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SIMULTANEOUS ANALYSIS AND FORCED DEGRADATION DETERMINATION OF HYDROCODONE AND PSEUDOEPHEDRINE IN TABLET DOSAGE FORMS

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ABSTRACT

A simple and selective method is described for the determination of hydrocodone and pseudoephedrinein tablet dosage forms. Chromatographic separation was achieved on a Water using mobile phase consisting of a mixture of 60 volumes of Methanol, 40 volumes of water 0.5% TEA with detection of 244 nm. Linearity was observed in the range 20 - 100 µg/ml for hydrocodone (r^2 =0.999) and 60-140 µg /ml for pseudoephedrine(r^2 =0.999) for the amount of drugs estimated by the proposed methods was in good agreement with the label claim. The proposed methods were validated. The accuracy of the methods was assessed by recovery studies at three different levels. Recovery experiments indicated the absence of interference from commonly encountered pharmaceutical additives. The method was found to be precise as indicated by the repeatability analysis, showing %RSD less than 2. All statistical data proves validity of the methods and can be used for routine analysis of pharmaceutical dosage form.

Key Words: hydrocodone, pseudoephedrine, forced degradation.

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INTRODUCTION

Chromatography is based on the separation of substances of interest by their differing affinity between a mobile phase and stationary phase. The mobile phase is usually a liquid or a gas while the stationary phase is usually a solid but may be an immobilized liquid.Relative affinity may be based on relative solubility, adsorption, size or charge. Differences in solubility are expressed by partitioning between the mobile and stationary phases. Adsorption differences cause the separation of molecules in a non-aqueous environment. Permeation (gel between similar materials. Commonly used chromatography methods are high performance/pressure liquid chromatography (HPLC), gas liquid chromatography (GLC) and thin layer chromatography (TLC).The importance of Chromatography is increasing rapidly in pharmaceutical analysis. The exact differentiation, selective identification and quantitative determination of structurally closely related compounds are possible with chromatography. Another important field of application of chromatographic methods is the purity testing of final products and intermediates (detection of decomposition products and by-products). As a consequence of the above points, chromatographic methods are occupying an ever-expanding position in the latest editions of the pharmacopoeias and other testing standards.There are many variations of chromatography, but all involve the dissolution of an analyte into a fluid known as the mobile phase and the passage of this fluid solution across a stationary

phase, often a solid or liquid-coated solid. As the mobile phase comes into contact with the stationary phase, some of the analytes molecules dissolve or adsorb onto the mobile phase. The more the molecules of that substance are retained, the slower their progress through the chromatographic apparatus. Different substances will then move through at different rates, ideally resulting in distinctly identifiable retention times for each substance.The root of the word chromatography, chroma (Greek khrōma, color) and grafein is "to write", indicates that the separated components in some forms of the technique can be identified by their color alone. But chromatography has now long been performed on colorless compounds that can be identified in other ways.Analyte components on thin-layer chromatography plates are often identified under ultraviolet light, or by chemical staining in, for example, an iodine chamber or potassium permanganate. Gas chromatographic analytes are detected by changes in the ionization levels of a flame at the output end of the column or by changes in the electrical conductivity of the gas mixture at the end of the column. Liquid chromatography fractions are often analyzed through spectrophotometric techniques, notably UV-visible spectroscopy. When separation with GC or LC is performed in tandem with mass spectrometry (the "hyphenated" techniques of GC-MS and LC- MS), masses of individual fractions are rapidly determined. These methods are frequently employed in analytical and forensic science [1-5]. Aim is to develop new RP-UPLC method for the hydrocodone and pseudoephedrine simultaneous estimation of in pharmaceutical dosage form.

MATERIALS AND METHODS

Preparation of standard stock solution of hydrocodone[6-8]

10 mg of hydrocodonewas weighed and transferred in to 100ml volumetric flask and dissolved in methanol and then make up to the mark with methanol and prepare 10µg /ml of solution by diluting 1ml to 10ml with methanol.

