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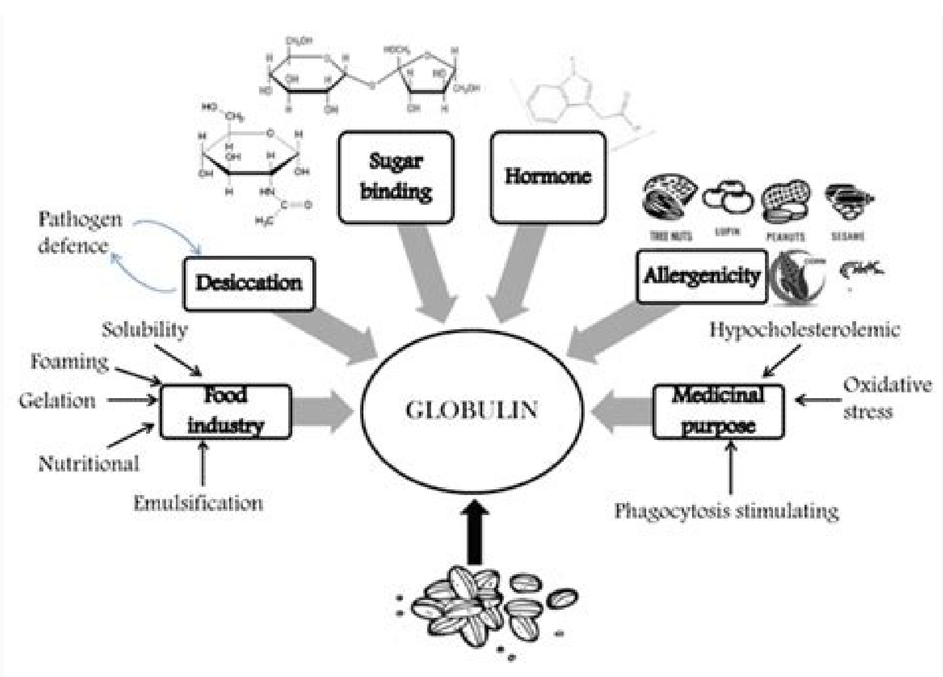
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