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GENOMICS BASED METHODOLOGY OF CELL –CULTURE MEDIA FORMULATION FOR IMPROVED BIO-THERAPEUTIC PRODUCTIVITY AND QUALITY CONSISTENCY

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Biosimilar drugs are emerging very fast as the patents of innovator's drugs are expiring. Media formulation development has to be carried out for each bio similar, which takes up a significant amount of time and generally, a random approach is taken to meet comparability requirement and improve the product titer. A targeted approach with genome information of host cell as a function of media composition can provide useful information to explain the product titer variability and comparability. A 2-step correlation model explaining relationship between cell-culture productivity and quality, and media compositions taking gene expression as intermediate attributes can provide a precise and robust platform. Experimental design was conducted for different media compositions having different productivity enhancer components to get a wide range of product titer. Gene expression data obtained from the above cell culture samples shows significant differences among these samples. This is an on-going work. Expected outcome of this work is the development of a novel mechanistic model based on gene expression data, which will potentially decrease the time for media formulation and is expected to be applicable to different types of cell clones.