV Spectrophotometer. The Wavelength selected for simultaneous analysis of Indacaterol chosen was 260 nm and for Momestasone Furoate was 224 nm. in Acetonitrile:Distilled Water (50:50 %v/v) mobilephase is used for good peaks, absorbance and better sensitivity. Shown in figure 3.

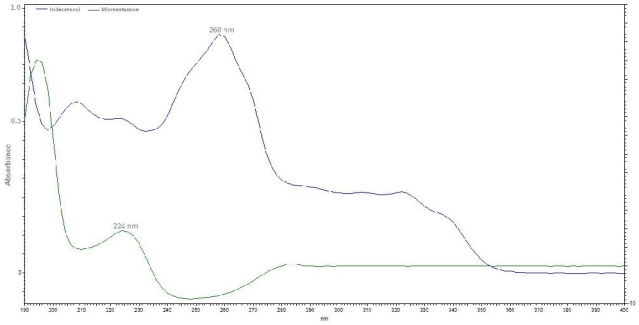

Figure 3: overlain spectra of Indacaterol Momestasone Furoate

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Preparation of Mobile Phase –
1000 ml of mobile phase was prepared by mixing 500 ml of Acetonitrile and 500 ml of distilled water.(50:50 %v/v)

Preparation of Standard Stock Solution of Indacaterol –
Initially Prepare a Standard Stock Solution of Indacaterol by adding 7.5 mg of Indacaterol in 10 ml volumetric flask & add 5 ml diluent, mix for 2 minutes and make the volume to 10 ml with diluent. (Conc. of Indacaterol = 750 µg/ml).

Preparation of Standard Stock Solution of Momestasone Furoate–
Then prepare a Standard Stock Solution of Momestasone Furoate by adding 16 mg in 10 ml volumetric flask & add 5 ml diluent, mix for 2 minutes and make the volume to 10 ml with diluent.(Conc. of Momestasone Furoate= 1600 µg/ml).
Then add 2.0 ml of Standard Stock Solution of Indacaterol & 2.0 ml Standard Stock Solution of MomestasoneFuroatein 100 ml volumetric flask and add 50 ml diluent and vortex and make up the volume with diluent. (Conc. of Indacaterol =15 µg/ml and Momestasone Furoate = 32 µg/ml).

Simultaneous estimation of Indacaterol and Momestasone Furoate –
Standard Solutions of different concentration of both drugs were prepared in mobile phase. Absorbance of Indacaterol (15 µg/ml) and Momestasone Furoate (32 µg/ml) were recorded at two wavelength 260nm and 224 nm by using simultaneous equation method.[8]

$$Cx = A1\ ay2 - A2\ ay1 / ax1ay2 - ax2ay1$$
$$Cy = A1\ ax2 - A2\ ax1 / ay1ax2 - ay2ax1$$

Where,
A1= Absorbance of formulation at 260 nm
A2 = Absorbance of formulation at 224 nm
ax1 & ax2 = Absorptivity of Indacaterol at 260 nm & 224 nm
ay1 & ay2 = Absorptivity of at Momestasone Furoate 260 nm & 224 nm
Cx = Concentration of Indacaterol
Cy = Concentration of Momestasone Furoate

Sample Preparation –
10 Capsules content of brand INDAMET 320 were weighed and calculate average weight of 1 capsule content.
Powder weight equivalent to 150 µg Indacaterol and 320 µg of MomestasoneFuroatewas weighed into 10 ml volumetric flask and add 5 ml diluent, sonicate for 5 minutes and make the volume to 10 ml with diluent. (Conc. of Indacaterol = 15 µg/ml and MomestasoneFuroate= 32 µg/ml).[9-12]

