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Optimization and Validation of Efavirenz Related Substances in Formulation by RP-HPLC Method

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Abstract: *A simple RP- HPLC method was developed and validated for Efavirenz and its related substances in bulk drug. The developed method was found to be reliable, precise, accurate, cost effective and reproducible. Efavirenz related impurities are spiked and quantified at 0.2% specification level of test concentration and these impurities are found to be within the acceptable levels in the bulk drug substance. Hence the developed method was found to be suitable for the detection as well as quantification of impurities of Efavirenz. Developed method was validated according to ICH guidelines. Specificity was established by spiking impurities at 0.2% specification level and it was observed there is no interference from blank as well as impurities. This method was found to be accurate over the range of 85 – 115% and linear up to 120% with an acceptable correlation coefficient i.e. 0.999. The sensitivity of the method was established by LOD & LOQ which was within the acceptable range. This method was found to be precise over the suitable range with a % RSD of less than 15. The method was found to be sufficiently robust and rugged with an acceptable system suitability factors and % RSD of below 15. Hence the developed and validated RP-HPLC method can be successfully employed for the detection and quantification of Efavirenz and its related impurities in bulk drug as well as in formulation.*

Keywords: RP- HPLC, Efavirenz, Reliable, Precise, Accurate

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