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Development and Validation of a Uv Spectroscopic Method for Laboratory Analysis of Paracetamol Bulk Powder and Various Manufactured Paracetamol Tablet in Indian Market.

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ABSTRACT
This study used UV spectroscopy to estimate the percent of paracetamol medicine in some manufactured tablets on the Indian market, by determining the active ingredient in ten distinct samples of tablets and comparing them to paracetamol standard material. It was designed and validated for the measurement of paracetamol using a mixed solution of methanol and phosphate buffer 6.8 in a 1:3 ratio, methanol and borate buffer 9.0 in a 1:3 ratio as a solvent (1:3) and also using a mixed solution of ethanol and phosphate buffer 6.8 in a ratio (1:3), ethanol and borate buffer 9.0 in a ratio (1:3) as a solvent The drug's max (absorption maximum) was discovered to be 245 and 300 nm.
keywords: Paracetamol, Spectrophotometry, Manufacture, Phosphate Buffer 6.8, Borate Buffer 9.0, Tablet, Indian Market

I. INTRODUCTION

UV-Vis spectroscopy is an analytical technique for determining the absorbance of ultraviolet or visible light through an analyte. The analyte's molecular absorption corresponds to both valence electron excitation and electron excitation in distinct atomic orbitals.UV-Vis Spectroscopy is a powerful tool for analysing organic and inorganic molecules in both qualitative and quantitative ways. Paracetamol and acetaminophen are the active metabolites of phenacitin. It's an antipyretic and analgesic that's available over the counter. 4-hydroxy acetanilide is the chemical name for it (acetaminophen) 1. Paracetamol and other NSAIDs have the same mechanism of action (inhibition of prostaglandin synthesis by inhibiting cyclooxygenase (COX)) but have different amounts of analgesic, anti-inflammatory, antipyretic, and anti-platelet effects. 2-3. Both the Indian and British Pharmacopoeias list paracetamol. Both compendia suggest titrimetric and UV spectrophotometric assay method for paracetamol in bulk and tablet formulations.

II. 2. MATERIALS AND METHOD

Instruments
UV-Visible double beam spectrophotometer (AU 2701) with software UV detective plus and a pair of 10 mm matched quartz cell was used.

Material
Himanshu Pharmaceuticals Pvt. Ltd. Bengaluru, Karnataka, India purchased the paracetamol (purity 99.99 percent) sample and utilised it as a reference standard. The paracetamol-containing commercial fixed-dose formulation (Apex, calpol, Arden, paracip, fepanil) was acquired from a local pharmacy shop. Methanol, ethanol, and phosphate buffer 6.8, as well as borate buffer 9.0, were utilised as solvents in the investigation to prepare the stock and working standard solutions. All of the chemicals and reagents were of the highest quality.

Preparation of standard stock solutions
Phosphate buffer and methanol

In a 100 ml volumetric flask, a standard stock solution of pure paracetamol (1 mg/ml) was made by dissolving 100 mg paracetamol in 100 ml of methanol and phosphate buffer 6.8 (in a 1:3 ratio). To make a stock solution with 100 g/ml of medication, 10 ml of this solution was taken and diluted to 100 ml with phosphate buffer 6.8.The stock solution was filtered using Whatmann filter paper. The above procedure is repeated using methanol to obtain the same concentration of paracetamol. To get various working solutions, the

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solution was further diluted with phosphate buffer 6.8.

Phosphate buffer and ethanol

In a 100 ml volumetric flask, a standard stock solution of pure paracetamol (1 mg/ml) was made by dissolving 100 mg paracetamol in 100 ml ethanol and phosphate buffer 6.8 (in a 1:3 ratio). To make a stock solution with 100 g/ml of medication, 10 ml of this solution was taken and diluted to 100 ml with phosphate buffer 6.8.The stock solution was filtered using Whatmann filter paper. The above procedure is repeated with ethanol to obtain the same concentration of paracetamol. To get various working solutions, the solution was further diluted with phosphate buffer 6.8.

