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# PROCESS BULLETIN

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Subject: Inhalation products
Pharmaceutical application of the high pressure homogenisation

Treatment of respiratory diseases like asthma and chronic obstructive pulmonary disease is advantages via inhalation route compared to the oral route since the active substances are available directly
Effective therapies directed against asthma have advanced since 1956 when the first pressurized metered dose inhaler was developed. The target for these anti-asthma medications is the smooth muscle cells concentrated in the pulmonary airways. Delivery of drugs directly to the lungs is an effective and relatively safe means of both local and systemic treatment of a variety of medical conditions. Medication delivery may be inefficient if particles aggregate in the inhaler itself, if they are filtered by the throat and mouth, and if mucociliary clearance processes remove them. In order to keep dry powder aerosols from depositing in the oropharyngeal cavity and inhaler, most have a geometric diameter of 1-3 um and particle mass density of ~ 1g/cm3.
Usually drugs are dissolved in an acqueous system, e.g. isotonic salt solution, and aerosolised droplets are generated by the very high pressure homogenisation of particles.

## The homogenisation process

It is a wholly mechanical process, obtained by forcing a flow of product through a homogenizing valve.
Due to well-known physical laws, inside the valve they take place some contemporaneous effects of compression, acceleration, and so on, which are the cause of the homogenizing process, that acts by shattering and dispersing the solid and semisolid suspended particles.
The solution is pumped to the high pressure homogeniser. The product is homogenised at room temperature and at 500 -1000 bar using one single stage and Rupture homogenizing valve.