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## Stability-indicating HPLC method for quantification of valsartan in pharmaceutical dosage forms

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A simple, precise, accurate, stability-indicating isocratic reverse phase High-performance liquid chromatographic (RP-HPLC) method was developed for the quantitative determination of purity of Valsartan drug substance in pharmaceutical dosage forms in the presence of its impurities and degradation products. The method was developed using shimadzu, lc-2010HT (LC SOLUTIONS software),Xterra RP18 (150mm x 4.6mm5 µm)column with mobile phase containing mixture of 45% of 0.05M Potassium dihydrogen phosphate buffer of pH 2.5and 55% of Acetonitrile.The flow rate was 1.5 mL/min and injection volume was 20 µL. The Column oven temperature was 30°C;diluent is mixture of water and acetonitrile in the ratio of 40:60. The eluted compounds were monitored at 254 nm, the run time was within 10 min,in which Valsartan and its impurities were well separated. Valsartan was subjected to the stress conditions of oxidative, acid, base, hydrolytic, thermal and photolytic degradation. Valsartan was found to degrade significantly in acid and oxidative stress conditions and stable in base, hydrolytic and photolytic degradation conditions. The degradation products were well resolved from main peak and its impurities,proving the stability-indicating power of the method. A study was carried out by spiking all impurities at 1% of sample concentration in sample solution and peak purity was evaluated. It was observed that there were no peaks interfering with the analyte which was evident from the purity data. The difference between the assay results of spiked sample solution and unspiked sample solution made as per the test method. The results were found to be within the specified limits. The developed method was validated as per international conference on harmonization (ICH) guidelines with respect to specificity, linearity, limit of detection, limit of quantification, accuracy, precision and robustness. This method was also suitable for the assay determination of Valsartan in pharmaceutical dosage forms.

## Quality control: A grade of excellence

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"Quality control" means checking and directing the degree or grade of excellence of processes and products. To the ethical pharmaceutical manufacturer it implies a detailed system of inspection and control covering the production, evaluation and distribution of every drug bearing his company's label.

Quality control is an essential operation of the pharmaceutical industry. Most often, it involves thoroughly examining and testing the quality of products or the results of services. The basic goal of this process is to ensure that the products or services that are provided meet specific requirements and characteristics, such as being dependable, satisfactory, safe and fiscally sound. It is the purpose of these operations to produce medications of superior efficacy, safety and elegance and to provide assurance to the physician, the pharmacist and the consumer that a given product performs uniformly and in a manner satisfactory for the purpose for which it is recommended. All measures taken, including the setting of specifications, sampling, testing and analytical clearance, to ensure that raw materials, intermediates, packaging materials and finished pharmaceutical products conform with established specifications for identity, strength, purity and other characteristics.

### Biography

Kapil Verma student of M.sc forensic science, Amity Institute of Forensic Science (AIFS) Amity University, Noida, Uttar Pradesh (India)-201303. He has completed his B. Sc from Punjab Technical University, Punjab (India). He has 12 paper publications, poster Presentations, literature reviews to National, International conferences, symposium and workshops and in reputed journals. Currently he is working on his Research topic related to the clinical research.