International Journal of ChemTech Research
CODEN (USA): IJCRGG, ISSN: 0974-4290, ISSN(Online):2455-9555
Vol.11 No.11, pp 56-64, 2018

Development and Validation of Stability Indicating HPLC Method for Epigallocatechin Gallate (EGCG)

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Abstract : A new, economical, precise and accurate stability indicating HPLC method wasdeveloped and validated for the EGCG as per ICH guidelines. The study deals with development and validation of HPLC method for estimation of EGCG. Chromatographic separation was performed on C_{18}column fitted with C_{18} guard column using mobile phase Methanol: Acetic acid (0.1%)(75:25v/v). The wavelength used for detection was 276 nm. Regression plots revealed a linearrelationship in the concentration range of 20-120 µg/ml. The retention time for EGCG was found to be 5.3min.TheLOD and LOQ were found to be5.07 and 15.27 µg/ml respectively. The method was validated as per International Conference on Harmonization (ICH) guidelines, demonstrating to be accurate and precise within the corresponding linearity range of titledanalytes. Stability of the drug was studied by exposing drug to acid, alkali, oxidative, photolytic and thermal conditions. Relevant degradation was found to take place under theseconditions. The proposed method has been validated as per ICH Q2 (R1) guidelines. This methodcan be used for routine quality control analysis of EGCG.

Keywords : Validation, Epigallocatechin Gallate (EGCG), HPLC, Stability indicating method.

Deepali Bansode et al /International Journal of ChemTech Research, 2018,11(11): 56-64.

DOI= http://dx.doi.org/10.20902/IJCTR.2018.111107

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