Table 1: Analysis of Marketed Formulation

Sr. no.	Indacaterol			Momestasone Furoate		
	Absorbance	Amount recovered in µg/ml	% Recovery	Absorbance	Amount recovered in µg/ml	% Recovery
1	0.931	14.99	99.93	0.868	32.02	100.06
2	0.932	15.01	100.07	0.866	31.95	99.84
3	0.930	14.97	99.80	0.667	31.98	99.93
average	0.931	14.99	99.93	0.80	31.98	99.95
STDEV	0.001	0.02	0.133	0.115	0.035	0.109
RSD	0.107	0.133	0.133	14.42	0.109	0.109

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IV. METHOD VALIDATION:

The developed method for simultaneous estimation of Indacaterol and Momestasone Furoate was validated in terms of linearity, accuracy, precision, robustness, LOD and LOQ according to International Conference on Harmonization guidelines (ICH).[13-14]

Linearity and Range

Linearity was studied by plotting absorbance vs concentration and was found to be directly proportional. A series of standard solution of Indacaterol were prepared in the concentration range of 12 µg/ml to 18 µg/ml and for Momestasone Furoate concentration range 25.6 µg/ml to 38.4 µg/ml is shown in table2 and table 3 respectively.
Linearity graph of Indacaterol and Momestasone Furoate shown in Figure 4 and 5.

Indacaterol		
% Level	Conc. (ug/ml)	Absorbance at 260 nm
80	12	0.729
90	13.5	0.832
100	15	0.931
110	16.5	1.03
120	18	1.120

Table 2: Conc. Range and absorbance of Indacaterol

Momestasone Furoate		
% Level	Conc. (ug/ml)	Absorbance at 224 nm
80	25.6	0.702
90	28.8	0.788
100	32	0.868
110	35.2	0.945
120	38.4	1.022

Table3: Conc. Range and absorbance of Momestasone Furoate

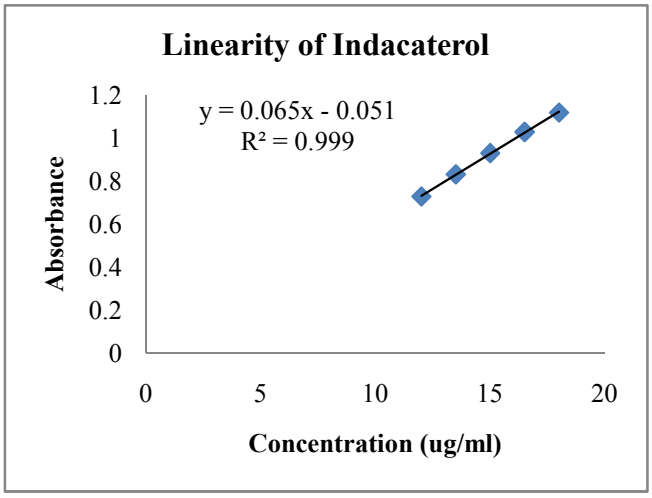

Figure 4: Linearity graph of Indacaterol

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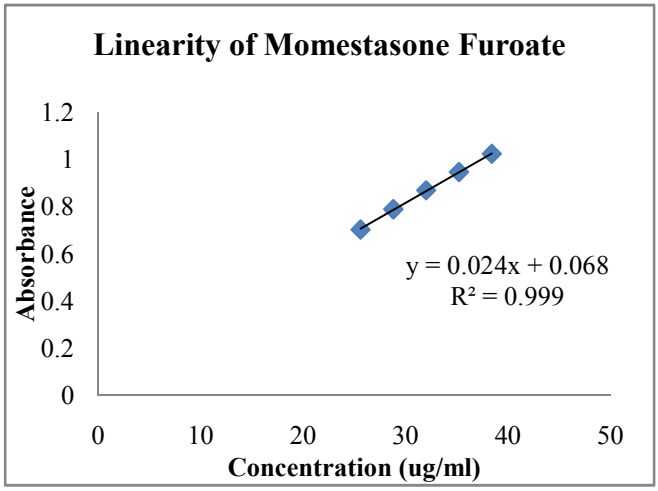

