

Chapter 41	Current	Official 1st Dec 2013, can be applied 3rd June 2013
Scope	Defines 'the requirement for balances used to weigh analytes for quantitative measures'	Same scope with improved wording for greater clarity
Calibrated Balance	Not specified	New requirement to use a calibrated balance
Number of Balance Test	1 – repeatability	2- repeatability and accuracy
Test 1 – Repeatability (A different and more stringent rounding rule has been introduced)		
Limit of repeatability test	≤ 0.1%	≤ 0.10%
Expansion factor	3	2
No. of replicate weighings	10	10
Acceptance criterion (RP)	3*s/m ≤ 0.1%	2*s/m ≤ 0.10%
Other criterion	No	If the repeatability obtained is smaller than 0.41 d, where d is the scale interval, replace the standard deviation with 0.41 d
Test 2 – Accuracy		
Limit of accuracy test	N/A	≤ 0.10%
Test weights	N/A	Must be between 5% and 100% of the balance capacity
Chapter 1251	Current	Official 1st Dec 2013, can be applied 3rd June 2013
Scope	Applies to 'all analytical procedures'	Same
Balance Test		
Performance Test	Drift check to be performed daily	Risk analysis determines the frequency of any test
Built-in weights	N/A, only a statement on www.fda.gov	Checks can be partially replaced using automatic or manually triggered adjustment by means of built-in weight.
Minimum Weight	Not specified	It is clearly stated that minimum weight applies to the sample weight, not the tare or gross weight
Calculation of Minimum Weight	Not specified	A new method for calculating minimum weight is given with the standard deviation, s, derived by using a test weight 'up to a few percent of the balance capacity': $m = 2000*s$
Repeatability Test	Not specified	As repeatability fluctuates over time, when possible, weighing should be performed at larger values than the minimum weight (safety factor).
Gravimetric Dosing	Not specified	Now described as an alternative to gravimetric-volumetric methods – so Quantos is accepted