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12 Handbook of Pharmaceutical Formulations: Liquid Products TABLE 2.5 Aqueous-Based Drug Products Stored in Semipermeable Containers Study Storage Condition Minimum Time Period Covered by Long-term 25°C ± 2°C, 40% RH ± 5% RH Data at Submission (months) Intermediate 30°C ± 2°C, 60% RH ± 5% RH 12 Accelerated 40°C ± 2°C, not more than 25% RH 6 6 Note.

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Handbook of Pharmaceutical Formulations: Liquid Products 10 drug substances that cannot tolerate freezing. Terms such as “ambient conditions” or “room temperature” should be avoided. A retest period should be derived from the stability information, and a retest date should be displayed on the container label, if appropriate. III.

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