Three steps of validation are differentiated:

Orientational
Preliminary
Complete

Table 1 lists the extent of validation for the three steps.

Table 1 Extent of Validation During Development

	Extent of validation		
Validation characteristic	Orientational	Preliminary	Complete
Specificity	x	x	x
Linearity	x	x	x
Quantitation limit	x	x	x
Detection limit[a]	x	x	x
Accuracy		x	x
Range		x	x
Repeatability		x	
Intermediate precision			x
Robustness	x	x	x
Validation report			x

[a] Only for semi-quantitative procedures instead of quantitation limit

2.4. Specifications

Fixing specifications is an evolving process that accompanies the development of the new drug substances and drug products.

It can be described as a four step-procedure; see Table 2.

For all four steps one has to differentiate between

Release specification
Shelf life specification

Table 2 The Four Steps of the Specification

Step of development drug substance, drug product	Specifications	Characterization
Preclinical Clinical phase I	Orientational	Target values
Clinical phases II/III Pivotal batches	Preliminary	Broader acceptance criteria, ranges, numerical limits
Pilot plant batches Registration batches	Registration	Acceptance criteria focusing on safety and efficacy
Production batches after marketing authorization	Post approval	Experience gained with manufacture of a particular drug substance or drug product