

Real time and accelerated shelf-life testing

Best Lab LLC can provide both real time and accelerated shelf-life studies for determining expiration (EXP), “Use by”, and “Sell by” dates for your product(s). These stability studies can vary depending on various parameters and requirements but usually contains the following testing:

- Physical testing (appearance/organoleptic, loss on drying, average weight)
- Pathogenic microbial testing (Aerobic plate count, *Salmonella* spp., *Staph. aureus*, coliforms/*E. coli*, yeast & mold)
- Chemical identification testing: TLC or HPLC fingerprint testing are commonly used methods. Testing details will depend on product label claims.
- Quantification assay: HPLC or other method to measure retained potency. May not be required for some products depending on label claims.

Shelf-life studies can be designed and customized to your requirements. There are several options for testing shelf-life up to 3 years:

1. Real time testing for 1, 2 or 3 years

Samples are stored at ambient conditions in real time. Samples must be tested at least annually for cGMP compliance. More frequent testing timepoints are required for NSF cGMP requirements (i.e. testing at 0, 3, 6, 9, 12, 18, 24, 36 months).

2. Accelerated testing for 1 – 2 years shelf-life (need 3 – 6 months real-time)

Samples are stored in a specialized chamber at elevated temperature and humidity to accelerate aging. Storage times are typically 3 or 6 months (3 months in accelerated conditions equivalent to 1 year; 6 months equivalent to 2 years). At least three testing time points are recommended for accelerated studies by NSF (i.e. testing at 0,1,3 months or 0, 3, 6 months).

3. Accelerated + Real time testing for 3 years shelf life (18 months real-time)

Sample is placed in accelerated conditions for 6 months followed by real-time testing conditions for 1-year to yield the equivalent to 3 years total shelf-life. Testing frequency would be similar as described above.

All shelf-life studies require sufficient individual product samples for testing at each time point. Final report is generated and delivered at the end of the study.

If you are interested in shelf-life testing for your products, please contact Best Lab so we can provide a quote and design a study to meet your needs.