(Prepared in August 2018)

Fig. Decision Tree for Assessment Type

All testing equipment/systems

Used for GMP testing?

Yes

No

Are GMP data maintained or output?

No

Yes

Group 1

Group 2

Shaker
Thermometer
Vernier calipers
Vacuum dryer
Disintegration tester
Dissolution tester

Are electronic data generated/retained?

No

Yes

Group 3

Balance (with printer)
Spectrophotometer
(without data maintenance
capabilities)
pH meter
Automatic potentiometric
titrator

Group 4

HPLC system
GC system
KF moisture meter
(with data maintenance
capabilities)
Spectrophotometer
(with data maintenance
capabilities)