DESIGN AND COST STUDY OF A cGMP DELOS PLANT FOR DRUG MICRONIZATION

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Abstract

The development of new technologies for the preparation of micro- and nanostructured materials with potential pharmaceutical applications has been subject of intensive research during last years. Methods involving the use of supercritical fluids or compressed fluids have proved to be able to yield very homogeneous materials in terms of size and internal structure. However, and in spite of their very remarkable environmental benefits, the real application of these high-pressure methods in industry will only be possible if these methods demonstrate their robustness and reproducibility at a productive scale with affordable costs. [1]

In our group we have developed a CO_2-based methodology, named DELOS, [2] in which micro and nanoparticulate materials are precipitated due to a large and abrupt temperature decrease occurred during the depressurization of a "CO_2-expanded solution". Its main advantages in relation to other compressed fluids-based processes are the mild pressure values employed (6-10 MPa), the low complexity of agitation system required and the use of simple valves instead of nozzles as injection or depressurization devices. These features make the DELOS process easy to scale up, giving highly reproducible results at different scales. [3]

Once the process reproducibility has been tested, it is necessary to establish its potential commercial viability. In this work we present an economic evaluation of a multi product DELOS plant, designed according to GMP requirements and capable of producing 50 tones of micronized drug per year. The study comprises process definition, schedule of batches, equipment specification, and capital and manufacturing costs estimation. Finally, a profitability (cash flow) analysis is presented.

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