RESEARCH ARTICLE

Design Expert-Supported Development and Validation of High-Performance Thin-Layer Chromatographic Stability-Indicating (HPTLC) Method: an Application in Quantitative Analysis of Ropinirole in the Bulk Drug and in Marketed Dosage Forms

Gulam Mustafa · Sanjula Baboota · Javed Ali · Alka Ahuja

Abstract A simple, precise and stability-indicating thin-layer chromatographic method for estimation of ropinirole HCl was developed and validated as per ICH guidelines. The mobile phase consisted of acetone–cyclohexane–6 M ammonia solution (8:5.5:0.5, *v/v/v*). Scanning the drug was done at 250 nm. Compact spots for ropinirole HCl were found at an R_f value of 0.51±0.002. The linear regression analysis data for the calibration plots showed good linear relationship with R^2 0.9976±0.0011 in the working concentration range of 100–3,000 ng spot^{-1}. The method was validated for precision, accuracy, ruggedness, robustness, specificity, recovery, limit of detection (LOD), and limit of quantitation (LOQ). The LOD and LOQ were 12.89 and 42.53 ng spot^{-1}, respectively. The drug was subjected to degradation; the peaks of degradation products were well resolved from the standard with significantly different R_f values. Hence, this method can be used for quality control assay of ropinirole.

Keywords Ropinirole · Design expert optimization · HPTLC · Stability indicating · Validation · Robustness · Precision

G. Mustafa · S. Baboota · J. Ali · A. Ahuja (✉)
Department of Pharmaceutics, Faculty of Pharmacy,
Hamdard University,
Hamdard Nagar,
New Delhi 110062, India
e-mail: alkaahuja@yahoo.com

A. Ahuja
Pharmacy Department, Oman Medical College,
P.O. 620, P.C. 130, Azaiba,
Muscat, Oman

Introduction

The clinical picture of Parkinson's disease (PD) was identified nearly 200 years ago, and in 1876, Charcot honoured James Parkinson by giving his name to the syndrome. It is most common progressive, neurodegenerative disorder primarily affecting dopaminergic neuronal systems, with impaired motor function as a consequence [1]. The disease is accompanied by the symptoms like rest, tremor, bradykinesia, rigidity, stooped posture and instability. Ropinirole hydrochloride, 4-[2-(dipropylamino)ethyl]-1,3-dihydro-2*H*-indole-2-one hydrochloride (Fig. 1), is a specific D2 and D3 receptor nonergoline dopamine agonist recently introduced, indicated for the treatment of PD [1] and has been proven to be effective in both monotherapy and combination therapy for Parkinson's disease [2, 3]. It is being increasingly used as monotherapy in the initial and late stage treatment of Parkinson's disease rather than as adjunct to levodopa [4]. In addition, ropinirole is also efficacious in the management of more advanced Parkinson's disease in patients experiencing motor complications after long-term levodopa use [5].