DEVELOPMENT AND VALIDATION OF ANALYTICAL METHOD FOR SIMULTANEOUS ESTIMATION OF ADAPALENE AND AZITHROMYCIN IN BULK AND IN ANTI ACNE FORMULATION

By

Nilesh Yeshvant Patil
Enrollment No. 102140804020

Guided by
Dr. Suresh M. Jain
M. Pharm, Ph.D
Associate Professor and HOD, Dept. of Pharmaceutical Quality Assurance

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Parul Trust
Limda, Ta. Waghodia, Dist. Vadodara 391760

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Nilesh Yeshvant Patil

Supervised By

Dr. Suresh M. Jain

M. Pharm., Ph.D

Associate Professor and HOD, Dept. of Pharmaceutical Quality Assurance,

Baroda College of Pharmacy

S Kant Healthcare Ltd.,

Vapi, (Gujarat)

ABSTRACT

Sensitive, accurate and precise methods were developed for the simultaneous estimation of Adapalene and Azithromycin in bulk and in anti acne gel formulation. A UV solvent extraction method has been developed, validated as per ICH guideline and was used for estimation of Adapalene and azithromycin in gel formulation. Solvents used for solvent extraction method were methanol and 0.2 N Sodium hydroxide. Both Adapalene and Azithromycin were detected at wavelength maxima of 318 nm and 219 nm respectively. The method was found to be linear in the range of 3-18 µg/ml and 15-90 µg/ml for Adapalene and Azithromycin respectively. The RP-HPLC method has shown adequate separation for Adapalene and Azithromycin in formulation. The separation was achieved on Phenomenex C18, (250mm x 4.6mm), 5 µm column, using a mobile phase consisting of Acetonitrile, Tetrahydrofuran, water and trifluoroacetic acid in ratio of 72:18:10:0.02v/v respectively at a flow rate of 0.7 ml/min, Injection volume 20µl with

detection wavelength of 215 nm. The described method was linear over a range of 30-105 µg/ml for Adapalene and 600-2100 µg/ml for Azithromycin. The correlation coefficient for Adapalene and Azithromycin were found to be 0.9987 and 0.9989 respectively. Proposed method was validated as per ICH guidelines for linearity, accuracy, precision, specificity and LOD and LOQ and was used for estimation of Adapalene and Azithromycin in gel dosage form and results were found to be satisfactory. Thus the developed and validated method can be used successfully in formulations.

Key words: Adapalene, Azithromycin, UV solvent extraction method, RP-HPLC method, Validation.