SYSTEM AND METHOD FOR OPTICALLY MEASURING THE STABILITY AND AGGREGATION OF PARTICLES

The invention generally relates to an apparatus or a system and a method for the optical measurement of the stability of particles. In particular, the invention relates to a system and a method by means of which not only the stability of particles but also the aggregation of particles can be measured optically. According to the invention, preferably the stability and aggregation of the particles may be measured with one single apparatus, preferably simultaneously or almost simultaneously.

BACKGROUND OF THE INVENTION

Since active agents, like for example antibodies, have been developed so as to be active only in their native form, denatured active agents are often not effective and have to be avoided. Denaturation means a structural transformation of the biomolecules, for example proteins, which in most cases is connected with a loss of the biological function of said molecules. Denaturation may be the consequence of either physical or chemical influences. Thus, active agent formulations have to be developed which prevent the denaturation of drugs, i.e. stabilize them for example thermally, chemically and/or with respect to time.

Aggregating active agents may lead to ineffectiveness as well. Furthermore, aggregated and/or denatured particles, for example aggregated antibodies, may provoke a reaction of the immune system in the body and thus have to be either avoided in drugs or their percentage in the drug has to be minimized.

Denaturation of particles, for example antibodies, has per se to be avoided since it reduces the effectiveness. The aggregation of particles, for example antibodies, has per se to be avoided since it provokes a reaction of the immune system and may also lead to a reduction of effectiveness.

It is often unclear why a particle aggregates and/or denatures: Does a particle aggregate because it denatures, i.e. because it is not in its native form or does it aggregate in its native form and denatures afterwards? Thus, in order to comprehensively characterize the particles, it is often not sufficient to analyze merely the aggregation or merely the denaturation separately from each other.

With the inventive system and method the denaturation as well as the aggregation of particles may be measured. In particular, with the inventive system and method, the denaturation as