pletely tested. Therefore monitoring of sample or standard stability will ensure that there is no degradation occurring due to hydrolysis, photolysis, or adhesion to glassware over the course of the run period. The FDA recommends that data to support the stability of sample or standard solution under normal laboratory conditions for a minimum period of 24 hours should be generated.

17.12. System Suitability Specifications and Tests

The accuracy and precision of HPLC data collected begin with a well-behaved chromatographic system. The system suitability specifications and tests are parameters that provide assistance in achieving this purpose. According to the ICH and the USP, system suitability testing is an integral part of chromatographic procedures. These tests are used to determine that the resolution and reproducibility of the system are adequate for the analysis to the performed. The basis for these tests is that the equipment, electronics, analytical operations, and samples to be analyzed constitute an integral system that can be evaluated as a whole. System suitability test parameters to be established for a particular procedure depend on the type of procedure being validated. In USP 23 General Chapter <621>, Chromatography, a section has been devoted to system suitability requirements. It is important to know what are regulatory requirements for system suitability tests and specifications for method validation. As stated earlier, system suitability involves checking a system to ensure it is performing adequately before or during the analysis of unknowns. To establish these required parameters [i.e., plate count, tailing factor, resolution (if by-products or impurity standards are available; otherwise a chromatogram from forced degradation studies may be used)], the reproducibility (% RSD) of five or six replicates is calculated and compared to predetermined specification limits. System suitability tests are performed prior to analysis of actual samples. These parameters are studied by analysis of a system suitability sample that is a mixture of main active drug and expected by-product or a known impurity. Table 11 summarizes the parameters to be measured and their recommended regulatory limits for the system suitability tests and specifications (38,40). Definition of terms for system suitability parameters is shown in Figure 5.

Table 11 System Suitability Parameters and Recommendations

Parameter	Recommendation
Capacity factor (k')	The peak should be well resolved from other peaks and the void volume, generally $k' > 2.0$.
Repeatability	RSD $\leq 1\%$ for $N \geq 5$ is desirable.
Relative retention	Not essential so long as the resolution is stated.
Resolution (R_s)	R_s of >2 between the peak of interest and the closest eluting potential interferent (impurity, excipient, degradation product, internal standard, etc.).
Tailing factor (T)	T of ≤ 2.
Theoretical plates (N)	In general should be >2000.

Source: Ref. 37 and 39.