Borate buffer and methanol

In a 100 ml volumetric flask, a standard stock solution of pure paracetamol (1 mg/ml) was made by dissolving 100 mg paracetamol in a 100 ml solution of methanol and borate buffer 9.0 (in a 1:3 ratio). To make a stock solution with 100 g/ml of medication, 10 ml of this solution was taken and diluted to 100 ml with borate buffer 9.0. The stock solution was filtered using Whatmann filter paper.To prepare the same concentration of paracetamol in methanol, repeat the above procedure using methanol. After that, the solution was diluted with borate buffer 9.0 to provide a variety of working solutions.

Borate buffer and ethanol

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Preparation of sample solutions for assay

Phosphate buffer

Methanol mixture

For quantification of drugs from the commercial formulation, 10 tablets of Apex, Calpol, Arden, Paracip, Fepanil, respectively containing 500 mg paracetamol each were weighed and ground in a powder. In a 100 ml volumetric flask, a weighed quantity of tablet powder equivalent to 100 mg paracetamol was transferred and diluted with methanol: phosphate buffer 6.8 (in 1:3 ratio)Then the resulting solution as allowed to stand for some time, filtered through Whatman filter paper and the filtrate as suitably diluted to produce the desired concentration using phosphate buffer 6.8. The solution's absorbance was measured at 245nm
and 300nm.

Ethanol mixture

For quantification of drugs from the commercial formulation, 10 tablets of Apex, Calpol, Arden, Paracip, Fepanil, respectively containing 500 mg paracetamol each were weighed and ground in a powder.In a 100 ml volumetric flask, a weighed quantity of tablet powder equivalent to 100 mg paracetamol was transferred and diluted with ethanol: phosphate buffer 6.8 (in 1:3 ratio) Then the resulting solution as allowed to stand for some time, filtered through Whatman filter paper and the filtrate as suitably diluted to produce the desired concentration using phosphate buffer 6.8. The solution's absorbance was measured at 245nm
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III. RESULTS AND DISCUSSION

METHANOL MIXTURE AND BORIC BUFFER PH 9.0

S.NO	BRAND	WAVELENGTH	RESULT	WAVELENGTH	RESULT
1	API	300nm	0.2034	245nm	0.1913
2	APEX	300nm	0.2745	245nm	0.2740
3	CALPOL	300nm	0.1854	245nm	0.1696
4	ARDEN	300nm	0.3332	245nm	0.3564
5	PARACIP	300nm	0.2295	245nm	0.2235
6	FEPANIL	300nm	0.3131	245nm	0.3298

ETHANOL MIXTURE AND BORIC BUFFER PH 9.0

S.NO	BRAND	WAVELENGTH	RESULT	WAVELENGTH	RESULT
1	API	300nm	0.4359	245nm	0.2045
2	APEX	300nm	0.4155	245nm	0.1987
3	CALPOL	300nm	0.4092	245nm	0.1994
4	ARDEN	300nm	0.3200	245nm	0.2111
5	PARACP	300nm	0.4155	245nm	0.1943
6	FEPANIL	300nm	0.4350	245nm	0.2210

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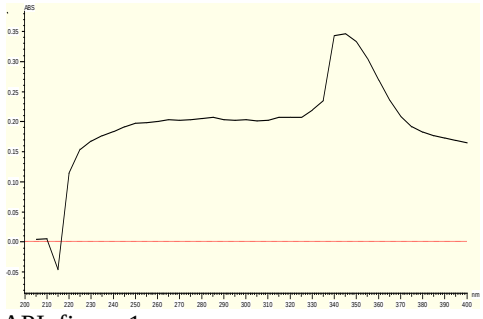
ETHANOL MIXTURE AND PHOSPHATE BUFFER PH 6.8

S.NO	BRAND	WAVELENGTH	RESULT	WAVELENGTH	RESULT
1	API	300nm	0.2726	245nm	0.1893
2	APEX	300nm	0.2513	245nm	0.1910
3	CALPOL	300nm	0.2854	245nm	0.2002
4	ARDEN	300nm	0.2936	245nm	0.2135
5	PARACIP	300nm	0.3095	245nm	0.1944
6	FEPANIL	300nm	0.3131	245nm	0.2334

