

Recombinant expression by *E.coli* is a widely used procedure to obtain sufficient and cost effective quantities of desired protein. Many of these recombinantly produced proteins are intended for use as therapeutic agents in human and animals and as such must be highly purified. The development of recombinant proteins as pharmaceutical drugs demands robust, sensitive, and specific analytical assays to characterize the purified drug with respect to its physicochemical as well as biological features. Also there is always the possibility that these articles may cause some undesirable effects in patients using them due to immunological sensitization as a result of a single or multiple molecular modifications. Such a possibility requires precise characterization of these substances. The evidence of purity of the purified product should be established. Physico-chemical, biological and immunological characterizations of purified product should also be obtained using a wide range of analytical tests.

Characterization tests of products include mainly protein estimation, peptide mapping, electrophoretic assays (SDS-PAGE, Western blot, isoelectric focusing), Residual DNA detection, RP-HPLC, ELISA, etc.