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Evaluating the Impact of an Ultra-High Solids Film Coating System on Process Times and Tablet Aesthetics

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PURPOSE

- Ultra-high solid film coating systems are designed to increase productivity while maintaining excellent product aesthetics and high gloss.
- State-of-the-art coating process equipment and these improved film coating systems facilitate shorter processing times due to more intense spray application and fast drying processes combined with the possibility to spray coating dispersions up to 35 % of solids.
- One specific challenge for high-solid coating systems is achieving good color uniformity within a batch (batch homogeneity) and between multiple batches (batch conformance).
- Furthermore, low surface roughness and high gloss of produced tablets are preferable aesthetic tablet characteristics.
- This study aimed to evaluate tablets coated with an optimized ultra-high solids film coating system under a wide range of processing parameters.

METHOD(S)

- Round placebo tablets (220mg, 8mm) were used as the substrate for this study.
- The tablets were coated with hpmc-based aquarius™ prime clear and HPC/copovidone-based ultra-high solids aquarius™ genesis yellow.
- Coating weight uniformity analysis was conducted on 200 individually marked tracer tablets.
- The batch was coated with hpmc-based clear, and the coating process was stopped at different weight gain (0.5% - 10.0%)
- The marked tablets were manually picked out, weighed, and returned to the batch, and the next coating trial segment was started.
- The individual tablet weights were used to calculate the weight gain's relative standard deviation (RSD).

$$RSD = \frac{standard\ deviation\ of\ weight\ gain}{mean\ of\ weight\ gain}$$

Figure 1: Coating trials were conducted in a BFC 50 tripan full perforated coating pan (L.B. Bohle, ennigerloh, Germany) equipped with six spray nozzles (type 970, schlick, Germany) with a batch size was 20 kg.

Five 20 kg tablet batches were coated with aquarius™ genesis yellow to a target weight gain of 3% by varying processing parameters such as drum speed, spray rate, airflow rate, and suspension concentration.

Table 1: coating parameters of tablets coated with Aquarius™ Genesis yellow. Five runs of 20 kg tablets were coated with Aquarius™ Genesis yellow, with a target weight gain of 3% using the following parameters

#	Drum rotation speed [rpm]	Airflow rate [m³/h]	Spraying rate [g/min]	Spraying time [min]	Suspension content [%]
1	15	550	103	29.17	20
2	15	800	163	18.42	20
3	15	550	101	19.85	30
4	15	800	162	12.38	30
5	22	800	159	10.75	35

20 Tablets were sampled at different coating weight gains and tested for color uniformity using a reflectance spectrophotometer, surface roughness by optical profilometry (roughness of <6 Sq is often regarded as a small roughness, and gloss (values > 70 GU can be considered as high gloss).

Reflectance Spectrophotometer DataColor™ 650

Gloss Surface Analysis System Tricor Systems

Surface Roughness Optical Profilometer Nanovea™

Color Analysis: ΔL*, Δa* and Δb* are the difference in the three light color components between the sample and the used standard. Table 2 depicts an example of ΔE ranges and how they are visually perceived

$$CIE\ \Delta E^* = \sqrt{(\Delta L^{*2} + D\Delta a^{*2} + \Delta b^{*2})}$$

ΔE	Rating	Example	ΔE	Rating	Example
0.0 - 0.5	almost imperceptible		**2.0 - 4.0**	perceived color difference	
0.5 - 1.0	only noticeable to the trained eye		**4.0 - 5.0**	significant, rarely tolerated color difference	
1.0 - 2.0	slight color difference		**above 5.0**	the difference is rated as a different color	

Table 2: Rating scale for measured color differences (ΔE) with respective examples

RESULT(S)

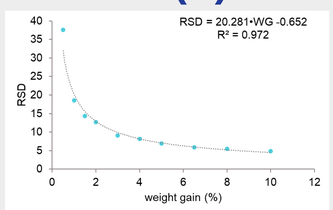


Figure 2: RSD of sampled 200 tablets as a function of the applied coating weight. The curve starts to flatten after a weight gain of about 3%.