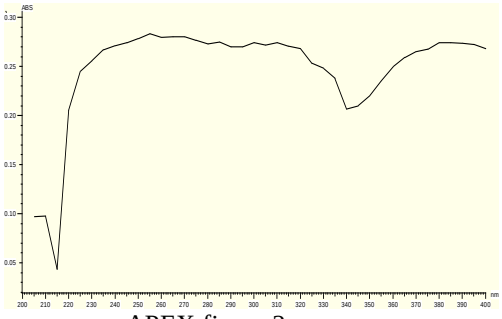
METHANOL MIXTURE AND PHOSPHATE BUFFER PH 6.8

S.NO	BRAND	WAVELENGTH	RESULT	WAVELENGTH	RESULT
1	API	300nm	0.3333	245nm	0.2289
2	APEX	300nm	0.2081	245nm	0.1869
3	CALPOL	300nm	0.2132	245nm	0.1949
4	ARDEN	300nm	0.1978	245nm	0.1805
5	PARACIP	300nm	0.1970	245nm	0.1706
6	FEPANIL	300nm	0.2132	245nm	0.1951

BORATE BUFFER (METHANOL SOLVENT)



API figure 1



APEX figure 2

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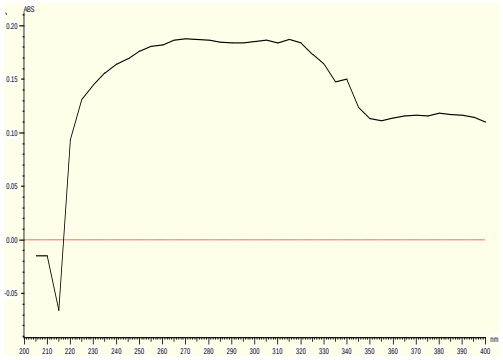
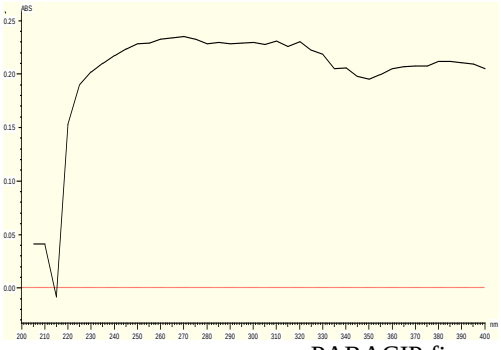
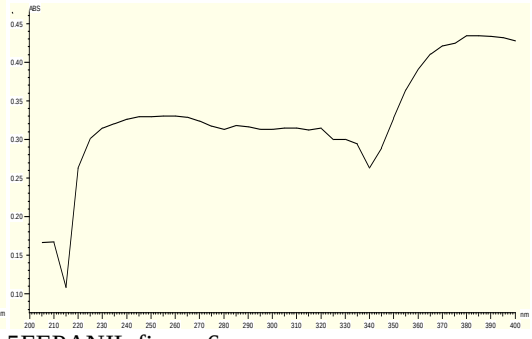


CALPOL figure 3

ARDEN figure 4

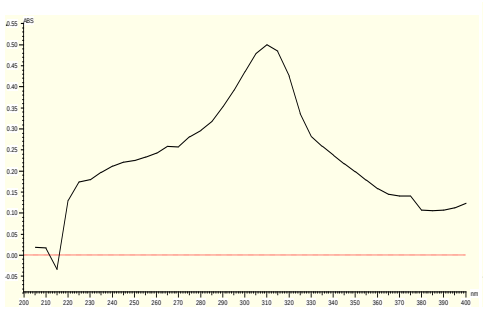


PARACIP figure 5

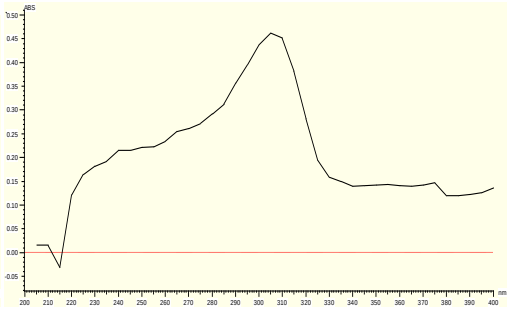


FEPANIL figure 6

BORATE BUFFER (ETHANOL SOLVENT)



