Macedonian Pharmaceutical Bulletin, 72 (Suppl 1) 149 - 150 (2026)
Online ISSN: 1857-8969
DOI: 10.33320/maced.pharm.bull.2026.72.03.xxx
Short communication

Effect of different drying technologies on quality attributes of tablets produced with wet granulation

Viktorija Bezhovska*, Mevlan Kanzoska, Krume Toshev, Natasha Anevska Stojanovska

Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje, Republic of North Macedonia

Introduction

Drying represents a critical process step in the manufacturing of solid oral dosage forms, with a direct impact on both product quality and process efficiency.

Drying technologies, including vacuum, fluid bed, and tray drying, differ in their heat and mass transfer mechanisms, which may influence granule structure, particle size distribution, and downstream processing behavior (Liu et al., 2021).

The aim of this study was to evaluate the influence of different drying technologies on selected critical quality attributes (CQAs) of film-coated tablets produced by wet granulation, as well as their impact on process efficiency.

Materials and methods

An immediate - release tablet formulation containing a BCS class IV active pharmaceutical ingredient was prepared using a wet granulation process.

Drying was carried out using three different systems, namely a single-pot vacuum processor (DIOSNA P/VAC 10), a fluid bed dryer (Mycrolab system), and a tray dryer (Panasonic MOV 212S-2).

The obtained granules and final tablet blends were evaluated for relevant quality attributes, including particle size distribution, porosity, and flowability, expressed through compressibility index and angle of repose. Final film-coated tablets were evaluated for critical quality attributes, including assay, dissolution, and related substances.

Process efficiency was assessed by comparing drying time per processing cycle for each drying technology.

Results and discussion

The effect of drying technology on granule and tablet properties was evaluated using single-pot vacuum, tray, and fluid bed drying.

Unless otherwise stated, results are presented in the order of single-pot, tray, and fluid bed drying.

Single-pot and fluid bed drying exhibited higher process efficiency compared to tray drying, with reductions in drying time of approximately 47% and 60%, respectively, reflecting enhanced heat and mass transfer under dynamic conditions.

The single-pot drying process exhibited reduced product temperature (approximately 25 °C) due to vacuum conditions, while fluid bed drying operated at an inlet air temperature of 50 °C, resulting in product temperatures of approximately 30–31 °C, and tray drying was performed at 50 °C under static conditions. The end-point loss on drying specification (max. 10% for tablets) was achieved in all cases, with

*vbezhovska@alkaloid.com.mk

LOD values of 8.9%, 9.4%, and 9.2% for granules and 8.7%, 8.7%, and 8.8% for the final blend, indicating uniform moisture distribution.

Drying technology primarily affected particle size distribution. The fraction below 0.150 mm for tablet granules was 71.5%, 58.7%, and 44.4%, respectively, with increased fines observed for single-pot drying, while tray and fluid bed drying produced lower fine fractions.

These differences are attributed to the drying mechanism. Single-pot drying involves continuous mixing under vacuum conditions, promoting granule breakage and more homogeneous structures, whereas tray drying results in higher heterogeneity due to static conditions, and fluid bed drying shows intermediate behavior (Giry et al., 2009; Franceschinis et al., 2024).

Porosity remained comparable across all technologies, with values of 57.1%, 57.2%, and 59.1%, indicating limited influence on internal structure.

Flowability of tablet granules showed no significant dependence on drying technology, with compressibility index values of 13%, 8%, and 12% and angle of repose values of 32.0°, 33.8°, and 35.2°. After mixing of final blend, values remained comparable across all systems (14%, 13%, and 12%; 34.0°, 34.4°, and 31.6°), indicating that blending reduced variability introduced during drying.

Final product quality attributes showed no significant dependence on the drying method. Tablet dissolution was 94.53%, 93.27%, and 94.05%, assay values were 99.37%, 98.01%, and 98.17%, and impurity levels were 0.3% across all technologies, indicating that variations in granule properties did not translate into differences in final product quality.

Conclusion

Drying technology influences granule formation through differences in drying mechanisms, resulting in variations in particle size distribution and granule uniformity. Single-pot drying produces more homogeneous granules, while tray drying leads to increased heterogeneity due to non-uniform drying conditions, and fluid bed drying shows intermediate behavior.

Despite these differences, no significant impact on critical quality attributes, including assay, dissolution, and impurity levels, was observed for either dosage form. Long-term stability testing will confirm the final effect on quality during the shelf-life of the product.

References

Franceschinis, E., Bressan, V., Fontanel, E., Realdon, N., Volpato, S. and Santomaso, A.C. (2024). Effect of the drying type on the properties of granules and tablets produced by high shear wet granulation. Powder Technology, 434, 119316. https://www.sciencedirect.com/science/article/abs/pii/S0032591023010999?via%3Dihub

Liu, B., Wang, J., Zeng, J., Zhao, L., Wang, Y., Feng, Y. and Du, R. (2021). A review of high shear wet granulation for better process understanding, control and product development. Powder Technology, 381, 204–223. https://doi.org/10.1016/j.powtec.2020.11.051

Giry, K., Viana, M., Genty, M., Louvet, F., Wüthrich, P. and Chulia, D. (2009). Comparison of single pot and multiphase granulation. Part 2: Effect of the drying process on granules manufactured in a single pot granulator and dried either in situ or in a fluid bed dryer. Pharmaceutical Development and Technology, 14(2), 149–158. https://doi.org/10.1080/10837450802588942