L.B. BOHLE COATING TECHNOLOGY

L.B. Bohle has been the technological leader for all film coating applications for more many years. L.B. Bohle Coaters guarantee excellent product processing with the highest profitability.

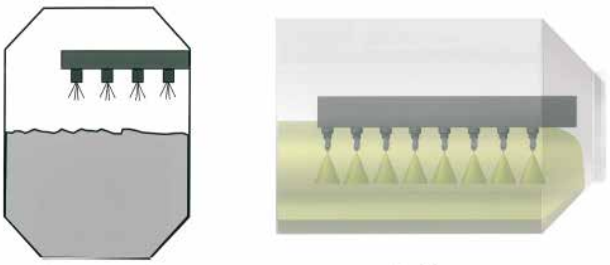
We assert our leading role through continuous developments and patented advantages.

Pharmaceutical film coating represents nowadays an important process step in the pharmaceutical industry. Derived originally from dragee pan processing, coating technology has developed continuously in the last decades. The majority of coating processes are performed for drug release modification, drug stability improvement against light or moisture and taste masking. Furthermore patient compliance issues play an important role, as swallowability improvement or a simpler identification due to a different colour.

Finally API coating is gaining more and more importance since it enables fixed dose combinations or the combination of incompatible drugs. Also different drug release characteristics can be realized by applying for example sustained release coatings in addition to immediate release coating layers. Such formulations sometimes consist of up to four coating layers, which leads to long processing times. To successfully develop and produce such formulations coating uniformity is a prerequisite and a quality attribute, since coated tablets have to pass the test on uniformity of dosage units according to the pharmacopoeias [1, 2]. As a coating process consists of simultaneous spraying, mixing and drying processes, a good coating uniformity can only be achieved with the choice of the proper parameters. To meet these requirements L.B. Bohle developed and improved its coater design in the last years.

The L.B. Bohle Coating Technology contains three unique design principles which assure a good coating uniformity:

L.B. Bohle pan geometry with an L/D ratio >1 offers a large tablet bed surface, which allows the incorporation of a high number of spray guns (Fig.1). Compared to conventional pan geometries that can be found in the market, process time can be saved up to 40% due to larger throughput of coating suspension. Besides the thinner tablet bed induces a minimum shear onto the tablets, which allows even the coating of very weak tablets.



Conventional pan geometry *L.B. Bohle pan geometry*

Figure 1: Pan geometry

The unique helical baffles consist of two layers of baffles (Fig. 2). They are responsible for the continuous and homogeneous axial mixing within the tablet bed. In addition the drum rotation is maintaining the radial mixing. Both movements are a guarantee for a dead zone free tablet bed.

Thus a homogeneous mixture in the tablet bed is usually achieved within a few minutes. Due to the constant tablet movement the tablets do not experience any acceleration peaks which could cause tablet damage or even twinning.

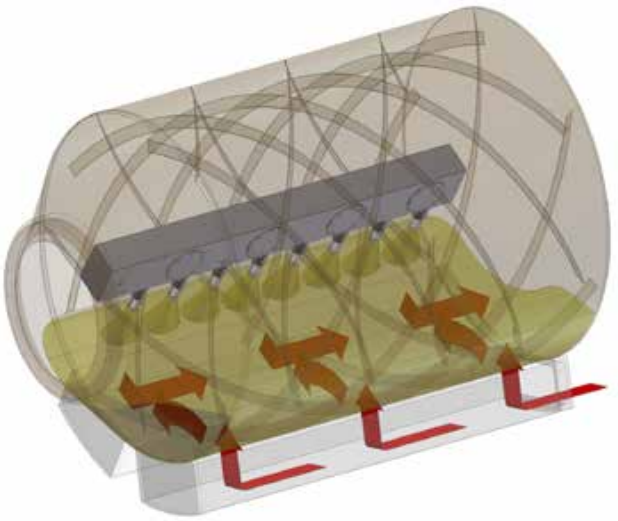


Figure 2: Helicle baffles

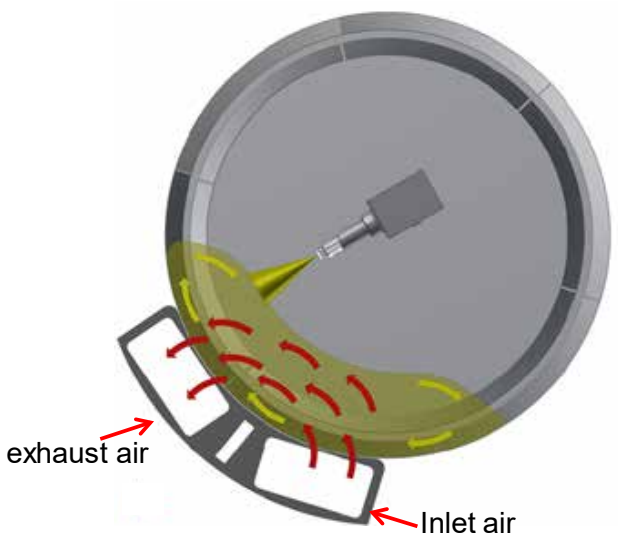


Figure 3: Air flow principle

The air principle in L.B. Bohle Film Coaters utilizes the drying capacity where it is most needed: in the tablet bed (Fig. 3). Thus most effectively the drying capacity of the inlet air is used without heating the rest of the coater inner parts. The inlet air is coming from below the tablet bed and is directly sucked through the rotating tablet bed into the exhaust air funnel.

This setup offers also another advantage: The spray guns are not being heated during coating and remain cool. Therefore spray losses are reduced to a minimum which leads to coating efficiencies of > 95% which is especially beneficial for API coating processes.

Besides these unique features making the L.B. Bohle Coating Technology so successful, these coating machines can be equipped with CIP systems. At high pressure values the cleaning takes place with a cleaning lance which effectively cleans the coater after production in an automated mode.

The L.B. Bohle coating equipment is available form lab scale to large production scale. Furthermore different configuration lines are available meeting different customer needs on all continents. Besides the classical batch mode machine types, semi continuous coaters are also available.

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References:

[1] European Pharmacopoeia, Monograph 2.9.40. Uniformity of dosage units, 7th ed., Directorate for the Quality of Medicines of the Council of Europe, Strasbourg, 2011.

[2] United States Pharmacopoeia, Monograph <905> Uniformity of Dosage Units, 35th ed., U. S. Pharmacopoeial Convention, Rockville, 2011

[3] Optimization of inter-tablet coating uniformity in an active coating process, Just S. et al., Poster presentation AAPS Annual Meeting, Chicago 2012