Qualitative and Quantitative Analysis of Paracetamol in Different Drug Samples by HPLC Technique

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Abstract: *HPLC is rapid more accurate,purity checking & separation method of paracetamolin different drug sample as compare with standard reference& sample solution within complies with Indian Pharmacopeia. This method is applicable to Forensic science laboratories also. It is very sensitive less time consumable but sharp peaks recorded. Chromatographic technique – stainless still column 20cm x 4.6mm packed with ocadesilance bonded to porous silica 10 micrometer. Flow rates 0.2ml /min. at 20 micrometer loop injector & spectrophoto-meter set at 272 nm. Retention time of std 4-ammino phenol & sample solution 4.388 & 4.542 respectively. La-beled amount 102.86% of paracetamol was observed. The % is indicated that the paracetamol is within limit of Indian pharmacopeia.*
Identification: Sample given Indian pharmacopeia identification test for the presence of paracetamol.
KeyWords:*Analysis, Chromatogram, Drug Sample, HPLC, Paracetamol, Retention time, Spectrophotometer*

I.   Introduction

Paracetamol, N (4hydroxy phenyl acetamideis analgesic and antipyretic drug.It is used to prevent fever, headaches & colds. It is one of the major drug & also used along with other drug. Paracetamol is part of the class of drug known as "aniline analgesic". So it is need to analyzeparacetamol quantitatively &qualitatively. A lower dosage of additional non steroidal anti –inflametry drug to be used by minimizing over all side effect [1-3] Present work includes analysis of paracetamol. It is active metabolite of phenacetin& not considered to be carcinogenic at therapeutic doses. Main aim of this study was to develop a new RP-HPLC [4-6] method for de-termination of sample and standard paracetamol from formulated tablet. This method has been reported for the analysis of paracetamol& its combination in pharmaceuticals or in biological fluids. Paracetamol has been de-termined in combination with other drug's using UV –spectrophotometry [7-10]. Paracetamol (PARA) is chem-ically N-(4-hydroxy phenyl) acetamide (amide derivative). It functioned as a weak inhibitor of the synthesis of prostaglandins (PGs) [11]. However, invivo effects of paracetamol are similar to those of the selective cyclooxy-ygenase-2 (COX-2) inhibitors [12]. Paracetamol also decreases PG concentrations invivo. Structure of Parace-tamol (PARA) is shown in Fig. 1.
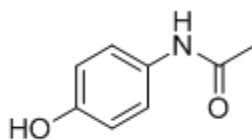
Structre of paracetamol tablet

Figure -1

II.   Experimental

Identification: Sample given Indian pharmacopeia identification test for the presence of paracetamol.

Paracetamol test for 4-aminophenol

Chromatographic technique
Stainless steel column 20cm x 4.6mm packed with ocadecysilance bonded to porous Silica 10 micrometer.

Mobile phase:
0.01M Sodium Butanesulphate in a mixture of 85 volume of water,
15 volume of methanol and 0.4 volume of formic acid
Flow rate 0.2 ml per minute.

Spectrometer set at 272nm.
At 20 micrometer loop injector

Preparation of standard test solution:
Approximately 4-5 gm of standard 4- aminophenol was taken in silica crucible covered with glass funnel and evaporated with continually. A sublimate of white powder was formed. Accurately 0.25mg of sample was taken in 1000ml standard flask and 15% methanol was added up to the mark. 1 ml of this solution was taken in 25ml standard flask diluted with methanol up to the mark. Filter this solution.Sonicator& then used for HPLC. Peak was recorded.as Shown in Fig. 2.

HPLC curve of Standard 4- amino phenol figure 2

Sample Name: STD-4-Aminophenol; Date Acquired: 4/30/2010 1:52:34 PM IST; Vial: 1; Injection: 2
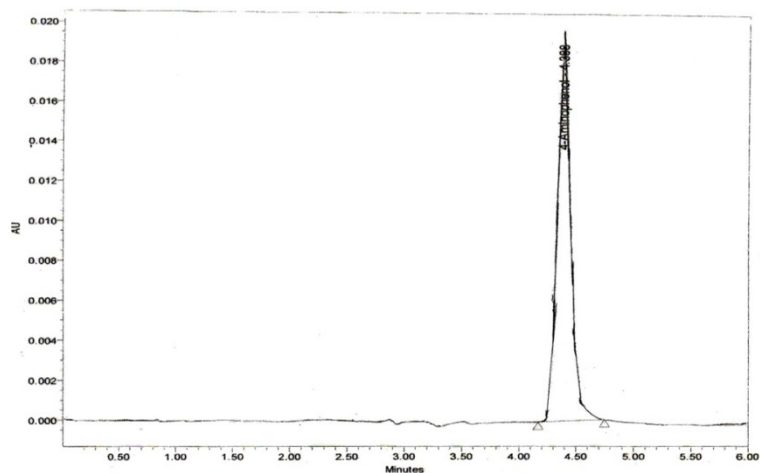
Peak Summary with Statistics
Name : 4-Aminophenol

	Sample Name	Vial	Inj	Name	Retention Time (min)	Area	% Area	Height	Amount
1	STD-4-Aminophenol	1	2	4-Aminophenol	4.388	160409	100.00	19588	10.0
Mean					4.388	160408.9			
Std. Dev.									
% RSD									

Preparation of paracetamol Sample solution (C_6H_7NO):
1.187gm of paracetamol was taken in 100ml standard flask & 15% methanols were added up to the mark and than solution wassonictored. This solution was filtered an and then used for HPLC. The chromatogram was recorded.as shown in fig. 3.

