

Appendix 1 API and Intermediate Sampling and Testing.

Appendix 1 API and Intermediates (this is an example only, these tests and limits not necessarily used in practice)

Process Step	Objective	Sampling & Testing	Criteria for Acceptance
Centrifuge and Pressure Filter (wet paste discharge)	To Demonstrate: Consistent operation of centrifuge. Batch Consistency/conversion/washing	Sample: B,M,E Test: LOD (Loss on Drying), Strength, RelatedSubstance(s).	LOD in - process limit Strength, related substance(s) to b
Dryer (batch e.g. agitated vacuum or pressure filter)	Uniformity of drying conditions & batch homogeneity. Effectiveness of normal Intermediate sampling.	Sample: B,M,E and composite Test: B,M,E for LOD, solvents, strength, Related substances. Composite: full spec test.	LOD in process limit. Strength, related substance solvent and eg +/- x % of mean. See Not

Process Step	Objective	Sampling & Testing	Criteria for Acceptance
All API	Effectiveness of milling. Effectiveness of the complete purification process & batch homogeneity. Effectiveness of normal end product sampling	Sample: B,M,E and composite. Test: B,M,E for strength, related substances, solvent(s) water, particle size and/or SSA. Composite: full spec test	All results in spec. and see Note 2 below