DETERMINATION OF FLURBIPROFEN PELLETS 57% USING DRUG RELEASE METHOD BY UV

Department of Chemistry, Sadineni Chowdaraiah College of Arts and Science, Maddirala, Chilakaluripet, Guntur, Andhra Pradesh- 5211 611, India.
1Department of Chemistry, GITAM university, Visakhapatnam
* E-Mail: vbrmandava@yahoo.com

ABSTRACT
UV Spectra method developed for the determination of Flurbiprofen. Dissolution test used by In-House method, apparatus (Basket), RPM75, temp37± 0.5˚C and time(2,4,6,8 and 12hrs) were analyzed. The determination was accomplished by spectrophotometry at 247nm. In-House limits dissolution 2nd hour Not more than 10%, 4th hour Not more than 60%, 6th hour Not less than 65.0%, 8th hour Not less than 75.0% and 12th hour Not less than 90%. OD was applied successfully to the determination of Flurbiprofen content in pellets and in vitro dissolution studies. The proposed method was validated in terms of linearity, repeatability, and accuracy. Linearity was obeyed in the range 0.5-2.5mg of Flurbiprofen, while the repeatability (%RSD 2.5) was satisfactory. The dissolution studies of Flurbiprofen pellets obtained by the proposed method were good.

Keywords: Flurbiprofen, HPLC method, linearity

INTRODUCTION
Flurbiprofen is used to treat Anti-inflammatory; analgesic. Chemically Flurbiprofen is known as (2RS)-2-(2-fluorobiphenyl-4-yl)propanoic acid. It is not official in any of the pharmacopoeias. A survey of literature reveals that HPLC methods1,2 and are reported for the determination of HPLC Analysis of Determination of flurbiprofen in human serum by reverse-phase high-performance liquid chromatography with fluorescence detection, Cloud point extraction-HPLC method for determination and pharmacokinetic study of flurbiprofen in rat plasma after oral and transdermal administration. How ever there is no HPLC method reported so for its estimation in commercial dosage form. Hence a Spectrophotometric method for the determination of Flurbiprofen in pharmaceutical solid dosage forms is described.

Flurbiprofen

EXPERIMENTAL

Process and used Ingredients: Flurbiprofen 57g (API), Sucrose 20g, Starch 8g, Methacrylic acid copolymer L-100 9g, Methacrylic acid copolymer S-100 2g, Ethyl cellulose N-50 3.5g, and Talc 0.5mg. Total 100.0g.
Method

Drug release
Apparatus: Basket rpm; 75
Medium 1 (0-2 hours) : 0.1N Hydrochloride, 900ml
Medium 2 (2-12 hours) : pH 7.2 phosphate buffer; 900ml

Medium-1: Dissolve 8.5 ml hydrochloric acid (37%) in 1000mL water

Medium-2 pH 7.2 phosphate buffer: Dissolve 6.8g of potassium hydrogen ortho phosphate in 1000ml water. Adjust with 2N Sodium hydroxide or 2N hydrochloric acid to a pH 7.2±0.05

Standard solution
Transfer about 25mg of Flurbiprofen WS, accurately weighed, to a 50 ml volumetric flask add 20ml of methanol, sonication for 10 minutes and dilute with Methanol to volume. Mix and filter. Transfer 5.0ml of this solution to a 50 ml volumetric flask, dilute with methanol to the volume and mix. Transfer 5.0ml of this solution to a 50 ml volumetric flask, dilute with Medium to the volume and mix.

Procedure: Determine the amount of Flurbiprofen dissolved by employing UV employing UV absorption at the wavelength of maximum absorbance at about 247nm on filtered portions of the solution under test, suitably diluted with Dissolution medium, if necessary in comparison with a standard solution having a known concentration of Flurbiprofen WS in the same medium.

Dissolution
5 ppm of standard and sample solutions checked into an UV spectra. The amount of Flurbiprofen calculated by comparing the absorbance, with that of the standard.

Recovery studies
To study the linearity, accuracy and precision of proposed method, recovery experiments were carried out. Known quantities of standard at two different levels were added to the pre-analyzed sample, the recovery was estimated to be more than 99%.

RESULTS AND DISCUSSION

LINEARITY:
The linearity of Flurbiprofen is established by plotting a graph of absorbance of standard solutions versus concentration. The linearity is found to be between 0.5 to 2.5mg

<table>
<thead>
<tr>
<th>Concentration</th>
<th>Absorbance</th>
</tr>
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<tbody>
<tr>
<td>0.48</td>
<td>0.024</td>
</tr>
<tr>
<td>0.96</td>
<td>0.048</td>
</tr>
<tr>
<td>1.44</td>
<td>0.073</td>
</tr>
<tr>
<td>1.92</td>
<td>0.096</td>
</tr>
<tr>
<td>2.40</td>
<td>0.12</td>
</tr>
</tbody>
</table>

The precision of the method is studied by making 5 samples of standard and very low RSD values indicate good precision. The reproducibility and reliability of the method has been tested by performing recovery studies which showed good results.
Table-1

<table>
<thead>
<tr>
<th>Semi formulation</th>
<th>Release rate in Hours and Limits</th>
<th>Bowl</th>
<th>% Drug Release</th>
<th>% Drug Release 6 bowls average value</th>
<th>SD</th>
<th>RSD</th>
</tr>
</thead>
<tbody>
<tr>
<td>P E L E</td>
<td>2nd hour (NMT10.0%)</td>
<td>1,2,3,4, 5 and 6</td>
<td>0.50%,0.49%,0.51%,0.50%,0.51%&amp;0.48%</td>
<td>0.498%</td>
<td>0.0117</td>
<td>2.34</td>
</tr>
<tr>
<td>L E</td>
<td>4th hour (NMT 60%)</td>
<td>1,2,3,4, 5 and 6</td>
<td>27.5%,27.9%,28.1%,27% &amp;28.3%&amp;28.5%</td>
<td>28.01%</td>
<td>0.360</td>
<td>1.28</td>
</tr>
<tr>
<td>T S</td>
<td>6th hour (NLT 65.0%)</td>
<td>1,2,3,4, 5 and 6</td>
<td>73.8%,75.2%,74.6%,75% &amp;74.3%&amp;75.9%</td>
<td>74.8%</td>
<td>0.734</td>
<td>0.982</td>
</tr>
<tr>
<td>T S</td>
<td>8th hour (NLT 75.0%)</td>
<td>1,2,3,4, 5 and 6</td>
<td>82.1%,83.9%,81.7%,84% &amp;83.5%&amp;82.8%</td>
<td>83.01%</td>
<td>0.9806</td>
<td>1.181</td>
</tr>
<tr>
<td>T S</td>
<td>12th hour (NLT 90.0%)</td>
<td>1,2,3,4, 5 and 6</td>
<td>94.7%,95.3%,96.2%,95% &amp;94.9%&amp;95.2%</td>
<td>95.31%</td>
<td>0.5344</td>
<td>0.5607</td>
</tr>
</tbody>
</table>

UV spectra
The concentration of Flurbiprofen found to be within limits and the RSD values are reasonably low.

Table-2

<table>
<thead>
<tr>
<th>S.NO</th>
<th>Parameter</th>
<th>Flurbiprofen</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>RSD Of 6 samples</td>
<td>1.4</td>
</tr>
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</table>

CONCLUSION
The proposed method is very simple, rapid and does not involve complicated sample preparation. High percentage of recovery shows that the method is free from interferences of the excipients used in the semi formulations. Therefore the method can be useful in routine quality control analysis.

REFERENCES

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