Preparation of standard stock solution of pseudoephidrine

10 mg of Pseudoephidrinewas weighed and transferred in to 100ml volumetric flask and dissolved in methanol and then make up to the mark with methanol and prepare

10 µg /ml of solution by diluting 1ml to 10ml with methanol.

Preparation of Sample solution

Crush more than 20 tablets then weigha quantity of powder equivalent to 100mg of Hydrocodoneand 50mg of Pseudoephidrine in 100 mL volumetric flask and add70mL of mobile phase then sonicated it for 30min intermittent shacking after 30min make up volume with mobile phase. Pipetted 5 mL of the clear solution in to 50 mL volumetric flask and make up volume with mobile phase. Filter the solution through 0.45µm filter paper.

Forced Degradation studies

The forced degradation study is considered a vital analytical aspect of the drug development program for small molecules. Forced degradation, commonly known as stress testing, is carried out to demonstrate as specificity to developed a stability-indicating analytical method, using HPLC or UPLC i.e., a single analytic method that is capable of separating the degradant peaks from the drug substance/drug product peak. As per International Conference on Harmonization (ICH) guidelines (Q1A), stability studies need to be performed to propose the shelf life of new drug substances and/or drug products. Shelf life studies are part of various regulatory submissions to the FDA.

RESULTS AND DISCUSSION

The percentage purity of both hydrocodone and pseudoephidrinewere found to be within the limits that is 98-102% (Table-1).

Table-1 Results for Hydrocodone and Pseudoephidrine

	HYDROCODONE		PSEUDOEPHIDRINE	
	Standard Area	**Sample Area**	**Standard Area**	**Sample Area**
Injection-1	1022197	1026668	2032157	2029924
Injection-2	1025670	1032616	2017044	2018744
Injection-3	1041099	1025772	2015194	2030331
Injection-4	1026496	1017071	2012644	1995114
Injection-5	1006266	1016907	2008604	2018534
Average Area	1024346	1023807	2017129	2018529
Assay(%purity)	99.94		100.06	

The %RSD of 6 determinations of HYDROCODONE and PSEUDOEPHEDRINE for System precision found to be within the acceptance criteria of less than 2.0% (Table-2).

Table-2 Method precision results for Hydrocodone and Pseudoephedrine.

Injection	**HYDROCODONE**		**PSEUDOEPHEDRINE**	
	Area	**%Assay**	**Area**	**%Assay**
1	1026668	99.6	2029924	100.0
2	1032616	100.2	2018744	99.5
3	1025772	99.6	2030331	100.0
4	1017071	98.7	1995114	98.3
5	1016907	98.7	2018534	99.5
6	1011321	98.1	2013040	99.2
Average	-	99.2	-	99.4
SD	-	0.8	-	0.6
%RSD	-	0.8	-	0.6

A graph was plotted for hydrocodone and pseudoephedrine gainst the concentrations of the solutions and the peak areas. The correlation coefficient R^2 was determined and was found to be 0.999 for hydrocodone and 0.999 for Pseudoephedrine (Fig-1 and 2)

