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# Development and validation of stability indicating HPLC assay method for Clofazimine capsules

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## Abstract

**Aim:** All the Methods which are available are on UV- visible spectroscopy, but there is interference observed at Clofazimine maxima of Clofazimine Related compound-B. Therefore need to develop method on HPLC. **Method:** To develop a rugged and appropriate HPLC method for determination of assay in different diluents, mobile phases and stationary phases were evaluated. In all trials with other columns poor retention times and unsatisfactory recovery were obtained for the determination of assay of Clofazimine in Clofazimine capsules. **Result:** The estimated percentage difference between unfilter, discarding 3 mL filtrate solution, 5mL filtrate solution and 7 mL filtrate solution is less than 2.0% RSD. Method precision for the Clofazimine is less than 2.0% RSD. Good linearity was observed for the Clofazimine over the concentration range 25ppm to 75 ppm, coefficient of determination $r$ = 0.99. **Conclusion:** A simple, specific, linear, precise, and accurate Assay determination method has been developed and validated for determination of the Clofazimine in Clofazimine Capsules. Method is precise, accurate stability indicating, and rousted which is better than that of methods for the Clofazimine capsule USP monograph.

**Keywords:** Clofazimine, UV- visible spectroscopy, HPLC, Related compound-B. USP Monograph

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