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SPECTROPHOTOMETRIC DETERMINATION OF CLOBETASOL PROPIONATE IN PHARMACEUTICAL PREPARATIONS AND ENVIRONMENTAL SAMPLES

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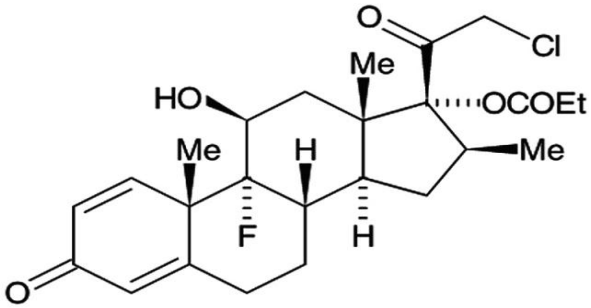
ABSTRACT

A simple, accurate, precise, rapid, economical and sensitive Uv spectrophotometric method has been developed for the determination of clobetasol propionate in pharmaceutical preparations and environmental wastewater samples, which shows maximum absorbance at 240 nm in distilled water. Beer's law was obeyed in the range of 2.5 -30 µg/ ml, with molar absorptivity of 1.35×10^4 $L.mol^{-1}.$ cm^{-1}, relative standard deviation of the method was less than 1.4%, and accuracy (average recovery %) was 100 ± 1.1. No interference was observed from common excipients and additives often accompany with clobetasol propionate in pharmaceutical preparations. The method was successfully applied to the determination of clobetasol propionate in some pharmaceutical formulations (tablets) and industrial wastewater samples. The proposed method was validated by sensitivity and precision which proves suitability for the routine analysis of clobetasol propionate in true samples.

KEYWORD: Clobetasol, Pharmaceutical Preparations, Environmental water samples.

INTRODUCTION

Clobetasol propionate [17-(2'-chloroacetyl)- 9-fluoro-11-hydroxy-10,13,16-trimethyl- 3-oxo-6,7,8,11,12,14,15,16-octahydrocyclopenta[a]phenanthren-17-yl] propanoate (Figure 1) is a corticosteroid used topically for its gluco- corticoid activity in the treatment of various skin disorders such as atopic dermatitis, capillaries dermatitis, and psoriasis. It is used for short term relief of anti-inflammatory.[1,5]



$C_{25}H_{32}ClFO_5$ 467.0

Figure 1: Chemical structure of clobetasol propionate.

Literature survey reveals that numerous methods have been published for quantitative analysis of Clobetasol Propionate alone and in combination with other drugs such as Spectrophotometric[6,7], LC-UV[8], high performance liquid chromatography HPLC[9,12] can be used for determination of drugs and for purposes of control throughout the entire manufacturing process of drugs, as well as quality control of the finished product. It has the advantages of being sensitive, selective, rapid, accurate and reproducible, TLC[13], and HPTLC.[14,15] The present paper reports the development of a new UV method for determination of clobetasol propionate in creams and environmental water samples.

EXPERIMENTAL

Apparatus

ShimadzuUV- 1700 pharma spec (double beam) spectrophotometer with 1.0 cm quartz cells was used for absorption measurement.

Reagents

All chemical used were of analytical or pharmaceutical grade and clobetasol propionate standard material was provided from AL-Hokamaa company for pharmaceutical industries (HPI) Mosul-Iraq.

Methanol: Water (80:20)(v/v) was used as a solvent.

Clobetasol propionate standard solution 50ppm

This solution was prepared by dissolving 50 mg of clobetasol propionate in 1000 ml of 80:20 methanol- distilled water in calibrated flask.

Determination of absorption maxima

The standard solution of clobetasol propionate (10µg/ml) was scanned in the range of 210-310 nm which shows maxima located at 240 nm Figure 2. Therefore, 240 nm wavelengths were selected for the construction of calibration curve.