HPLC curve Sample solution of 4- amino phenol figure 3
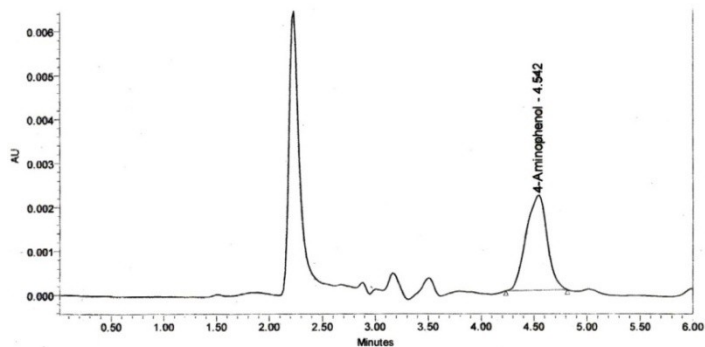
	Peak Name	RT	Area	% Area	Height	Amount	Units
1	4-Aminophenol	4.542	29748	100.00	2160	1.855	mcg/ml

Sr. no.	weight of paracetamol tablet	In gram
1	weight of 20 tablets	11.861
2	Average weight of 20tablet	0.593
3	% deviation =5%	0.029
4	Lower limit	0.563
5	Upper limit	0.622

III. Result & discussion

In chromatogram obtained with the test solution, the area of any peak corresponding to 4- aminophenol is not grater than the area of peak in the chromatogram obtained with the reference solution. In the chromatogram obtained with the test solution peak with long retention time.

Uniformity weight of tablets

Sample complies with Indian pharmacopeia requirement for uniformity weigh of paracetamol tablet 1.

Standard weight of paracetamol as shown in tablet 1

Sr. no.	weight of tablet(gm)	Sr. no.	weight of tablet(gm)
1	0.5924	11	0.5946
2	0.5996	12	0.5934
3	0.5947	13	0.6002
4	0.5858	14	0.5853
5	0.5993	15	0.5910
6	0.5900	16	0.5853
7	0.5876	17	0.6011
8	0.5857	18	0.5951
9	0.5962	19	0.5892
10	0.6065	20	0.5913

Different weight of paracetamol as shown in tablet 2

Calculation:

Weight of paracetamol= sample area /standard area x standard weight / standard dilution / sample weight xaverage weight x purity of sample.

= 0.5468/0.715 x 10/1000 x 20/0.1762 x 0.5931 x 100

= 0.764 x 0.01 x 1135.07 x 10 x 10 x 0.5931

=514.33mg of paracetamol

=514.33/500 x100

Weight of paracetamol =102.86% of label amount.
I.P. limit 95% to 105% of label amount)

IV. Dissolution of Paracetamol tablets:

Sample complies with Indian pharmacopeia requirement for dissolution test.

27.8gm of standard paracetamol was taken in 50ml standard flask and diluted with water.1ml of this solution was taken in another 50ml standard flask and diluted up to the mark, using distilled water.

6 tablets was taken for sampling each tablet was dissolved in separate 900 ml of distilled water and phosphate buffer PH 5.8 futher it was dissolved for 30 minute at 50 RPM, it becomes totally dissolved. 1ml of this solution was taken in 50 ml standard flask and dilute with distilled water up to the mark. Absorbance was measured at243 nm.as shown in fig. 4.
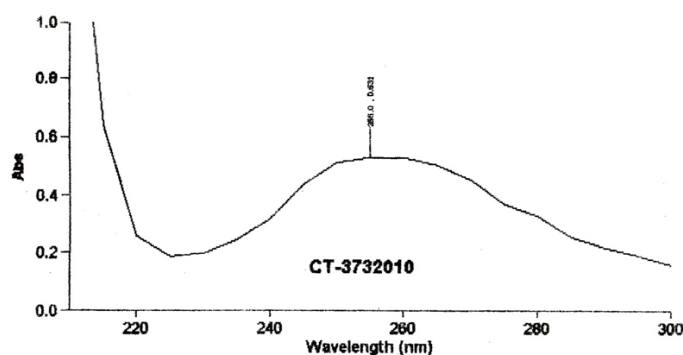
UV graph figure 4

Figure -4

V. Conclusion:

On the basis of above observation, measured sample solution at 243 nm. UV- Spectrophotometer the concentration of ParacetamolRs. Calculated the content of paracetamol was not less than 80% of the standard amount of Paracetamol. The observed percentage is indicated that the Paracetamol is within the limit of Indian pharmacopeia. The Paracetamol sample is indicated that there is rare side effect in the human body may be formed. High speed analysis, less time consumable checking purity of sample & more intense peak recorded in RP-HPLC technique. It can be simultaneous determination for standard reference solution & sample solution of Paraccetamol.

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