Dynamic Vapor Sorption for Quality Assessment of Pharmaceutical Coatings: A Case Study in Enteric Protection

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1. Methodology

Tablet Manufacturing and Coating Procedure

The tablet blend was prepared using a Rhönrad-type hoop mixer (J. Engelsmann AG, Germany) operated at 28 rpm for 20 minutes to ensure uniform distribution of excipients. Subsequently, sodium stearyl fumarate was incorporated as a lubricant and the mixture was subjected to an additional 5-minute blending cycle. Compression of the final blend was performed using a rotary tablet press (Model Fette 102i, Fette Compacting GmbH, Schwarzenbek, Germany) fitted with eight 8-mm concave punches (Adamus S.A., Szczecin, Poland).

Film coating was carried out in a Solidlab 1 coating system (Syntegon Technology GmbH, Waiblingen, Germany), using a 951 Form 7-1 S24 ABC spray gun (Düsen-Schlick GmbH, Germany). For each coating batch, 400 g of tablets were processed. Coating dispersions were prepared according to manufacturer specifications and homogenized with an IKA® Ministar 20 overhead stirrer (Breisgau, Germany) at controlled agitation speeds and time (*Table S1*). The rationale for these parameters was based on supplier recommendations and prior experimental experience. (1–4)

Table S1. Preparation parameters of applied coating suspensions

Parameter	*Opadry® II*	*Acryl-Eze®® II*	*Aquarius™ Control ENA*	*Nutrateric®*
% weight coating in purified water	8	20	20	1.5% NS Enteric 34% Surelease
Agitation (rpm)	410	430	390	400
Homogenization time (min)	45	20	60	90
Final Sieve mesh (µm)	250	250	800	Not applicable

A protective sub-coating layer of Opadry® II was applied prior to the enteric coating. This step was necessary to prevent potential degradation of omeprazole caused by interaction with aqueous enteric polymers, particularly polymethacrylate-based systems known to contain methacrylic acid moieties. The sub-coat served as a barrier between the API core and the enteric layer.

Three enteric coating formulations (Acryl-EZE® II, Aquarius™ Control ENA, and Nutrateric®) were applied using process parameters optimized from initial trial runs and guided by manufacturer recommendations. Parameters such as spray rate, atomization pressure, inlet/outlet temperature, drum rotation speed, and target weight gain are described in *Table S2*. More details on the manufacturing process and evaluation are literature (2,5,6).

Table S2. Summary of applied in-process coating parameters. located in lit

Parameter	*Opadry® II (sub coat)*	*Acryl-Eze® II*	*Aquarius™ Control ENA*	*Nutrateric®*
Spray Rate (g/min)	3.5	1.5	1.5	3.0
Atomizing pressure (bar)	0.8	0.8	1.0	0.8
Preheat outlet temperature (°C)	42	32	40	45
Inlet temperature (°C)	70	52	63	70
Outlet temperature (°C)	40	36	42	45
Drum speed (rpm)	30	30	30	20
Weight gain (%)	2	5-12	3-12	1-10

During process development, pan loading and spray conditions were adjusted to prevent over-wetting and edge build-up. Tablets were inspected visually, and the OCT images confirmed uniform coverage without edging or collar formation.

Analytical Methods (Content determination and dissolution).

Table S3. Chromatographic methodology conditions for the omeprazole content determination and dissolution.

Chromatographic feature	*Content determination and dissolution*
Mobile phases	A: 10 mM ammonium bicarbonate buffer pH 8.75 B: Acetonitrile
Gradient program	$\%A_{0min}$=90, $\%A_{3min}$=90, $\%A_{10min}$=40, $\%A_{11min}$=90 and $\%A_{15min}$=90
Flow	1.9 ml/min
Injection volume	5 µl (content uniformity, assay) 40 µl (dissolution)
Time per injection	15 min
Column temperature	35 °C
Sample temperature	20 °C
Detector wavelength	305 nm

Table S4. Summary of analytical validation results for omeprazole quantification by UPLC and coating thickness determination by OCT.

Attribute	***Result (UPLC)***	***Result (OCT)****
Mean precision	RSD=0.9%	RSD=2.2%
Mean Accuracy	Recovery=97.7%	Recovery=99.8%
Sensitivity	0.02%	3.2 µm

*The results are taken from previously published studies (7)

2. Results and Discussion

Coating Thickness and dissolution determination in the acid stage

Table S5. Exponential fitting parameters for acid-stage dissolution performance of enteric-coated tablets.

Formulation prototype	***Equation***	***R^2***
Acryl-Eze®	$63.315e^{-0.039x}$	0.9991
Aquarius™ control ENA	$71.846e^{-0.033x}$	0.9974

Nutrateric®	$87.178e^{-0.035x}$	0.9973

3. References

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