Ongoing innovations have further increased the sprayable solids content. Aquarius Genesis is a film coating system using a unique combination of film forming polymers that is sprayable up to 35% . This can drastically reduce coating process times and facilitates the introduction of continuous coating processes.

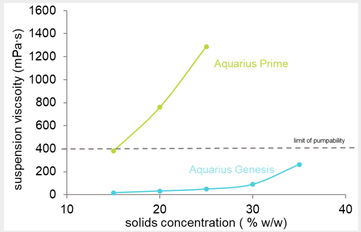


Figure 3: Viscosity of suspensions of different concentrations of used coatings

Table 3: coating parameters and results. All runs resulted in very short total spraying times of less than 30 minutes, decreasing with increasing solids content of the suspension and increasing spraying rate.

#	Drum rotation speed [rpm]	Air flow rate [m3/h]	Spraying rate [g/min]	Spraying time [min]	Solids content [%]	RSD [%]	ΔE
1	15	550	103	29.17	20	12.7	0.35
2	15	800	163	18.42	20	19.9	0.55
3	15	550	101	19.85	30	15.3	0.83
4	15	800	162	12.38	30	24.7	0.44
5	22	800	159	10.75	35	23.7	0.38

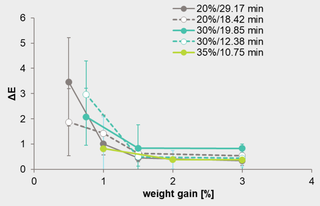


Figure 4: development of ΔE vs applied coating weight gain; n=20, mean ± standard deviation. All trials resulted in a ΔE < 1 already at 1.5% weight gain and after that there was only a slight further reduction of ΔE to the final weight gain of 3%. 7 minutes of spraying time in run 5 at 35% solids content resulted already in acceptable aesthetics of film coated tablets.

Figure 5: Impression of the perception of the color difference of samples taken compared to the final product; data for run 2 (20% suspension content, 18.42 minutes spraying time). At a weight gain of 1.5% the color differences are already almost hardly perceivable (ΔE=1.34)

Such results emphasize that it is possible to obtain already a good color homogeneity at a very short time, far before achieving 3% weight gain.

Roughness and gloss were measured for the longest run (run 1, at a weight gain of 0.5%, 1.5% and 3%) and the shortest run (run 5 at a weight gain of 1%, 2% and 3%) were analyzed for roughness and gloss. The roughness increased with increasing weight gain. However, since all values are below Sq=6, the tablets are regarded as smooth. Glossiness increased with increasing weight gain. All tablets were glossy with a gloss value > 70 GU.

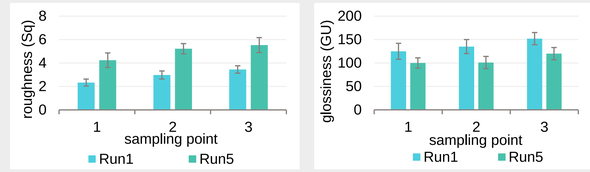
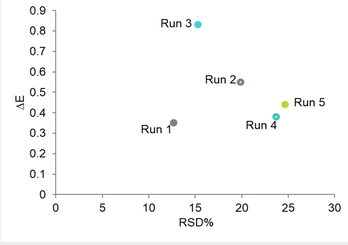


Figure 6: Roughness and glossiness results of runs 1 and 5 (mean ± SD)



This leads to the conclusion that there is no necessity of low values of RSD to obtain tablets, which are visually perceived as similar. Values of RSD in the range of 12.7-24.7% were good enough to obtain good coating quality.

Figure 7: Interrelation between ΔE and RSD for the coating runs.

CONCLUSION(S)

- Combination of appropriate equipment and optimized film coating systems such as aquarius™ genesis significantly reduced film coating process time while maintaining good visual tablet aesthetics.
- Tablets coated with aesthetic film coatings that aim for quality specs such as low color difference, low surface roughness, and high film coating gloss can be produced to a high quality in a very short time (well below one hour).
- While the measurement and indication of the color difference ΔE using Datacolor analysis is an acceptable and accurate method to assess the visual quality of a coated tablet, it requires equipment that is not generally available at pharma companies.
- Alternatively, an accurate RSD determination is a good way to assess film-coated tablets.

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