API figure 7



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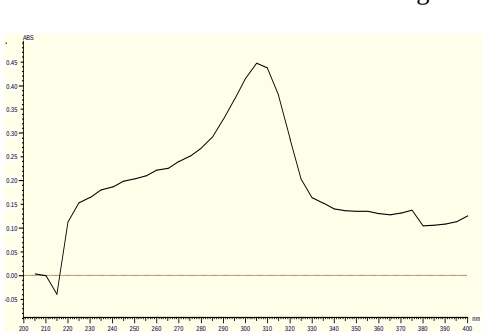
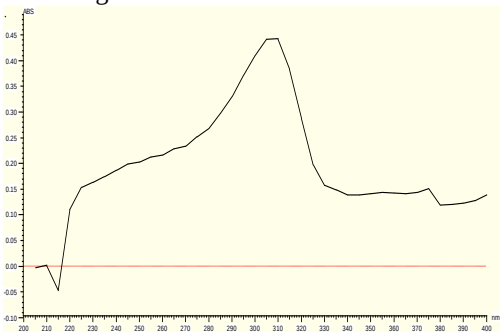


CALPOLfigure 9



ARDEN figure 10

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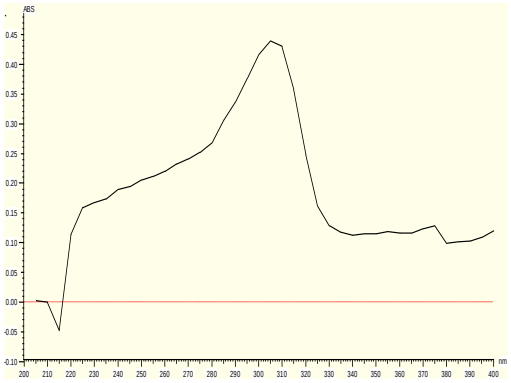
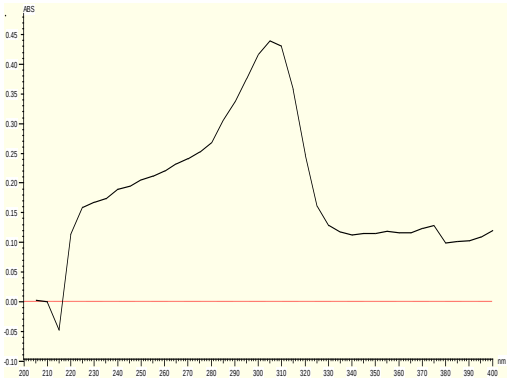
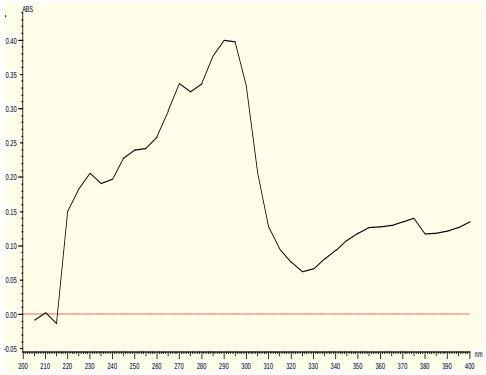
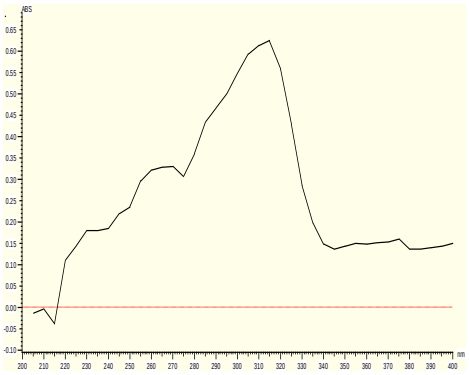
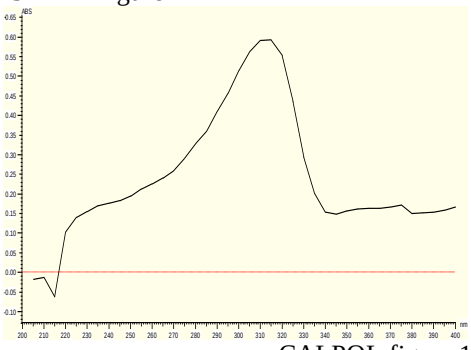
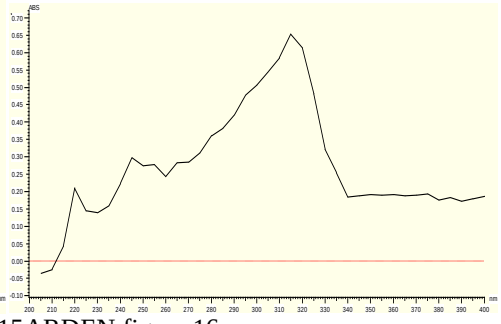