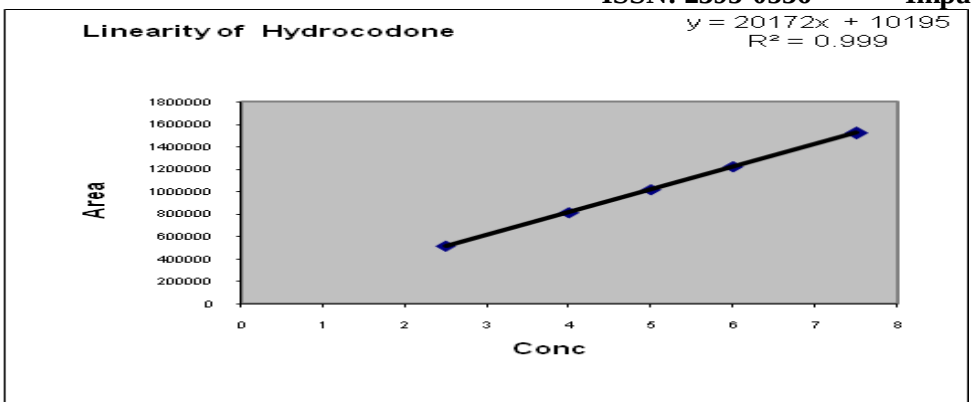

Fig-1 Graph for Linearity data of hydrocodone

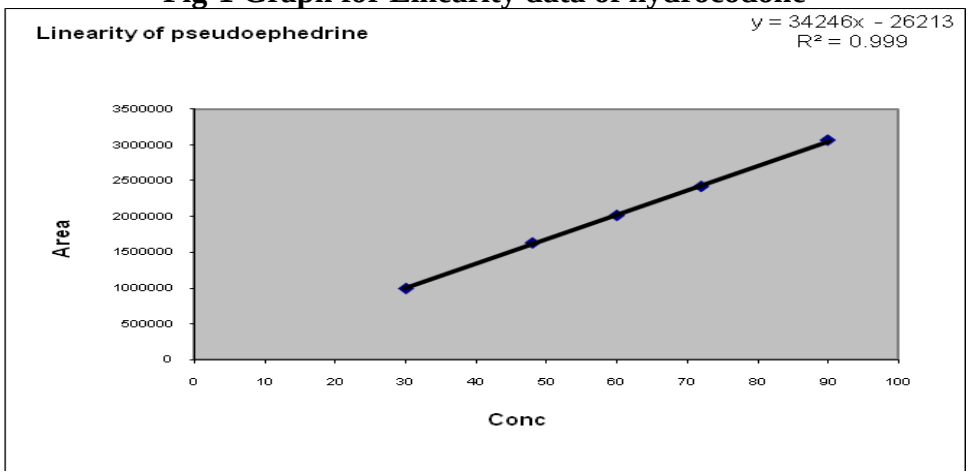

Fig-2 Graph for Linearity data of Pseudoephedrine

The % mean recovery of Hydrocodone and Pseudoephedrine was founded between 98.0 to 102.0.As per International Conference on Harmonization (ICH) guidelines (Q1A), stability studies need to be performed to propose the shelf life of new drug substances and/or drug products. Forced degradation studies does not affect the analysis (Fig-3-5).

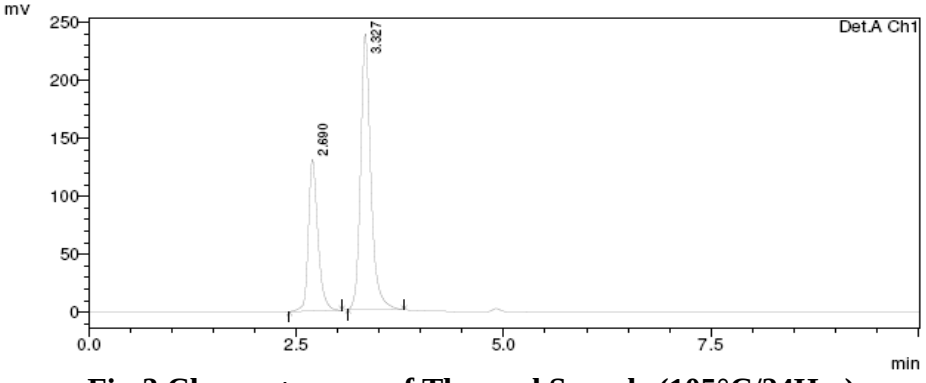

Fig-3 Chromatogram of Thermal Sample (105°C/24Hrs)

