Form-340
Issue date:

Trial Checklist

(Ref. SOP VAL-045)

Trial: _____

	Trial Activities	Needed (Y/N)	Person Responsible	Date Required	Comments
INITATION	Reason for Trial and its objective have been identified				
	Is this the most practical, cost effective way of achieving the trial outcome?				
EARLY PREPARATION	Trial co-ordinator appointed				
	Trial acceptance criteria established				
	Timeframe for completion established				
	Does change control system need to be followed as a result of the trial?				
	Does this trial have any impact on the product registration?				
	Any GMP issues identified				
	Any EHS issues identified				
	Does each department, including the laboratories, have the resources to support the trial - List each affected department separately?				
	Number and size of product batch to be used decided				
	Product saleable or non-saleable				
	Has time been planed into the production schedule for trial				
	Are all trial components available? List all components required separately				
	Are test methods available for all required testing?				
	Trial protocol and documentation written and approved				
	Are Manufacturing Instruction sheets available?				
	Any amendment to Manufacturing Instruction sheets required?				

Trial Checklist

(Ref. SOP VAL-045)

	Trial Activities	Needed (Y/N)	Person Responsible	Date Required	Comments
	Trial BPN raised (if appropriate)				
	Deviation Report (DR) raised to hold the batch if saleable product.				
	Laboratory has been made aware of dates and number of samples for testing.				
	Pre-trial training required?				
Execution of Trial					
COMPLETION	Nominated person assigned on process area				
	Completed trial documents have been reviewed by production				
	Completed trial documents have been reviewed by production				
	Trial conclusion written and approved				
	Trial outcome has been communicated to all affected parties				
	Any affected documentation has been updated				
	All non-saleable trial material has been destroyed				

Comments: _____

_____

_____

_____

_____

Completed by: _____ **Date:** _____

Reviewed by: _____ **Date:** _____