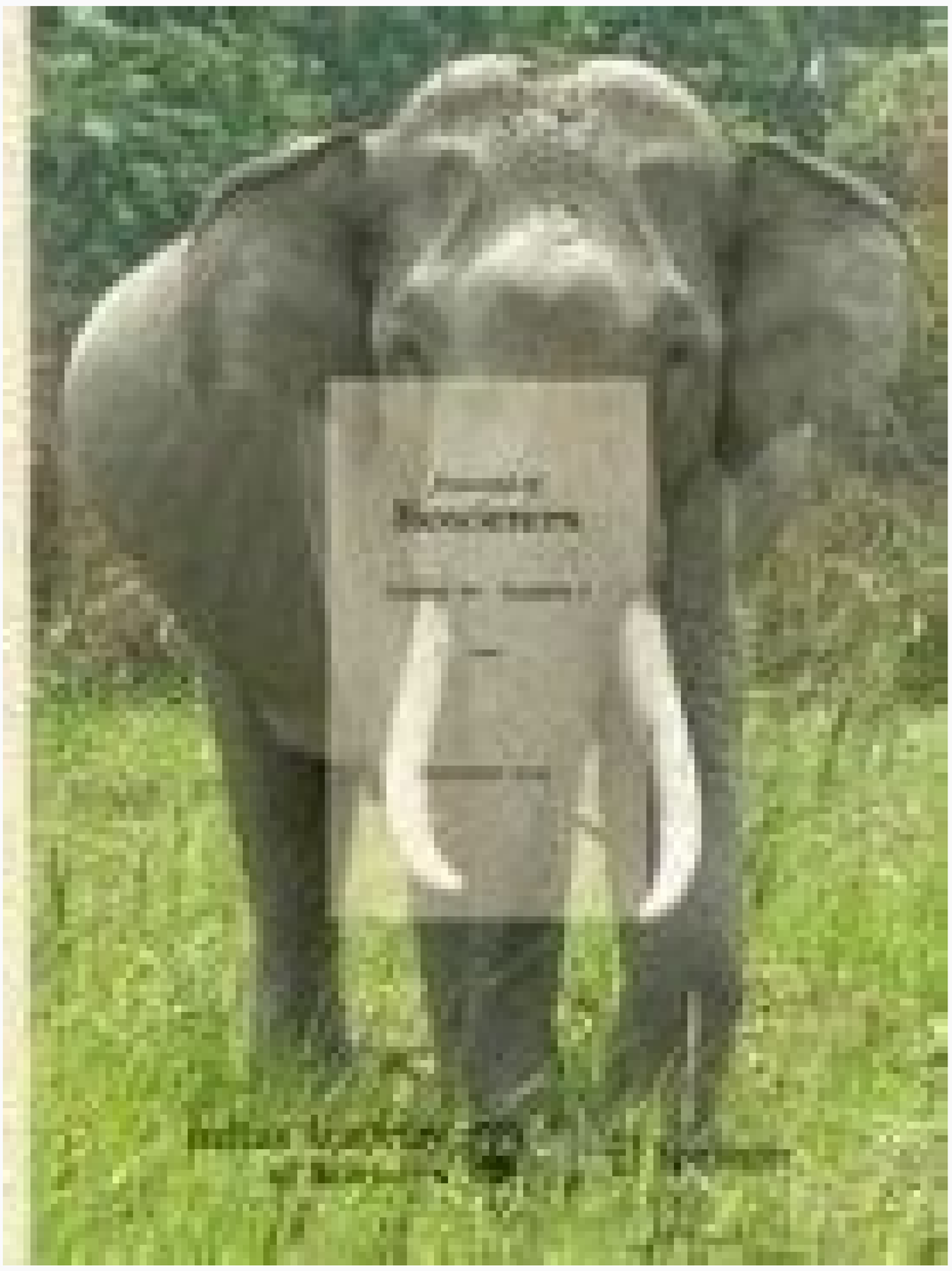
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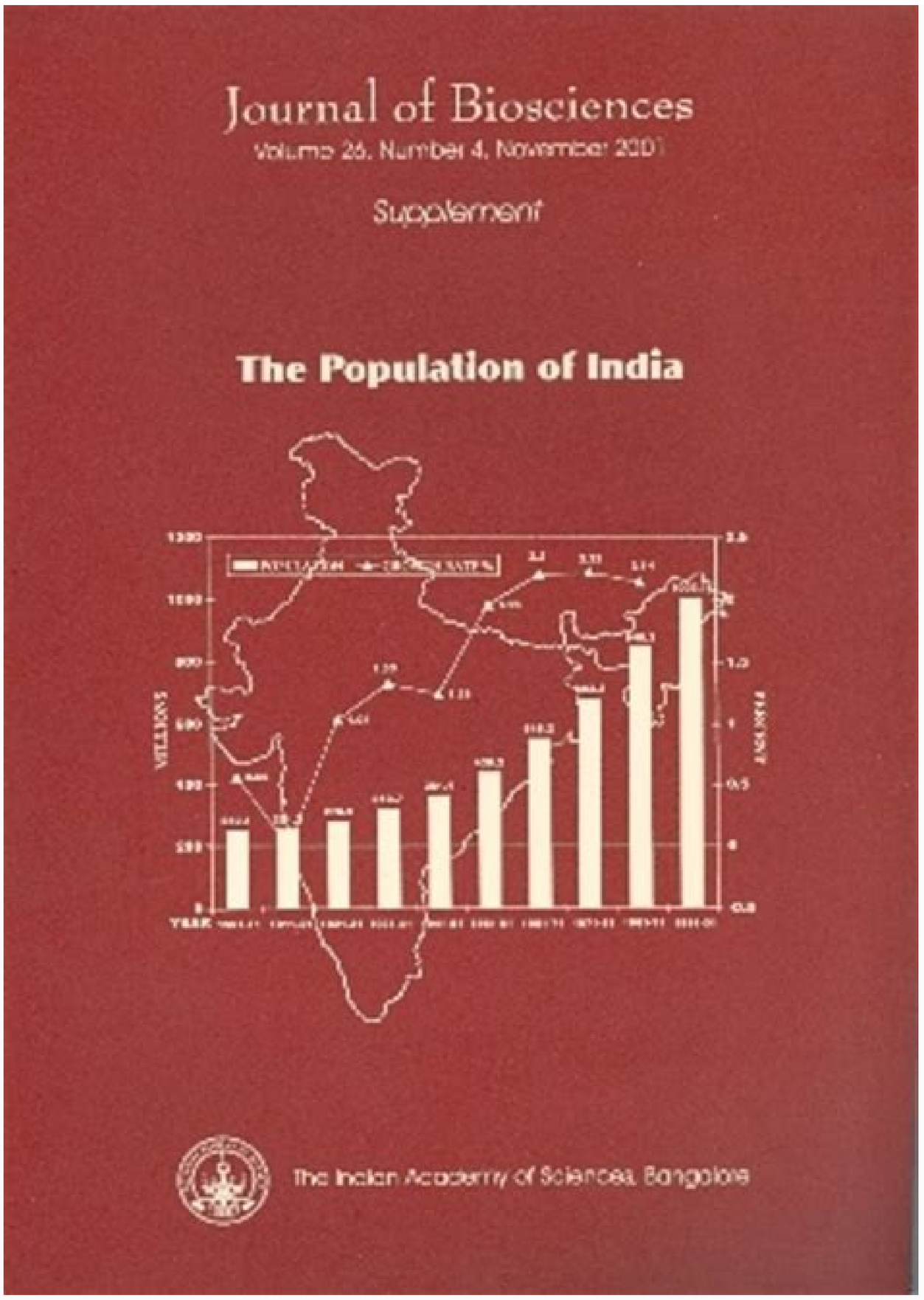

