Only WHO guidelines are available for hold time studies. Rest as below:

EMA Guidelines:

The European Medicines Agency (EMA) emphasizes that hold time studies should be perfor med during the development phase on pilotscale batches and confirmed during the process validation of commercial-scale processing.

- The guidelines require that the maximum storage period for bulk products be declare d in the marketing authorization application (MAA). If the storage exceeds 30 days, st ability data must be provided to support the chosen bulk packaging.

The U.S. FDA guidelines:

for hold time studies emphasize the importance of establishing maximum allowable hold tim es for inprocess and bulk drug products to ensure product quality and stability.

Attached WHO guidelines