Figure 5: Linearity graph of Momestasone Furoate

Table 4: Linearity values of Indacaterol and Momestasone Furoate

Parameter	Indacaterol	Momestasone Furoate
Range	12-18 µg/ml	25.6-38.4 µg/ml
Slope	0.0653	0.0249
Intercept	0.0516	0.068
Corelation Coefficient	0.9994	0.9994

Precision/Repeatability –

Precision studies were carried in terms of Intra-day (at different time intervals on same day) and Inter-day (on three different days). It was performed as of three different concentrations of Indacaterol (12, 15 and 18 µg/ml) and Momestasone Furoate (25.6, 32, 38.4 µg/ml). The %RSD was calculated shown in table.

conc. µg/ml	Absorbance			Mean Absorbance	SD	%RSD
	Trial 1	Trial 2	Trial 3			
12	0.729	0.728	0.730	0.729	0.001	0.137
15	0.931	0.930	0.932	0.931	0.001	0.107
18	1.120	1.121	1.122	1.121	0.001	0.089

Table 5: Intra-day precision study of Indacaterol

conc. µg/ml	Absorbance			Mean Absorbance	SD	%RSD
	Trial 1	Trial 2	Trial 3			
12	0.721	0.726	0.727	0.724	0.003	0.443
15	0.918	0.916	0.925	0.919	0.004	0.513
18	1.116	1.119	1.117	1.117	0.001	0.136

Table 6: Inter-day precision study of Indacaterol

conc. µg/ml	Absorbance			Mean Absorbance	SD	%RSD
	Trial 1	Trial 2	Trial 3			
25.6	0.706	0.702	0.701	0.703	0.002	0.376
32	0.865	0.868	0.867	0.866	0.001	0.176
38.4	1.024	1.022	1.027	1.024	0.002	0.245

Table 7: Intra-day precision study of Momestasone Furoate

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Table 8: Inter-day precision study of Momestasone Furoate

conc. µg/ml	Absorbance			Mean Absorbance	SD	%RSD
	Trial 1	Trial 2	Trial 3			
25.6	0.699	0.697	0.702	0.699	0.002	0.359
32	0.858	0.864	0.867	0.863	0.004	0.531
38.4	1.021	1.019	1.020	1.020	0.001	0.098

A single sample of each drug were prepared as described and 6 measurements of absorbance were made at 260 nm and 224 nm.% RSD was calculated for the obtained absorbances.

Table 9: Repeatability study of Indacaterol and Momestasone Furoate

	Indacaterol	Momestasone Furoate
	Absorbance at 259 nm	Absorbance at 224 nm
Rep 1	0.931	0.868
Rep 2	0.932	0.866
Rep 3	0.930	0.867
Rep 4	0.931	0.865
Rep 5	0.933	0.869
Rep 6	0.931	0.868
Average	0.931	0.867
STDEV	0.001032796	0.00147196
RSD	0.11	0.17

Accuracy

This parameter is performed to determine the closeness of the measured value to the true value which is expressed as % recovery. These studies were performed at three different levels (i.e. at 80%, 100% and 120%) and the % recovery of Indacaterol and Momestasone furoate was calculated and shown in table 10 and table 11 respectively.

STD wt. (mg)	Purity (%)	Potency (ug/ml)	STD Area
15	99.97	149.955	0.931

Table 10: Recovery study of indacaterol

Sample ID	Reps	Spiked Conc. (ug/ml)	Absorbance at 260 nm	Amt Recovered (ug/ml)	% Recovery	Average	STDEV	RSD
80%	Rep 1	12.00	0.729	11.74	97.84	97.75	0.154979	0.16
	Rep 2	12.00	0.729	11.74	97.84			
	Rep 3	12.00	0.727	11.71	97.58			
100%	Rep 1	15.00	0.931	14.99	99.96	99.96	0.107373	0.11
	Rep 2	15.00	0.932	15.01	100.07			
	Rep 3	15.00	0.930	14.97	99.86			
120%	Rep 1	17.99	1.120	18.03	100.21	99.95	0.54427	0.54
	Rep 2	17.99	1.110	17.87	99.32			
	Rep 3	17.99	1.121	18.05	100.30			

