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Method Development and Validation of Process Impurities Inritonavir Drug Substance by GCMS Technique

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Abstract: *'Quality' is the one of the important attributes, when it comes to pharmaceutical preparations. For both bulk drug industry and pharmaceutical manufactures, quality means maintaining drug standards conforming to a variety of conditions and generating profit out of it. Majority of pharmaceutical products are produced either by total synthesis approach or by altering a naturally existing product. In any case, a wide range of reactive reagents& chemicals are used. Therefore, it is accepted that trace levels of such reagents or by products are present in the final active pharmaceutical ingredient (API) or drug product as impurities. The article represents the analytical method for quantification of such process impurities from Ritonavir drug substance which is widely used as anti-retroviral agent for the treatment of HIV-AIDS. Analytical method is developed using GCMS technique. Effective validation performed as per ICH Q2 guideline suggests that the method is suitable for routine use in pharmaceutical industry.*

Keywords: Ritonavir, MTV, GCMS, Process impurities

REFERENCES

[1]. ICH Q3A (R), impurities in new drug substances (revised guideline), 2008.
[2]. ICH Q3A (R2), impurities in new drug substances (revised guideline), 2006.
[3]. ICH Q3B (R2), impurities in new drug products (revised guideline), 2006.
[4]. ICH Q3C (R8), impurities in new drug products (revised guideline), 2021.
[5]. Prajapati P. and Agrawal Y., Analysis and impurity identification in pharmaceuticals, Rev Anal Chem 2014; 33(2): 123–133.
[6]. Venkatesan P. and Valliappan K., Impurity Profiling: Theory and Practice, J. Pharm. Sci. & Res. Vol. 6(7), 2014, 254-259.
[7]. Rao, N., Mani Kiran, S., and Prasanthi N.L., Pharmaceutical Impurities: An Overview, Indian J. Pharm. Educ. Res. 44(3), Jul-Sep 2010.
[8]. Koppala S., Panigrahi, B., Raju, S.V.N., Reddy, K., Reddy, V., and Anireddy J., Development and Validation of a Simple, Sensitive, Selective and Stability-Indicating RP-UPLC Method for the Quantitative Determination of Ritonavir and Its Related Compounds, Journal of Chromatographic Science, 2015; 53:662–675, doi:10.1093/chromsci/bmu097.
[9]. P.R. Kakadiya, P., Reddy, B., Singh, V., Gangulya, S., Chandrashekhara, T., and Singh, D., Low level determinations of methyl methane sulfonate and ethyl methane sulfonate impurities in Lopinavir and Ritonavir Active pharmaceutical ingredients by LC/MS/MS using electrospray ionization, Journal of Pharmaceutical and Biomedical Analysis, 55 (2011) 379–384, doi:10.1016/j.jpba.2011.01.039.
[10]. Wagh, V., Singh, S., Buchade, R., Shariff, A., Tandale, S., and Chaure P., Synthesis, Characterization and Development of Validated Analytical Methods for Process Related Impurity in Ritonavir Hydrochloride Bulk and Formulation, J. Pharm. Sci. & Res. Vol. 11(8), 2019, 2878-2885.

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[11]. Venugopal, N., Reddy, A., Madhavi, G., Development, and validation of a systematic UPLC–MS/MS method for simultaneous determination of three phenol impurities in ritonavir, Journal of Pharmaceutical and Biomedical Analysis 90 (2014) 127– 133, http://dx.doi.org/10.1016/j.jpba.2013.11.029.