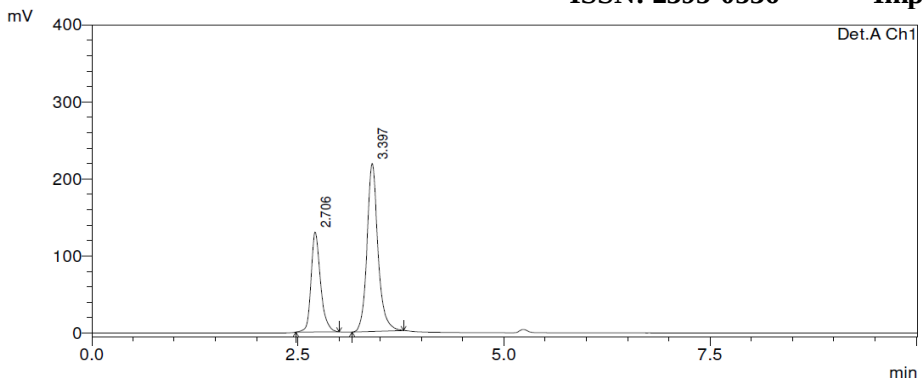

Fig-4 Chromatogram of Photolytic Sample (1.2mil LUX hrs)

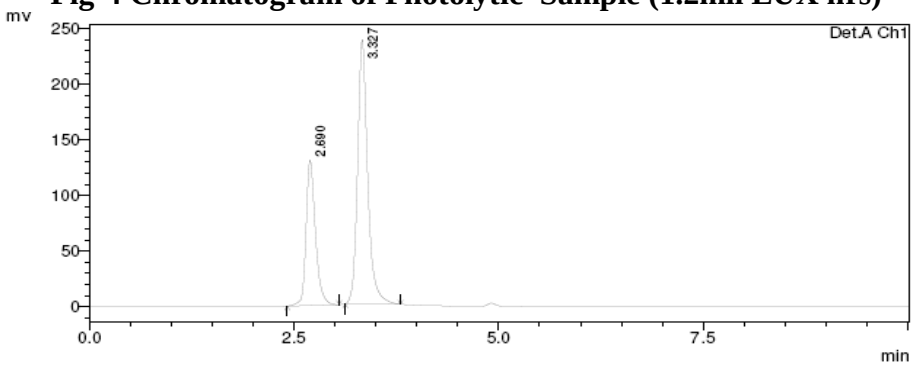

Fig-5 Chromatogram of Acid Sample preparation (5N HCl /4Hrs/60°C)

CONCLUSION

From the above experimental results and parameters it was concluded that, this newly developed method for the simultaneous estimation ofhydrocodone and pseudoephedrinewas found to be simple, precise, accurate and high resolution and shorter retention time makes this method more acceptable and cost effective and it can be effectively applied for routine analysis in research institutions, quality control department in meant in industries, approved testing laboratories studies in near future.

REFERENCES

1. Chatwal**,** R. G.**;** Anand**,** K. S. High performance liquid cromatography**.**Instrumental methods of chemical analysis**,** 5thed**.;** Himalaya publishers**:**Mumbai, 2010**;** 2.570-2.629**.**
2. Sharma**,** B**.** K**.** High performance liquid chromatography**.**Instrumental methods of chemical analysis**,** 24th ed**.;** Goel publishers**:**Meerut**,** 2005**;** 295 - 300**.**
3. Dong,W. M. HPLC instrumentation and trends. Modern HPLC for practicing scientists, USA, 2006; 5-10, 78-110.
4. Swartz,M. E.; Ira Krull, S, Analytical method development. Analytical method development and validation, 1st ed.; Marcel Dekker, Inc: New York, 2009; 17-80.
5. Satinder, A.; Dong, M. W. Method development and validation. Pharmaceutical analysis by HPLC, 15th ed.; New York, 2005; 16-70.
6. ICH, Text on Validation of Analytical Procedures, ICH – Q2A, International Conference on Harmonisation, IFPMA, Geneva, 1995, 2-3, A–1 to A–3.
7. ICH, Validation of Analytical Procedures: Methodology, ICH – Q2B, International Conference on Harmonisation, 1996, 1-3.
8. ICH Guidelines, Q2 (R1) - Validation of Analytical Procedures:Text and Methodology,2005, 1-6.