

Annexure-I

Sampling stage and testing frequency for hold time study

Company Logo Here

XX PHARMACEUTICALS LIMITED

117 Adams Street, Brooklyn, NY 11201, USA

Sampling stage and testing frequency for hold time study

Sl. No.	Sampling Stage	No. of sample	Sample Quantity	Testing frequency	Testing parameters	Remarks
01	Dispensing	02	10 gm	7 days & 15 days	Description, LOD & Assay	Only active materials to be considered
02	Blending	02	10 gm	7 days & 15 days	Description, LOD & Assay	
03	Compression	02	30 Tablets	7 days & 15 days	Description, Hardness, Friability LOD & Assay	
03	Encapsulation	02	30 Capsules	7 days & 15 days	Description, LOD & Assay	
04	Coating	02	30 Tablets	7 days & 15 days	Description, LOD & Assay	
05	Powder filling & Sealing	03	2 filled bottles	15days, 30 days & 60 days	Description, LOD & Assay	To be done for once of the first manufactured products and the result is applicable for the specific dosage forms.
06	Blistering	03	30 Tablets/ Capsules	15 days, 30 days & 60 days	Appearance, LOD & Assay	