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Short communication

Process visibility and in-process control/critical quality attribute outcomes during film coating: A retrospective comparison

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Introduction

Film coating is a multiparametric unit operation in which reproducibility depends on coordinated control of coating-liquid delivery, atomization, tablet-bed movement, heat transfer and drying capacity. Process air flow, inlet/exhaust and product-bed temperatures, solution-flow rate, pan speed and air-pressure settings influence coating distribution and process-related defects (Pandey et al., 2014; Seo et al., 2020). In retrospective equipment comparisons, the key endpoint is whether available records allow phase-specific reconstruction of critical process parameters (CPPs) and control strategy, not only whether batches meet specification (Korasa and Vrečer, 2018). This study compared documented process visibility, phase-specific controllability and available IPC/CQA outcomes for the same anonymized film-coated tablet product manufactured on DIAF and O'Hara Labcoat 100; IPC/CQA data were used as compliance context, not as proof of product-quality superiority.

Materials and methods

Process validation documentation, batch records and equipment-related reports were reviewed for three DIAF and three O'Hara industrial batches of the same anonymized product. The nominal core batch mass was 463.5 kg, corresponding to 618,000 tablets with a nominal 750 mg uncoated-tablet mass and 765 mg ± 3 % target coated-tablet mass. Data were classified as batch-record/validation data, interface/recipe-setting data or derived estimates. O'Hara interface values were treated as setpoints, while missing DIAF values were treated as documentation gaps, not proof of absent capability. O'Hara nominal active spray time was estimated from coating-stage quantities and solution-flow setpoints (3000 g / 180 g/min + 9400 g / 210 g/min = 61.4 min) and was not interpreted as actual cycle time. Apparent weight gain was calculated from the nominal 750 mg core mass and was not interpreted as true coat gain because complete solids and batch-level reconciliation were unavailable. IPC/CQA outcomes were summarized descriptively without inferential statistics.

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Results and discussion

The reviewed records showed greater retrospective CPP visibility for O'Hara. DIAF records provided inlet air temperature (50 °C) and process inlet air flow (700 m³/h), while other phase-specific CPPs were not available and were interpreted as documentation gaps. O'Hara records showed a phase-structured recipe with preheating/drying, two coating stages and cooling, including 65 °C during preheating, 60 °C during spraying, 1800 m³/h air flow during preheating/spraying, 1900 m³/h during cooling, approximately 41.5 °C exhaust/product-bed temperature during coating, 6 rpm pan speed, 2.5 bar atomizing air, 3.0 bar pattern air and -50 Pa pan differential pressure. The two quantity-controlled coating stages used 3000 g and 9400 g with 180 and 210 g/min solution-flow setpoints, giving an estimated nominal active spray time of 61.4 min. Automated reporting and alarm-monitoring functions further supported greater O'Hara process visibility and traceability (Korasa and Vrečer, 2018).

The available IPC/CQA data showed compliance for both systems. Average mass was comparable (762.83-763.69 mg for DIAF; 763.2-763.5 mg for O'Hara) against the 765 mg ± 3 % target, and hardness, tablet height/thickness, dimensions, disintegration, assay and UDU were within available limits. Descriptive trends did not establish superiority: DIAF showed higher dissolution (98-99 % vs. 89.4-97.4 %) and yield (97.02-97.31 % vs. 95.65-95.81 %), whereas O'Hara showed lower moisture (6.66-7.38 % vs. 8.3-9.1 %); all values met the available criteria. Apparent weight gain was similar (1.71-1.83 % for DIAF; 1.76-1.80 % for O'Hara), slightly below the nominal 2.00 % target, and no formal deviations were reported.

Several potentially useful performance metrics could not be calculated reliably from the available data. True coating efficiency or coat-gain efficiency was not derived because coating-dispersion solids content, actual sprayed amount and complete batch-level coating reconciliation were unavailable (Wang et al., 2012). Quantitative comparison of coating defects, roughness, twinning or coating-uniformity defects was not possible because only the absence of reported deviations could be retrieved. Process capability analysis was also not appropriate because of the small retrospective dataset and insufficient batch-level capability data. Actual total cycle time was not calculated because batch-level cycle-duration records were unavailable.

Conclusion

In this retrospective comparison, both DIAF and O'Hara Labcoat 100 produced batches compliant with the available IPC/CQA criteria, and no superiority in final coated-tablet quality can be concluded. The main supported difference was documentation depth: O'Hara provided greater phase-specific CPP visibility, including traceable recipe structure, solution-flow setpoints, air-flow/temperature control, pan speed, air pressures, pan differential pressure and automated monitoring functions. Therefore, O'Hara offers a stronger basis for process monitoring, control-strategy evaluation and future optimization, while the limited DIAF data should be interpreted as a documentation limitation rather than proof of absent equipment capability.

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