QUALITATIVE ESTIMATION OF NEVIRAPINE IN PHARMACEUTICAL DOSAGE FORMS BY RP-HPLC

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ABSTRACT

A simple, precise, rapid and reproducible method has been developed and validated for estimation of nevirapine in pharmaceutical dosage forms by RP-HPLC. The separation was achieved using SUPELCOSIL LC-ABZ end capped (5 µm) 150 x 4.6 mm column in isocratic mode with mobile phase ammonium phosphate buffer : acetonitrile(4 : 1) were flushed at a flow rate of 1.0 mL/min. Detection was carried out at 220 nm. The retention time for nevirapine was 7.347 min. The percentage recovery was found to be 99.0-101.0%w/w.

Key words: Nevirapine, RP-HPLC

INTRODUCTION

Nevirapine is a non-nucleoside reverse transcriptase inhibitors used to treat HIV-1 infection and AIDS.

The literature surveys revealed that number of methods have been reported for

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estimation of nevirapine in pharmaceutical dosage forms. The present method was developed keeping the current regulatory requirements in mind. This paper presents a simple, accurate, reproducible and rapid method for the estimation of nevirapine in pharmaceutical dosage forms.

**EXPERIMENTAL**

Chemito isocratic liquid chromatographic system equipped with model K-501 pump and knauer injector with 20JL11 fixed loop and LC-1600 UV detector was used.

**Chemical and reagents**

Monobasic a mmonium phosphate buffer of AR grade and acetonitrile of HPLC grade were used.

**Mobile phase**

Mixture of acetonitrile (150.0 mL) and a mmonium phosphate buffer (600.0 mL) were taken and filtered through 0.45µ filter paper.

**Standard stock solution**

(i) Accurately weighed 24 mg of nevirapine was dissolved in 84 mL mobile phase in a 100 mL volumetric flask.

(ii) Accurately weighed 6 mg of nevirapine was dissolved in 80 mL mobile phase in a 100 mL volumetric flask.

**Mixed working standard**

2.0 mL of standard stock solution A and 5.0 mL standard stock solution B were transferred in 50.0 mL volumetric flask, mixed and made up to volume with mobile phase.

**Sample preparation**

Twenty tablets were weighed and crushed to fine powder and the powder equivalent to 24 mg of nevirapine was taken in 50 mL volumetric flask, 4 mL of acetonitrile and 80 mL of mobile phase was added and kept in ultrasonic bath for 15 minutes and volume was made up to 50 mL with mobile phase and then filtered through 0.45 µ filter paper.
Chromatographic conditions

Mode of separation isocratic  Reverse phase

Column  SUPELCOSIL LC-ABZ end capped (5 µm)
         150 x 4.6 mm pre-washed with mobile phase
         (30 min) prior to analysis

Mobile phase  Mixture of acetonitrile (150.0 mL) and
              ammonium phosphate buffer (600.0 mL) were
              taken and filtered through 0.45µ filter paper.

Injection volume  25 µL

Flow rate  1.0 mL/min

Wavelength  UV 220.0nm

Procedure

The column was flushed with mobile phase till stable base line was obtained and then 25 µL of standard and sample solutions were injected separately under the chromatographic conditions described above and scanned. The amount of nevirapine in sample was calculated by comparing the peak area ratio from standard.

Recovery

To establish the accuracy, reproducibility and precision of the proposed method, recovery experiments were carried out by spiking the pre-analysed samples at different levels. The results are recorded in below Table 1.

Table 1. Recovery studies

<table>
<thead>
<tr>
<th>S. No.</th>
<th>Nevirapine</th>
<th>Claim</th>
<th>Found</th>
<th>Recovery</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td>200</td>
<td>199.2</td>
<td>99.59</td>
</tr>
<tr>
<td>2</td>
<td></td>
<td>200</td>
<td>199.5</td>
<td>99.74</td>
</tr>
</tbody>
</table>

RESULTS AND DISCUSSION

Under proposed chromatographic conditions, the drug nevirapine retention time was found to be 7.347 min and linearity was in the range of 0.008 mg/mL to 0.012 mg/mL.
The chromatogram was scanned at 220 nm.

A simple and accurate reverse phase HPLC method has been thus proposed for estimation of nevirapine in dosage form. The assay value and recovery data indicate that the method is free from interference of excipient and can be effectively used for routine quality control.

![Chromatogram of nevirapine](image)

**Fig. 1 : Chromatogram of nevirapine**

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**REFERENCES**


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