USP SCC Stability Study Checklist			
Drug Name			
Author, Title of Article, Publication			
Screening Tools		**Y/N**	**Comments**
1	Complete formula composition		
2	Samples are evaluated with ≥ 1 intermediate time point		
3	Sample storage conditions are described		
4	Stability-indicating nature of the analytical method		
Stability Study Guidelines			**Comments**
1	Published in a peer-revered journal or is equivalent		
2	Lot number for components of the study preparation		
3	Equipment specified with manufacturers and model numbers		
4	Sufficient detail for reproducibility		
5	Components are USP, NF, FCC, or ACS		
6	An initial ime zero evaluation		
7	Time intervals between assays are reasonable		
8	Sample schedule for evaluation is reasonable		
9	Time zero testing is performed on at least 3 replicates		
10	No overlap or interference with the intact drug peak		
11	Accerlerated decomposition to loss of 25-75% of the drug		
12	LC MS performed		
13	Sample chromatograms or elutions times		
14	Reference standard calibration curve range 80% -120%		
15	Reference standard calibration curve linearity ≥ 0.995		
16	Limit of quantification of the analyte should be stated		
17	Method repeatbility for ≥ 6 replicates and should not > 2%		
18	Intraday and interday coefficients of variation are < 3%		
19	Evaluation of unacceptable particulate matter		
20	For solutions, no visible particulate matter		
21	For inj & opth, evaluation for microparticulate formation		
22	Changes in color and turbidity		
23	For susp, evaluation of uniformity, settling, caking, resuspend		
24	For emulsions, eval of uniformity, creaming, layering, etc		
25	Analytical replicates do not exceed 2% variation		
26	Anomalous results are adequately explained		
27	The BUD that is proposed shows < 7% loss		
28	Appropriate BUD is not longer than the length of study		
29	Conclusion does not overreach the data and reasonable		