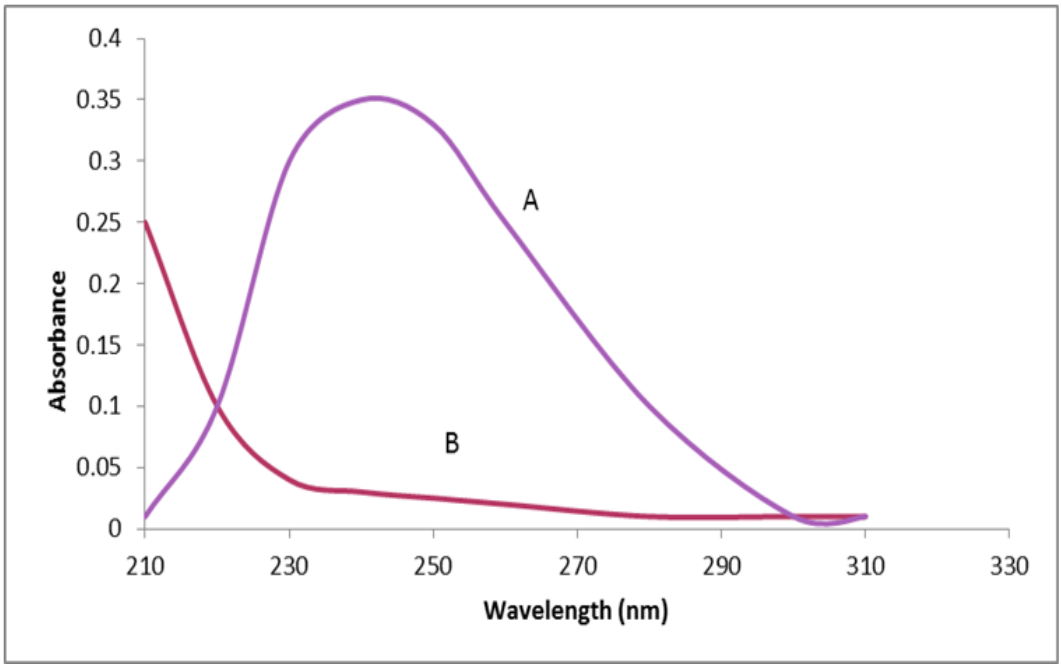


Figure 2: Absorption spectra of (A) 10µg/ml clobetasol propionate against blank (80:20 methanol: water), (B) blank against distilled water.

Recommended procedure

From the absorption maxima, calibration curve was prepared in the concentration range of 2.5-30 µg/ml. The absorbance was measured at 240 nm against methanol-water 80:20 as a blank. The concentration of the sample solution can be determined by using the calibration curve.

Procedures for pharmaceutical preparations (ointments)

Disperse a quantity of the ointment containing 1.0 mg of clobetasol Propionate in 20 ml of methanol (80%) in a 125-ml separating funnel containing 50 ml of petroleum ether. Heat the contents over a water bath(40-60 Ċ) and shake gently for 20 minutes. Allow the layers to separate and transfer the lower layer to a 50 ml flask. Repeat the extraction with a further 2X10 ml of methanol 80%. Dilute the combined extracts to 100ml with the methanol 80% to get 10µg/ml solution. Measure the absorbance at 240 nm using methanol 80% as blank and the concentration was calculated by using the calibration curve of this method.

Procedure for real water samples

To demonstrate the practical applicability of the proposed method, real water samples were analyzed by this method. Industrial waste water from AL-hokamaa company for pharmaceutical industries (HPI) Mosul-Iraq, were fortified with the concentrations in the range of 5, 10, 30 µg/ml of clobetasol propionate. The fortified water samples were analyzed as described above for recommended procedure and the concentration was calculated by using the calibration curve of this method.

RESULT AND DISCUSSION

UV- Visible estimation is still considered to be simple, low cost, convenient and widely used method for the determination of pharmaceuticals.[16,18] This method used for the determination of clobetasol propionate in pharmaceutical preparations and environmental wastewater samples was found to be sensitive, simple, accurate, and reproducible. Beer s law was obeyed in the concentration range of 2.5-30 µg/ml Figure 3 with correlation coefficient of 0.998, intercept of 0.0214 and slope of 0.0297. The conditional molar absorptivity was found to be $1.35x10^4$ l/mol.cm.

