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Analytical Method Development and Validation of Stability Indicating RP-HPLC method for Related Substances of Apremilast in Tablet Dosage Form

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Abstract: *The present work involves the development of simple, accurate, precise and stable RP- HPLC method for the estimation of Apremilast in the tablet dosage form. The method has several advantages, including simple and mobile phase, low cost solvents, rapid analysis, and simple sample preparation. In developed method, the analyte was resolved by using isocratic method and mobile phase was used methanol: acetonitrile: water in proportion of (35v:38v:27v), at a flow rate 1.0 ml/min, the detection was carried out at 230 nm. The results of analysis in the method were validated in terms of accuracy, precision, linearity, robustness. Linearity for Apremilast was found in the linear concentration range of 1-6µg/ml with regression coefficient r2 = 0.9998. The % RSD values for intra-day and inter-day precision studies were found to be less than 2%. The % recovery was found to be within an acceptable limit 98%-102%. Therefore the developed method said to be linear, precise, accurate, and robust. Since the method does not require use of expensive reagent and also less time consuming, it can be performed routinely in industry for a routine analysis of marketed product of Apremilast in tablet dosage form*

Keywords: Apremilast, HPLC, Validation, Method Development

REFERENCES

[1]. European Medicines Agency (EMA). Assessment report: Otezla. International non-proprietary name: apremilast.
[2]. Papp, K., Cather, JC., Rosoph, L., et al. Lancet, 2012. 380:738–746
[3]. Mendham j., denny r. C., thomas m.; vogel's text book of quantitative chemical analysis; pearson education limited; 6th edition, 2008, 29-39.
[4]. Chatwal g. R., anand s. K.; instrumental methods of chemical analysis; himalaya publishing house, mumbai; 11th edition, 2005, 1.1-1.2, 2.108-2.109, 2.151-2.153.
[5]. Hemaraj R. Patil, Dr. S. T. Patil, V. H. Jain AndDr. S. P. Pawar. Devlopment And Validation of UV-Spectrophotometric and Hplc Method for Apremilast In Bulk and Tablet Dosage Form. Ejpmr, 2019,6(8), 233-239
[6]. Gupta V, Jain AD, Gill NS, Gupta K. Development and validation of HPLC method-a review. Int. Res J Pharm. App Sci. 2012;2(4):17-25
[7]. Gupta V, Jain AD, Gill NS, Gupta K. Development and validation of HPLC method-a review. Int. Res J Pharm. App Sci. 2012;2(4):17-25
[8]. Kasture a. V., wadodkar s. G., mahadikk.r., more h.n.; pharmaceutical analysis instrumental methods; niraliprakashan; 12th edition, 2005; 148-156.
[9]. Bhardwaj SK, Dwivedia K, Agarwala DD. A review: HPLC method development and validation. International Journal of Analytical and Bioanalytical Chemistry. 2015;5(4):76-81.
[10]. ICH, Specifications, International Conference on Harmonization, IFPMA, Geneva, 1999
[11]. International Conference on Harmonization (ICH), Guidance for Industry, Q1A (R2): Stability Testing of New Drug Substances and Products, IFPMA, Geneva,2003.

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[12]. Rina Mohan Sonawane, Rutuja PrabhakarSonare, Snehal Ganpat TekawadeAndDr. Ashok Pandurang Pingle. Chromatographic Method Development and Validation of Assay of Apremilast In Bulk and Tablet Dosage Form Ejbps, 2018, Volume 5, Issue 8, 412-417.

[13]. Schett, G., Sloan, VS., Stevens, RM., et al. Ther Adv Musculoskelet Dis, 2010. 2: 271–278.

[14]. Paul, C., Cather, J., Gooderham, M., et al. Br J Dermatol, 2015.173:1387–1399.

[15]. Skoog d., holler f., timothy a., nieman n.; principles of instrumental analysis; saunders college publications, london; 4th edition, 1992; 1-2, 338-340.