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Title: PAI Protocol for Drug Product	Implementation Date:	Version Number 1.0

PAI Protocol for Drug Product	Name of document to be prepared / Document No.	Planned completion target Date	Status of document 6 months before filing	Status of document 3 months before filing	Status of document before filing	Status of document 1 week before inspection	Responsible Expert for document preparation	Responsible Expert for presentation during inspection	Location of storage / archive

13. Microbiological testing									
13.1 Environmental monitoring									
Microbiological testing for environmental monitoring: history of test methods and specifications PAI Protocol DP Attachment 14									
OOS failure investigation reports List of all related OOS All OOS closed in timely manner									
13.2 Drug Product									
Microbiological testing for Drug Product: history of test methods and specifications PAI Protocol DP Attachment 15									
Rationale for specifications									

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