PARACIP figure 11FEPANIL figure 12

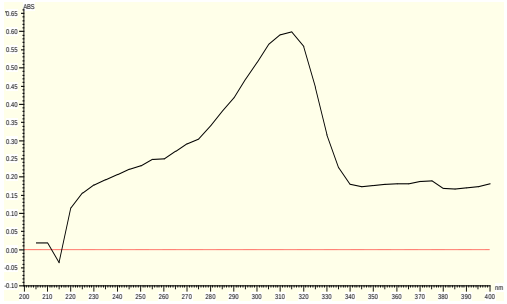
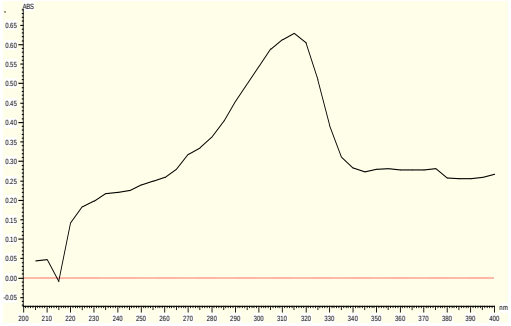
PHOSPHATE BUFFER (METHANOL MIXTURE)

API figure 13APEX figure14

CALPOL figure 15ARDEN figure 16

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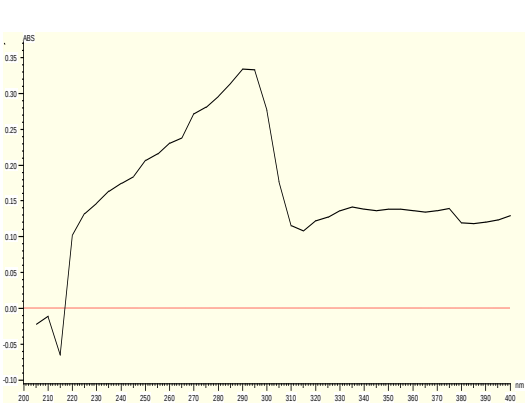
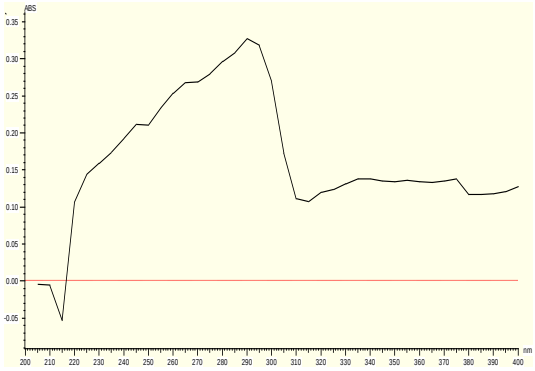
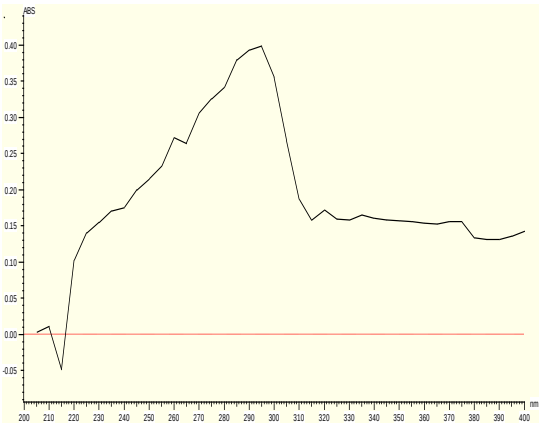
PARACIP figure 17FEPANIL figure 18

