Varaprasad Adepu, J Develop Drugs 2015, 4:4
http://dx.doi.org/10.4172/2329-6631.C1.011

OMICS International
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4th International Summit on
GMP, GCP & Quality Control
October 26-28, 2015 Hyderabad, India

Estimation of Ramelteon in bulk and tablet dosage form by HPLC

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A simple, accurate and precise reverse phase HPLC method was developed, described and validated for the determination of ramelteon in bulk and tablet dosage form. Chromatography was carried on an ODS column using a mixture of acetonitrile and 0.05 M phosphate buffer, pH 6.8 (in the ratio 40:60 v/v) as the mobile phase at a flow rate of 1.2 mL/min with detection at 285 nm by ultraviolet detector i.e. incorporated in HPLC. The retention time of the drug was found to be 7.0 min. The method validation proofs were carried out as per the ICH guidelines. The developed method was validated for linearity over a range of 500 µg/mL to 1500 µg/mL with a correlation coefficient of 0.999, which shows the method is quite linear. Further precision, ruggedness, accuracy were validated. The %RSD for system precision was observed to be 0.7, whereas the method precision was observed to be 0.5. And for ruggedness the observations were found to be 0.5 and 0.4, respectively. The average recovery of 100.0% indicates the capability of the method, and finally no significant differences in %RSD values w.r.t retention time prove the robustness of the method. As per ICH guidelines, method validation results are in good agreement. The proposed approach is effective and can be applied for the estimation of ramelteon in bulk and tablet dosage form.

Biography

Varaprasad Adepu has completed MPharm and is pursuing PhD in JNTU, Kakinada. He has published more than 5 papers in national and international journals and presented more than 4 papers in national and international conferences.

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