Spectrophotometric Determination of Alendronate Sodium by using Sodium-1,2-Naphthoquinone-4-Sulphonate

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ABSTRACT

A simple, precise and accurate spectrophotometric method was developed for analysis of the osteoporosis drug alendronate sodium (ALS). The method is based on reaction of the drug with sodium-1,2-naphthoquinone-4-sulphonate (NQS) in presence of alkali to form a brown colored complex giving absorption maximum at 525 nm. The drug obeyed Beer’s law in the range of 5-70 µg/ml with a correlation coefficient of 0.999. The LOD and LOQ values are 1.7 µg/ml and 5.0 µg/ml, respectively. The average recoveries for recovery study were found to be in the range of 99.37%-100.46%. The R.S.D. values for intraday and inter-day precision were found to be 0.48 and 0.62, respectively. The optimized assay conditions were applied successfully for determination of ALS in pharmaceutical dosage forms. No interference was observed from the excipients present in the dosage form. The method is statistically validated as per the ICH requirements.

KEYWORDS: Alendronate; bisphosphonates; ICH; spectrophotometry; sodium-1,2-naphthoquinone-4-sulphonate; chromogenic reagent.

Introduction

Alendronate sodium (ALS) is used in treatment of osteoporosis (Prinsloo and Hosking, 2006). Chemically it is sodium [4-amino-1-hydroxy-1-(hydroxy-oxido-phosphoryl)-butyl]phosphonic acid trihydrate (Vachal et al., 2006). The bisphosphonates do not possess any chromophoric group in their chemical structure, which are responsible for giving spectra in UV-visible region. So the drug cannot be directly assessed by dissolving in solvents using UV spectrophotometry. So derivatization of the drug with chromogenic reagents or fluorogenic reagents can be carried out for spectrophotometric determinations. Many methods have been reported so far for analysis of the drug by various analytical techniques. The reported methods include spectrophotometric estimation by using o-phtalaldehyde at basic pH (Aldeeba and Hamdan, 2004), ion-pair complex formation with Cu(II) ions (Koba et al., 2008). Spectrofluorimetric method include by conjugating the drug with Rhodamine B sulphonyl group and its subsequent determination (Jeong et al., 2011). Other methods include electrophoretic methods (Pruthiwasan and Suntornsuk et al., 2010; Svidritskii et al., 2010), potentiometry (de Haro Moreno et al., 2004), HPLC methods (Sibel fi et al., 2003; Yun and Kwon et al., 2006; Tsai et al., 1992; Kang et al., 2006; Chen et al., 2010; Meng et al., 2010; Liu et al., 2008; Hu et al., 2009; Yun et al., 2006).

Sodium-1,2-naphthoquinone-4-sulphonate (NQS) is a chromogenic reagent which has been used previously for determination of pharmaceuticals containing primary amino group (Ashraf et al., 2009; Li et al., 2007; Hasani et al., 2007; Li and Yang, 2007; Darwish, 2005; Xu et al., 2004). But as per literature review, no method has been reported so far for determination of ALS by using NQS. So a successful attempt was made to develop and validate a simple, precise and accurate spectrophotometric method for determination of ALS in bulk drug and pharmaceutical dosage forms.

Materials and Methods

Instrumentation

A Shimadzu 1800 UV Visible Double beam Spectrophotometer (Shimadzu,Tokyo, Japan) with 10 mm matched cuvettes, compatible with UV Probe 2.1 software was used. A high precision analytical balance, Model-GR-202 (AND Instrument India Pvt. Ltd., Gurgaon, India) of sensitivity 0.1 mg was used to weigh the chemicals and reagents. A water bath (Thermolab, India) with a thermostat was used for heating the drug solutions.

Chemicals and Reagents

All the chemicals used were of analytical grade. The drug alendronate sodium (ALS, purity 99.8%) was received from Novartis Healthcare Ltd., Hyderabad, India. Purity of the drug was assured by determining the melting point.

ABBREVIATIONS: ALS, Alendronate sodium; NQS; Sodium-1,2-naphthoquinone-4-sulphonate.