Table 11: Recovery study of Momestasone Furoate

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STD wt. (mg)	Purity (%)	Potency (ug/ml)	STD Area
32	99.97	319.904	0.867

Sample ID	Reps	Spiked Conc. (ug/ml)	Absorbance at 224 nm	Amt Recovered (ug/ml)	% Recovery	Average	STDEV	RSD
80%	Rep 1	25.59	0.702	25.90	101.19	101.19	0.144148	0.14
	Rep 2	25.59	0.701	25.86	101.05			
	Rep 3	25.59	0.703	25.93	101.34			
100%	Rep 1	31.99	0.868	32.02	100.10	99.98	0.115318	0.12
	Rep 2	31.99	0.866	31.95	99.87			
	Rep 3	31.99	0.867	31.98	99.98			
120%	Rep 1	38.39	1.022	37.70	98.21	98.21	0.096098	0.10
	Rep 2	38.39	1.021	37.67	98.12			
	Rep 3	38.39	1.023	37.74	98.31			

Robustness

The analytical technique's robustness is a measure of its ability to remain unaffected by tiny but deliberate modifications in method of parameters, and it gives an indicator of it depend ability in routine use. The Robustness was performed by changing the Diluent concentration by ± 2%.

Table 12: Robustness study of Indacaterol and Momestasone Furoate

Diluent Ratio			
Condition	Sample	Indacaterol	Momestasone Furoate
		Assay	Assay
52A-48W	DP 1	99.87	99.81
50A-50W	DP 2	99.91	99.84
48A-52W	DP 3	99.85	99.79
	Average	99.88	99.81
	SDEV	0.030	0.025
	RSD	0.030	0.025

LOD and LOQ –

LOD and LOQ calculated for both drugs using ANOVA technique.

$$LOD = \frac{3.3 \times Std.Error\ of\ Intercept}{Coefficients\ of\ X\ Variable\ 1}$$

$$LOQ = \frac{10 \times Std.Error\ of\ Intercept}{Coefficients\ of\ X\ Variable\ 1}$$

Sr no.	Name of drug	LOD in µg/ml	LOQ in µg/ml
1	Indacaterol	0.68	2.06
2	Momestasone Furoate	1.45	4.39

Table13: LOD and LOQ values of Indacaterol and Momestasone Furoate

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V. FORCE DEGRADATION STUDY

To evaluate the stability condition of the developed UV-spectroscopic method samples were stressed in condition such as acid, base, oxidation, thermal and photolytic degradation. In all studies % degradation was calculated.[15-16]

Acid Degradation –

Acid degradation were carried out by weighing 15 mg Indacaterol and 32 mg Momestasone Furoate in 10 ml Volumetric Flask. After addition of 1 ml 1 N HCL, the solution is stored at room temperature. Later the solution is diluted with diluent up to the mark. Further 1 ml of this solution is transferee in to 100 ml volumetric flask and diluted with diluent. This acid treated solution is scanned in UV range 190-400 nm.

Base Degradation -

Base degradation was carried out by weighing 15 mg Indacaterol and 32 mg Momestasone Furoate in 10 ml Volumetric Flask. After addition of 1 ml 0.05 N NaOH, the solution is stored at room temperature. Later the solution is diluted with diluent up to the mark. Further 1 ml of this solution is transferee in to 100 ml volumetric flask and diluted with diluent. This acid treated solution is scanned in UV range 190-400 nm.

Oxidation –

Oxidative degradation was carried out by weighing 15 mg Indacaterol and 32 mg Momestasone Furoate in 10 ml Volumetric Flask. After addition of 1 ml 30% hydrogen peroxide, the solution is stored at room temperature. Later the solution is diluted with diluent up to the mark. Further 1 ml of this solution is transferee in to 100 ml volumetric flask and diluted with diluent. This acid treated solution is scanned in UV range 190-400 nm.

