

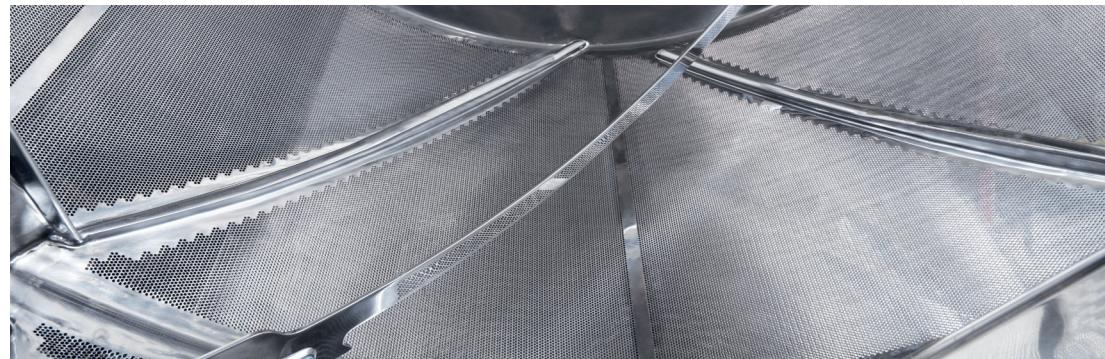
Perfima Extra: your way to boost productivity keeping process quality at the highest standard.

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White paper

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Increasing competition, changing regulatory requirements, disruptive technologies and various other factors are pushing pharmaceutical manufacturers to fast track innovation to boost their productivity and product quality. Improving processes and assets by taking advantage of manufacturing and control technology can help.

Perfima Extra is developed to target the above-mentioned focus: high production speed combined with the best product quality and, at the same time, minimum requirement of intermediate step as cleaning, to save water and energy washing.

Perfima Extra is specifically designed to increase the machine flexibility in terms of workable products and range of batches to be processed.

The shape of the drum guarantees the uniform mixing of the product, while the removable mixing baffles allow different machine configurations ensuring a wider range of batches that can be processed in the same pan (from 10% to 100% of the pan capacity).

The installation of 6 cross baffles in the drum can be done easily in less than 10 minutes: this configuration ensures perfect cores mixing, gentle product handling providing no stress on the tablets. The final result is that at high peripheral speed the spray rate can be increased by 50% respect to typical production values, reducing process time by 40%.



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Case study: round biconvex tablets, 9 mm diameter coated with Opadry 85F PVA based 20% concentration.

Tablets were coated up to a theoretical weight gain of 3% in 33 minutes of spray time with parameters reported in **Table 1**.

Process was managed smoothly and final tablets resulted perfectly coated and with uniform colour, providing a ΔE lower than 1.5.

The standard deviation of colour difference between calculated ΔE values of the individual tablets from each set of samples were compared as a measure of coating uniformity. A ΔE value of < 2 indicates no visual difference in colour from the target reference colour.

The drum was very clean at the end of the process enabling the repetition of the production up to 30 times: final process yield of 99.7% was kept all along the repetition of the production.

Very fragile cores find in Perfima Extra their perfect coating option: at very low peripheral speed (like 3.5 rpm could be in a 250 L drum) soft cores can be easily handled and worked without any stress on the tablets enabling the use of a quite high spray rate (like 500 g/min). Perfect mixing is kept even reducing the pan speed by increasing cores exposure to spray accordingly.

So Perfima Extra is the perfect solution to improve productivity while keeping the product quality at the highest standard.

Cores	9 mm biconvex 270 mg
Drum filling (%)	100
Batch size kg/L	190/250
Weight gain (%)	3
Total dispersion to be sprayed (kg)	28.5
Pan speed (rpm)	10
Inlet air flow rate (m ³ /h)	3,500
Inlet air T (°C)	65-75
Cores T (°C)	43
Outlet T (°C)	44
Average spray rate (g/min)	860
AA/PA pressure (bar)	2.2/2.2
Depression (Pa)	-30
Guns distance (cm)	25
Guns type	4 Schlick ABC
Nozzle diameter (mm)	1.5
Spray time (min)	33
Configuration	6 cross baffles

Table 1: coating parameters.

