

ランソプラゾール口腔内崩壊錠の先発品と後発品の 物理的品質の比較

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Comparison of Physical Qualities of Branded and Generic Lansoprazole Orally Disintegrating Tablets

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Summary

We compared the press-through package (PTP) ejection force, tablet strength (hardness and friability), hydrophilicity, stability in saliva, gastric acid resistance, and intestinal dissolution behavior of one branded and two generic lansoprazole orally disintegrating (OD) tablets (formulations A, B, and C). The PTP ejection force was approximately 20–30 N in all formulations, suggesting that many users would find no difficulty in ejecting a tablet. The hardness and friability of formulation B were more than 0.02 kg/mg and less than 1%, respectively; therefore formulation B should be secure from damage in the automatic packing machine and from vibration during transport. However, formulations A and C showed hardness of less than 0.02 kg/mg. The wetting time of formulation B (14 ± 1 s) was significantly shorter than that of formulations A (25 ± 2 s) and C (22 ± 1 s). These findings suggest that the time required for disintegration of formulation B in the oral cavity may be shorter than that of formulations A and C. Lansoprazole OD tablets are compressed tablets consisting of enteric granules of lansoprazole, which is unstable to gastric acid. We found these enteric granules were stable in artificial saliva and gastric juice. The formulations showed no difference in dissolution behavior in artificial intestinal juice. Our findings indicate that the physical qualities of the three formulations were almost equivalent, with the exception of hardness and hydrophilicity.

Key words

Lansoprazole, Orally disintegrating tablet, PTP (press through package) ejection force, Hardness, Friability, Hydrophilicity, Salivary stability, Gastric acid resistance, Dissolution behavior