This concept of different acceptance criteria for release versus shelf life specifications applies to products only, not for drug substances.

The ICH Guideline requires this distinction between release and shelf life specification.

Release specifications describe the quality after manufacture and include

Analytical variability
Manufacturing variability

The variability is described by

RSD of repeatability or intermediate precision of the analytical procedure. Accordingly, validation has to be performed, preliminary or complete.
Data of ≥ 3 batches to describe the manufacturing variability.

Shelf life specifications describe the quality at the end of the shelf life and include

Tolerable changes during storage and shipment.

Therefore corresponding stability data are required with organoleptical, physicochemical, chemical, and microbial tolerable changes.

2.5. Storage Conditions

A basic distinction is drawn between stress, accelerated, and long-term storage conditions; see Table 3.

Table 3 Stress, Accelerated, and Long-Term Storage Conditions

Type	Condition
Stress	Temperature: 10°C higher than accelerated temperature of 40°C, e.g., 50°C, 60°C, 70°C ≥ -10°C Temperature cycle 5–40°C Open storage at 25°C/60% r.h., 30°C/70% r.h. and 40°C/75% r.h. Xenon lamp 48 hours
Accelerated	40°C/75% r.h. (30°C/70% r.h.)
Long-term	25°C/60% r.h. 30°C/70% r.h.

The conditions used in stress and accelerated tests are above those of the relevant climatic zones, allowing

The discriminatory power of the analytical procedure to be verified.
Weaknesses of a formulation to be identified.
Stability information to be generated.

The last-named aspect is particularly important in designing a stability program for clinical samples. To ensure continuous development, specific stress and acceleration tests are carried out, which are then verified by long-term tests.