Thermal Degradation –

Thermal degradation was carried out by weighing 15 mg Indacaterol and 32 mg Momestasone Furoate in 10 ml Volumetric Flask. The solution is stored at 80˚C for 8 hrs. Later the solution is diluted with diluent up to the mark. Further 1 ml of this solution is transferee in to 100 ml volumetric flask and diluted with diluent. This acid treated solution is scanned in UV range 190-400 nm.

Photolytic Degradation –

Photolytic degradation was carried out by weighing 15 mg Indacaterol and 32 mg Momestasone Furoate in 10 ml Volumetric Flask. The solution is stored at 254 nm for 6 hrs. Later the solution is diluted with diluent up to the mark. Further 1 ml of this solution is transferee in to 100 ml volumetric flask and diluted with diluent. This acid treated solution is scanned in UV range 190-400 nm.

Table 14: Degradation study of Indacaterol and Momestasone Furoate

Condition	Indacaterol		Momestasone Furoate	
	% Recovery	% Deg.	% Recovery	% Deg.
Control	100	-	100	-
Acid	94.61	5.39	97.63	2.37
Base	97.63	2.37	88.56	11.44
Peroxide	96.54	3.46	98.82	1.18
Heat	97.57	2.43	90.12	9.88
UV	98.36	1.64	97.65	2.35

VI. RESULTS AND DISCUSSION

The proposed method is based on spectrophotometric simultaneous estimation of Indacaterol and Momestasone Furoate.In this method Acetonitrile: distilled water(50:50 %v/v) isused as mobile phase. The Wavelength selected for simultaneous analysis of Indacaterol chosen was 260 nm and for Momestasone Furoate was 224 nm.

Linearity-

Linear regression data for the calibration plots revealed good linear relationship between absorbance and concentration over the ranges 12 µg/ml to 18 µg/ml of Indacaterol and 25.6 µg/ml to 38.4 µg/ml of Momestasone Furoate. The linear equation for the calibration plots were y = 0.0653x - 0.0516andy = 0.0249x + 0.068with Regression(R^2) being 0.9994 and 0.9994 for Indacateroland Momestasone Furoate, respectively.

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Precision -

The precision of method was expressed as relative standard deviation (RSD%). The %RSD values for intra-day precision study and intra-day study listed in (Table 5,6, 7 and 8)were < 2 %, confirming that the method was sufficiently precise.

Accuracy-

When the method was used for accuracy and subsequent analysis of both the drugs from the pharmaceutical dosage form and spiked with 80, 120% of additional pure drug, the recovery was found to be 97.75and 99.95% for Indacaterol and 101.19and 98.21% for Momestasone Furoate.

LOD and LOQ -

The LOD and LOQ were calculated by equation. The LOD and LOQ values were 0.68 µg/ml and 2.06 µg/ml for Indacateroland 1.45 µg/ml and 4.39 µg/ml for Momestasone Furoate.

Force degradation study –

The % degradationby acidic, basic, oxidation, thermal and photolytic degradation of Indacaterol was found to be 5.39, 2.37,3.46, 2.43 and 1.64 %, while of Momestasone Furoate it was 2.37, 11.44, 1.18, 9.88 and 2.35%.

VII. CONCLUSION

The proposed method was developed for the Simultaneous estimation of Indacaterol and Momestasone Furoate was validated and found to be simple, accurate, precise and economical. The short spectral time makes this method suitable for processing of multiple samples in short time.which indicates its competence for routine pharmaceutical analysis of Indacaterol and Momestasone Furoate in pharmaceutical dosage form.In addition, a forced degradation study can be used to determine the degradation pathways and degradation product of the APIs that could form during storage and facilitate formulation, development, manufacturing, and packaging.

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