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GMP Series

Technical Agreement and Delimitation of Pharmaceutical Responsibilities

VAV No:	**Corresponds to QSV No:**	**Date: <date>**
Contract giver: <name> <address>		**Contract acceptor:** <name> <address>

1 Subject of the contract

Product: <...description…>			
ID-# of contract giver	<...article or material No…>	ID-# of contract acceptor	<...article or material No…>
Strength		…	
Dosage form		…	
Package size		…	
Short description of tasks to be outsourced: <…e.g. bulk manufacturing, packaging and market release of xy-Tabs…>, <… e.g. packaging of ab-IMP…>, <… e.g.. fgh-analysis of z-caps…>			
Remarks:			

2 Delimination of pharmaceutical responsibilities

	Task		Responsible		Not Applicable
			Contract Giver	Contract Acceptor	
I.	**General**				
I.1	Training of staff in the context of method transfer / technology transfer				
I.2	Lead management of technology transfer				
I.3	Proper disposal of excess material	Supplied excipients			
		Supplied drug substance			
		Printed packaging material			
		Bulk product			
		Primary packaged product			
		Finished product			
		Samples			
		Returns			
		Nonconforming product			
		…			
I.4	Definition of transport conditions and transport packaging	Bulk product			
		Finished product			
		Samples			
		…			
I.5	…				
II	**Testing**				
II.1	Supply with reference standards for	Excipients			
		Drug substances			
		Bulk product			
		Finished product			
		Stability tests (degradation products)			
		…			

	Task			Responsible		Not Applicable
				Contract Giver	Contract Acceptor	
II.2	Sampling	Excipients				
		Drug substances				
		Bulk product				
		Finished product				
		Primary packaging material (not printed)				
		Printed primary packaging material				
		Secondary packaging material (not printed)				
		Printed secondary packaging material				
		For stability testing				
		…				
II.3	Test methods for excipients (incl. identity tests of each container)		compile			
			approve			
II.4	Validation of test methods for excipients		perform			
			approve			
II.5	Testing of excipients					
II.6	Test methods for drug substances (incl. ID-tests of each container)		compile			
			approve			
II.7	Validation of test methods for drug substances		perform			
			approve			
II.8	Testing of drug substances					
II.9	Test methods for bulk product		compile			
			approve			
II.10	Validation of test methods for bulk product		perform			
			approve			
II.11	Testing of bulk product					
II.12	Test methods for primary packaging material (not printed)		compile			
			approve			
II.13	Validation of test methods for primary packaging material (not printed)		perform			
			approve			

	Task		Responsible		Not Applicable
			Contract Giver	Contract Acceptor	
IV.17	Assigning a batch numbers for bulk product				
IV.18	Production of bulk product according to batch record				
IV.19	Approval of executed batch record for bulk product				
IV.20	Cleaning procedures	compile			
		approve			
IV.21	Validation of cleaning procedure	perform			
		approve			
IV.22	Cleaning according to cleaning procedures				
IV.23	Define test methods for in process controls (IPC)				
IV.24	Perform IPCs				
IV.25	Storage of reference samples of bulk product				
IV.26	…				
V	**Primary Packaging**				
	Purchase of packaging material				
V.1	Specifications of primary packaging material (not printed)	compile			
		approve			
V.2	Specifications of primary packaging material for bulk product	compile			
		approve			
V.3	Purchase of primary packaging material (not printed)				
V.4	Specifications of printed primary packaging material	compile			
		approve			
V.5	Specifications of printed primary packaging material				
V.6	Supply with reference samples of printed primary packaging material				
V.7	Storage of reference samples of printed primary packaging material				
V.8	…				
	Primary Packaging and IPCs				
V.9	Identity testing of bulk product				
V.10	Assigning batch numbers				

	Task		Responsible		Not Applicable
			Contract Giver	Contract Acceptor	
V.11	Assigning of expiry dates				
V.12	Primary packaging procedure (incl. line clearance)	compile			
		approve			
V.13	Validation of Primary packaging procedure	perform			
		approve			
V.14	Cleaning procedures	compile			
		approve			
V.15	Validation of cleaning procedures	perform			
		approve			
V.16	Test methods for in process controls	compile			
		approve			
V.17	Perform in process controls				
V.18	Perform primary packaging				
V.19	Approve executed batch record for primary packaging				
V.20	Storage of reference samples of primary packed product				
V.21	…				
VI	**Secondary Packing and Release Testing**				
VI.1	Purchase of packaging material				
VI.2	Specifications for secondary packaging material (not printed)	compile			
		approve			
VI.3	Purchase of secondary packaging material (not printed)				
VI.4	Specifications for printed secondary packaging material	compile			
		approve			
VI.5	Purchase of printed secondary packaging material				
VI.6	Supply with reference samples of printed secondary packaging material				
VI.7	Storage of reference samples of printed secondary packaging material				
VI.8	…				