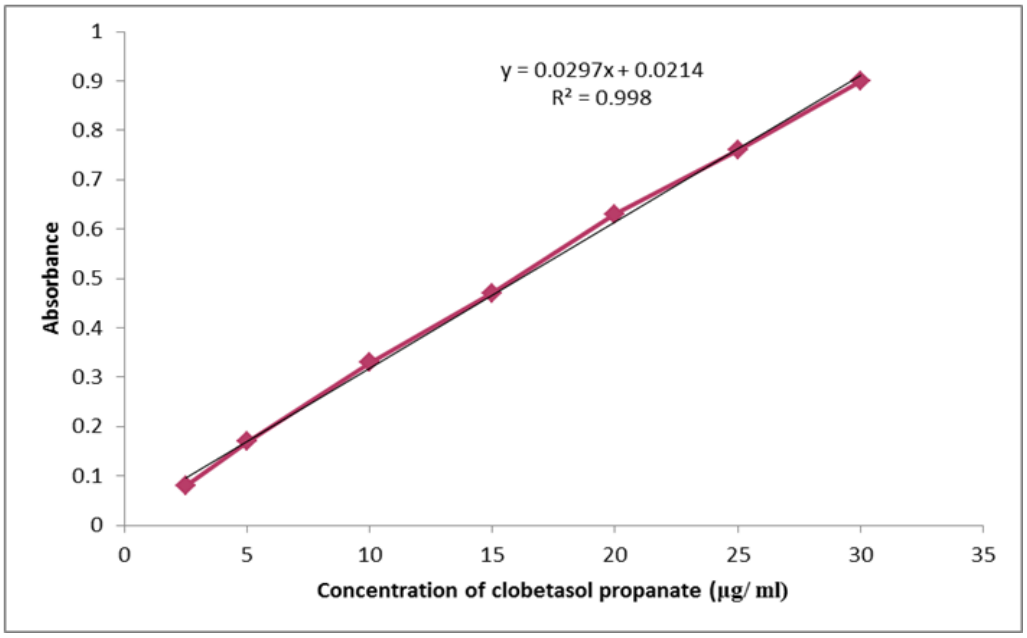


Figure 3: Calibration graph of clobetasol propionate.

The accuracy and precision of the method, a pure drug solution was analyzed at three different concentrations, each determination being repeated six times. The relative error (%) and relative standard deviation values are summarized in Table 1. From table 1 the values of

standard deviation were satisfactory and the recovery studies were close to 100%,. The RSD% value is less than 1.4 indicative of accuracy of the method.

Table I: Accuracy and precision of the proposed method.

Clobetasol propionate (taken µg/ml)	Er (%)[a]	RSD (%)
5	1.1	1.3
15	0.9	1.1
25	1.0	1.3

a: Mean of six determinations.

Analytical application

The proposed method was satisfactorily applied to the determination of clobetasol propionate in its pharmaceutical preparations ointments and wastewater samples, the results of the assay of the pharmaceutical preparations revels that there is close agreement between the results obtained by the proposed method and the label claim Table 2, and the results of water samples Table 3 show that the recovery values obtained were closed to 100%.

Table 2: Determination of clobetasol propionate formulations.

Pharmaceutical formulations	Proposed method found*	Label amount
Dermodin ointment(NDI)	0.497%	0.5%
Dermodin ointment(HPI)	0.504%	0.5%

*Mean of ten determinations.

Table 3: Determination of clobetasol propionate in industrial wastewater samples.

Wastewater samples	Added µg/ml	Found* µg/ml	Recovery %(n=10)
Industrial wastewater	5	5.05	101
	10	9.97	99.7
	20	20.15	100.75

*Mean value of ten determinations.

CONCLUSION

The developed method is found to be high sensitive, accurate, simple, precise and economical, and can be used for routine quality control analysis of clobetasol propionate in pure form, pharmaceutical formulations and environmental wastewater samples.

