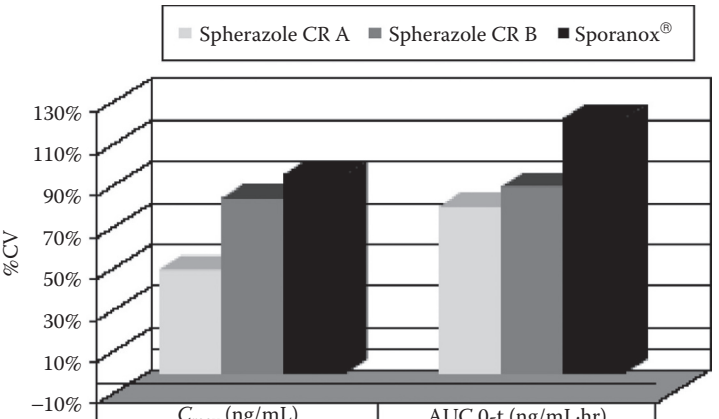

	C_{max} (ng/mL)	AUC 0-t (ng/mL·hr)
Spherazole CR A	49.60%	80.00%
Spherazole CR B	84.00%	89.40%
Sporanox®	85.30%	122.40%

FIGURE 22.19 Calculation of percentage coefficient of variation (% CV) of *C*max and AUC0-t for Spherazole™ CR tablet, 100 mg, compared with Sporanox® capsule. (Note: Types A and B are differed in levels of rate-controlling excipients.) (Adapted from Jacob, J., *Gastroretentive, bioadhesive drug delivery system for controlled release of itraconazole: Pharmacokinetics of Spherazole™ CR in healthy human volunteers*, Controlled Release Society 34th Annual Meeting and Exposition, 2006.)

FUTURE PERSPECTIVES

Given the abundance of water-insoluble or poorly water-soluble drugs, as well as drugs exhibiting other development challenges such as metabolic and enzymatic instability, the pharmaceutical industry continues to seek solutions to overcome these limitations to develop innovative, clinically safe, and patient-friendly products. As said earlier, MR delivery products offer tremendous advantages with respect to therapeutic indices, pharmacoeconomics, and patient compliance. In addition, the MR products provide prolonged market life and are cited as one of the most important life-cycle management strategies for the innovative, therapeutically effective compounds.

One of the future focuses in research and development of MR oral dosage forms for poorly water-soluble drugs will be to conduct systematic studies to address the challenges associated with the functional parameters, in particular, physicochemical properties of the compound and GI physiological environment and factors that have significant impact on dosage form design. Efforts should also be made to improve the robustness and capability of various delivery designs applicable to poorly water-soluble drugs that have been discussed in this chapter with continuous understanding of delivery mechanism and product performance *in vitro* and *in vivo.*

ACKNOWLEDGMENTS

We are grateful to Dr. M. Brewster and Dr. L. Dong for their critical reading and comments of the manuscript.

REFERENCES

Alakhov, V., G. Pietrzynski, K. Patel, A. Kabanov, L. Bromberg, and T. A. Hatton. (2004). Pluronic block copolymers and Pluronic poly(acrylic acid) microgels in oral delivery of megestrol acetate, *J. Pharm. Pharmacol*., 56: 1233.

Appel, L. E., W. J. Curatolo, S. M. Herbig, J. A. Nightingale, and A. G. Thombre. (2004). Controlled release by extrusion of solid amorphous dispersions of drugs, US Patent 6706283.