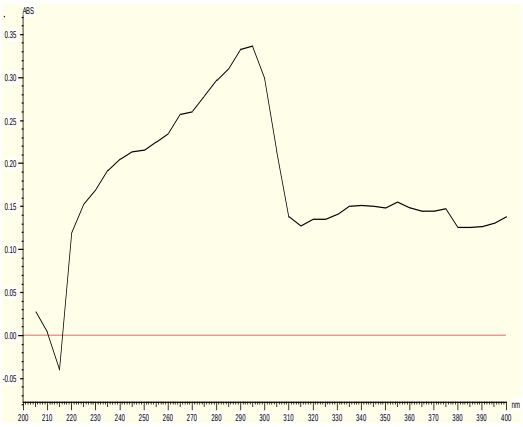
PHOSPHATE BUFFER (ETHANOL MIXTURE)



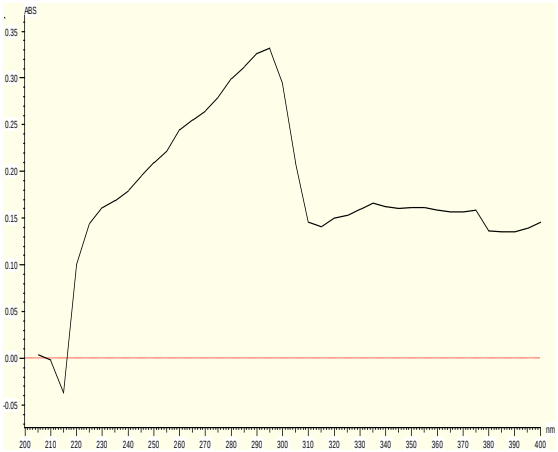


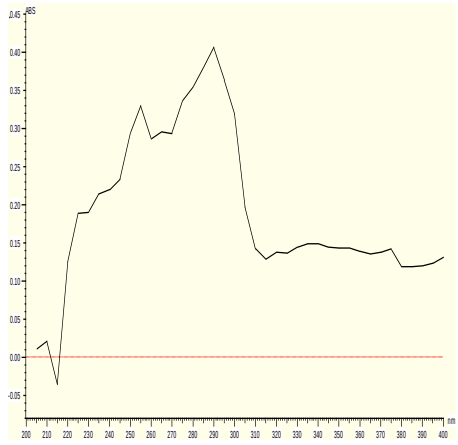
API figure 19APEX figure 20





ARDEN figure 22 CALPOL figure 21





PARACIP figure 23FEPANIL figure 24

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IV. CONCLUSION

A simple and rapid UV spectrophotometric method was developed and validated for the quantitative determination of paracetamol in bulk and different branded tablet

The obtained results indicate that the quantity of paracetamol in tablets is accepted within the normal percentage 90%- 110%, according to IP and there is a significant difference in the weights of tablets in the same sample of different brand tablets such as (Apex, Calpol, Arden, Paracip, Fepanil)

The comparison of the results obtained from the application of two solvents on the test sample, indicates that the five brand tablets are same effect are produced but small variation of using different types of buffer and different types of solvent.

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