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A New Analytical Method Development and Validation for Related Substances of Rabeprazole in Active Pharma Ingredient by HPLC-PDA Detector

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Abstract : A simple and inexpensive method was developed with high performance liquid chromatography with PDA detection for determination of Rabeprazole and related impurities (2-[4-(3-Methoxy-propoxy)-3-methyl-pyridin-2-ylmethylsulfanyl]-1H-benzoimidazole, 2-[4 (3-Methoxy-propoxy)-3-methyl-1-oxy-pyridin-2-ylmethanesulfinyl]-1H-benzoimidazole ,2-[4-(3-Methoxy-propoxy)-3-methyl-pyridin-2-ylmethanesulfonyl]-1H-benzoimidazole sodium salt and2-(4-Methoxy-3-methyl-pyridin-2-ylmethanesulfinyl)-1H-benzoimidazole).The chromatographic separations were achieved on (250×4.6 mm), 5.0 µm, Phenomenex C18 column employing 0.02M K2HPO4: Acetonitrile: Methanol (85:5:10 v/v)as mobile phase with gradient programmed at flow rate 1.0 mL/min was chosen. Four impurities were eluted within 30 minutes. The column temperature was maintained at 30°C and a detector wavelength of 285 nm was employed. The method was successfully validated by establishing System Suitability, Specificity, Linearity, Accuracy, limit of detection and Limit of quantification.
Key words : HPLC-PDA, Method validation, related impurities, Rabeprazole, LOQ, LOD

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