Bulletin of Pharmaceutical Research 2011;1(3):13-7
An Official Publication of Association of Pharmacy Professionals
ISSN: 2249-6041 (Print); ISSN: 2249-9245 (Online)

RESEARCH ARTICLE

FORCED DEGRADATION STUDY OF PARACETAMOL IN TABLET FORMULATION USING RP-HPLC

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Received: November 01, 2011 / Revised: November 20, 2011 / Accepted: November 22, 2011

This study describes the development of stability indicating RP-HPLC method for paracetamol (PCT), an analgesic and antipyretic. In order to investigate the stability of drug, a stress testing of drug sample by exposing it to variety of forced degradation conditions has been recommended. PCT was subjected to stress degradation under different conditions recommended by International Conference on Harmonization (ICH). Stress testing methods are screening methods to be used to understand the degradation chemistry of a drug and therefore do not need to be validated to the extent of final control methods. The sample so generated was used to develop a stability indicating high performance liquid chromatographic method for PCT. The chromatographic separation of PCT and its degradation products was done on C_{18} column. The mobile phase containing mixture of acetonitrile and methanol in ratio 60:40 was found to be most satisfactory at a flow rate of 1 ml/min. Detection was carried out using single wavelength detector at 230 nm.

Key words: Forced degradation study, Paracetamol, RP-HPLC, ICH guideline.

INTRODUCTION

Paracetamol (PCT) (4-hydroxylacetanilide) (**Figure 1**) is used in the treatment of pain and inflammation (Indian Pharmacopoeia, 1996). It is commonly used for the relief of headaches, other minor aches and pains, and is a major ingredient in numerous cold and flu remedies. In combination with opioid analgesics, paracetamol can also be used in the management of more severe pain such as post surgical pain and providing palliative care in advanced cancer patients (SIGN guideline, 2008). Analysis of PCT tablet was reported by UV spectroscopy, HPLC and HPTLC. The UV spectroscopy and RP-HPLC method were also developed for the analysis of PCT in combined dosage form (Likhar and Gupta, 2010; Gupta *et al* 2010; Shukla *et al* 2011). The pharmaceutical products are prone to undergo degradation in various physical and chemical conditions and yield impurities which adversely affect the performance of drug substance. Hence, it has been mandated by regulatory agencies of various countries to submit the stability indicating data of the drug substance and drug product before approval for commercialization of products. Hence, it is necessary to develop stability indicating method for analysis of drug substance, drug product and their impurities. In continuation of efforts made for RP-HPLC/UV spectrophotometric method developments for determination of drugs (Patil *et al* 2011; Prasanthi *et al* 2011; Shah *et al* 2011), the present work was aimed at the development of forced degradation study of PCT in tablet formulation using RP-HPLC as per ICH guideline.

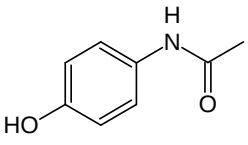

Fig. 1. Structure of paracetamol (PCT)