

PharmaHelp Additional Inclusions

Category	Description	Inclusion	Option	Comment
Specification	Compounder URS	x		Proposal as it is customer document
Specification	Safety Cabinet URS	x		Proposal as it is customer document
Specification	Compounder Functional Specification	x		
Specification	Safety Cabinet Functional Specification	x		
Qualification	IQ Safety Cabinet		x	
Qualification	OQ Safety Cabinet		x	
Commissioning on site	Commissioning protocol	x		
Qualification	IQ Plan		x	
Qualification	IQ Execution and respective report		x	
Documentation	Functional FAT Tests	x		
Documentation	Functional SAT Tests	x		
Qualification	OQ Plan		x	
Qualification	OQ Execution and Report		x	
Qualification	PQ Plan		x	
Documentation	Technical Documentation	x		
Documentation	Manual Pharma Help	x		
Documentation	Manual Safety Cabinet	x		
Documentation	System Installation Plan	x		
Documentation	Software Installation Instruction	x		
Documentation	Maintenance and Cleaning Recommendations	x		
Certificates	EC declaration of conformity	x		
Training in Enschede	5 days on site training	x		Expenses covered by customer
Installation on site and start up		x		Excluding GMP cover on top of the workbench and adaptations in customers clean room
PharmaHelp software		x		