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Impurity profiling, method development, validation and estimation of sulfametapyrazine by UFLC, 2DNMR and mass spectroscopy

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A simple, sensitive, specific RP-UFLC method has been developed and validated for determination of sulfametapyrazine and its related substances in API. The method was developed by low-pressure gradient mode and the separation was achieved using Phenomenex Hyper clone BDS C18 (5.0µm, 250×4.6mm) column using mobile phase Acetonitrile (A) and Ammonium formate buffer (B) in the ratio 40:60, pH4.0 adjusted with orthophosphoric acid with a flow rate of 1.0ml/min and the eluent was monitored at 254nm using PDA detector. The selected chromatographic conditions effectively separated sulfametapyrazine and its related substances with retention time of 3.04, 3.64 and 6.12min respectively. The drug was found to be linear in the range of 2-10µg/ml. The LC MS studies on the API gave prominent peaks with molecular weight 281, 143 and 427 respectively. The correlation coefficient was found to be 0.992 for the drug substance. The developed method was validated according to the ICH guidelines for limit of detection, limit of quantification, linearity, precision, ruggedness and robustness. The validation parameters were found to be well within the acceptance limits.