DEVELOPMENT AND VALIDATION OF ASSAY METHOD FOR MELOXICAM TABLETS BY RP-HPLC

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ABSTRACT

A simple, precise, accurate and economical RP-HPLC method has been developed and validated for the assay of Meloxicam tablets. The method was developed using pH 7.0 Phosphate buffer: Acetonitrile (40:60 v/v) in isocratic mode and Waters Xterra C 18 (150 X 4.6mm), 5µ column. Flow rate and detection wavelengths were fixed at 0.8 ml/min and 344 nm. Retention time for Meloxicam was found to be 2.448 minutes. Method was validated as per ICH guidelines to test its suitability for intended purpose. Linearity range for Meloxicam was set at 10-75 µg/ml with correlation coefficient 0.999. Accuracy values for method were found to be 99.53-99.66%. Method found to be robust against changes in flow rate, organic composition, pH of mobile phase and detection wavelength. The proposed method is suitable for quality control analysis of Meloxicam tablets.

Key words: Meloxicam, RP-HPLC, Method development and Validation.

INTRODUCTION

Meloxicam is a potent non-steroidal anti-inflammatory drug of the enolic acid class of oxicam derivatives. Chemically it is 4-hydroxy-2-methyl-N-(5-methyl-2-thiazolyl)-2H-1, 2-benzo-thiazine-3-carboxamide-1, 1-dioxide ($C_{14}H_{13}N_3O_4S_2$).It is more effective at low doses with a good gastrointestinal tolerability. Literature survey reveals the availability of various analytical methods for quantitation of meloxicam present in different matrices i.e. biological and tablet, by employing different techniques like UV-Visible Spectrophotometry, Fluorimetry, RP-HPLC, LC-MS, LC-MS/MS and Capillary Zone Electrophoresis. Many of reported methods employed internal standard for the estimation of meloxicam present in matrix, which turned the analytical procedure tedious. Some RP-HPLC methods are not economical in terms of mobile phase composition, column dimensions and run times. Hence there is need for the development of newer analytical method to overcome above discussed hurdles for the estimation of meloxicam present in tablets. Aim of the present study is to develop a simple, precise and accurate method for the estimation of meloxicam in formulations by RP-HPLC.

MATERIALS AND METHODS

Chemicals and Solvents: Meloxicam working reference standard (Potency-99.95 %w/w on as is basis) was obtained from Dr.Reddy's Laboratories Ltd., Hyderabad. HPLC grade- Acetonitrile and Water were procured from E.Merck (India) Ltd., Mumbai, India. Orth AR grade – Potassium dihydrogen orthophosphate and Triethylamine were obtained from E.Merck (India)Ltd., Mumbai, India. Muvera 7.5 manufactured by Sun Pharma Limited,Sikkim were procured from local pharmacy.

Preparation of Phosphate Buffer: 21.10 gm of Potassium dihydrogen orthophosphate was weighed and dissolved in 3000 mL of water (HPLC grade). pH was adjusted to 7.01 with triethylamine and sonicated for 10 min. Filtered through 0.45 µ Millipore Nylon filter.

Preparation of Mobile Phase: A mixture of pH 7.01 phosphate buffer 2400 mL (40%) and acetonitrile 3600 mL (60%) were mixed well, degassed in a sonicator for about 10 minutes and filtered through 0.45 µ Millipore Nylon filter.

Diluent: Mobile phase was used as diluent

Chromatographic Conditions: Assay of Meloxicam tablets was carried out on a Waters HPLC system equipped with Aliance 2695 binary pump, a 100 µL injection loop, auto sampler and a 2487 dual wavelength UV detector and running on Waters Empower software. The chromatographic conditions are as follows, Column: Waters Xterra C18 (150 x 4.6mm), 5µ; Flow rate: 0.8 ml/min; Detection wavelength: 344 nm; Injection volume: 20 µl; Runtime: 6 minutes; Column temperature: Ambient and Sample cooler temperature: 20°C

Preparation of Standard Stock Solution for Assay: Accurately 50.07 mg of Meloxicam working reference standard was weighed and transferred into a 50 mL clean dry volumetric flask. 10 mL of diluent was added and sonicated for 10 min for complete dissolution of the drug. Finally the volume was made up to the mark with the diluent.

Preparation of Standard Solution for Assay: 3 mL of standard stock solution was pipetted into a 100 mL volumetric flask and diluted up to the mark with diluent. Filtered through 0.45µ Millipore Nylon filter.

Preparation of Sample Stock Solution for Assay: 20 tablets were weighed and the average weight was determined. Tablets were crushed into fine powder.

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