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REFERENCES

1. British National Formulary (BNF) Royal Pharmaceutical Society, 2016; 70: p.1025.
2. Sweetman SC, editors. Martindale, 'The Complete Drug Reference. 36th Edition. London: Pharmaceutical Press, 2009: P. 1522.
3. British pharmacopoeia, H.M. Stationery office, London, UK, 2014: P.576.
4. The United State Pharmacopeia. USP33-NF28, 2010, p. 2560.
5. Mazzotta. A, Esposito. M, Carboni.L, Schipani.C, and Chimenti.S,' Clobetasol propionate foam 0.05% as a novel topical formulation for plaque-type and scalp psoriases. J. Dermatol. Treat, 2007; 18: 84–87.
6. Kamalakannan D, Jambulingam M, Ananda Thangadurai S, Dhanam S, Jeyanthi R, Parvin Banu M, Vasanthi M, Vinodha Rashini J, Haritha Siva Ganga Lakshmi D. New simple spectrophotometric estimation of clobetasol propionate in bulk and pharmaceutical dosage form. J Der Pharmacia Lettre, 2014; 6(4): 52–7.
7. Mostafa AA, Bebawy LI, Refaat HH, 'Spectrophotometric determination of clobetasol propionate, halobetasol propionate, quinagolide hydrochloride, through charge transfer complexation. J Pharm Biomed Anal, 2002; 27(6): 889-99.
8. Ulya Badilli, Gülin Amasya, Sibel Özkan, Nilüfer Tarimci; Simultaneous Determination of Clobetasol Propionate and Calcipotriol in a Novel Fixed Dose Emulgel Formulation by LC-UV, Chromatographia, 2013; 76(3): 133-140.
9. Fontana M.C, Bastos M.O, and Beck R.C,' Development and Validation of a Fast RP-HPLC Method for the Determination of Clobetasol Propionate in Topical Nano capsule Suspensions, Journal of Chromatographic Science, 2010; 48: 637-640.
10. Prakash M and Ajay V, 'Cleaning Method: A Validated HPLC method for Determination of Clobetasol Propionate Residues on the Surface of Manufacturing Equipment, International Journal of Analytical and Bioanalytical Chemistry, 2012; 2(2): 133-138.
11. Gunasekar Manoharan,' Development and validation of stability-indicating RP-HPLC method for the estimation of clobetasol propionate in bulk and ointment dosage form, European Journal of Pharmaceutical and Medical Research, 2017; 4(05): 119-126.

12. The United State Pharmacopeia. USP34-NF29, 2011: p. 2383. Turabi ZM, Khatatbeh OA. Simultaneous determination of clobetasol (as propionate) and chlorocresol in cream by stability indicating RP-HPLC method. Int J Pharm Sci Drug Res, 2014; 6(2): 140–144.
13. Yasmine Farouk Bassuoni and Eman Saad Elzanfaly, 'Development and validation of stability indicating TLC densitometric and spectrophotometric methods for determination of Clobetasol propionate, Bulletin of Faculty of Pharmacy, Cairo University, 2016; 54: 165–174.
14. Mrinalini C. Damle Anuradha R. Polawar,' Stability Indicating HPTLC Method for the Estimation of Clobetasol Propionate in Presence of Alkali Induced Degradation Product. IJPRIF, 2014; 6(6): 1914-1925.
15. Malani PS, Raj HA, Jain VC,' Development and validation of analytical method for simultaneous estimation of miconazole nitrate and clobetasol propionate in cream by HPTLC method. J Pharm Sci Monit, 2014; 5(2S1): 386–99.
16. Nief Rahman Ahmed and Ola Hajum,' Spectrophotometric determination of pyridoxine hydrochloride via complexation with Fe (III)in pharmaceutical and environmental wastewater samples Iraqi National Journal of Chemistry, 2012; 48: 413-423.
17. Nief Rahman Ahmed,' Ultraviolet Spectrophotometric Determination of Trifluoperazine. HCl in Pharmaceutical Preparations and Environmental Wastewater Samples: Application to Content Uniformity Testing. Research & Reviews: Journal of Pharmaceutical Analysis, 2014; 3(2): 30-34.
18. Nief Rahman Ahmed,'A sensitive spectrophotometric determination of tadalafil in pharmaceutical preparations and industrial wastewater samples, J. Baghdad for Sci, 2013; 10(3): 1005-1013.