



#	Request	Response or attachment reference
1. General Information		
1.1	Provide an SOP index with dates of approval and revision numbers for all applicable SOPs. Applicable SOPs include all SOPs applicable to the manufacturing, testing, storage, and shipping of the (b) (4) [REDACTED] BMN 270 finished drug product (DP), as well as all applicable facility and equipment SOPs.	
2. Quality Systems		
2.1	List/Index of all current GMP SOPs, including titles, version numbers and approval dates. Please note that this list should encompass QA responsibilities such as batch release, deviation investigations, etc. Additionally, please list any SOPs relevant to QC testing and supporting processes such as critical utilities testing. This list/index should include SOPs for laboratory assays conducted for in-process, bulk release, stability, and characterization testing of the FBDS and DP. Please Include the corresponding methods SOP number, sampling SOP number, and validation document number.	
2.2	Provide the SOP(s) for: <ol style="list-style-type: none"> 1. Change Controls 2. Batch Record Review 3. Training Program 4. Managing Retention Samples 5. Document Control 6. Raw material and starting material qualification and testing procedures. 7. Product Change-over / Clearance 8. Reworking and/or Reprocessing (if applicable) 9. Handling / Investigating OOS Test Results and Re-Test Procedures 10. Analytical methods used for release and stability of FBDS and DP 11. The qualification of new reference standards/materials for FBDS and DP testing 	



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	12. Control of data and sample handling and tracking	
2.3	List of deviations/non-conformances/OOS results and a brief description from February 10, 2020 to present. For each event, please include the corresponding lot/batch number, investigation number, date of occurrence, date of initiation, date of closure, status (open, closed, or unclassified; pending classification), and any associated CAPA. Sort according to criticality. Please provide this information in an organized and easily reviewable and accessible format (preferably in Excel format).	
2.4	List of all change controls that either affected or were opened during the time of process qualification through lot manufacture of your product. This list should be sorted by categories such as facilities, utilities, acceptance criteria (e.g., cleaning or sterilization), equipment, production, and QC. Include status, date of initiation, and (where applicable) date of closure. Sort according to criticality. Please provide this information in an organized and easily reviewable and accessible format (preferably in Excel format).	
3. Production / Aseptic Processing		
3.1	Provide a list of all FBDS and BMN 270 lots manufactured or attempted. Include lot number, dates of manufacture and their disposition, including those aborted or failed and include engineering runs. The list should also include information on the use of each lot (e.g., comparability, stability, development, process validation).	
3.2	SOP(s) governing aseptic process validation (APV).	
3.3	SOP(s) for sterile filter validation.	
3.4	Provide microbial quality (bioburden and endotoxin) (b) (4) results for all batches/lots of BMN 270 manufactured.	
3.5	Provide summaries for any investigations that involved reprocessing or reworking. Ensure the affected FBDS lot(s) are identified.	
4. Facility and Equipment		
4.1	Provide HVAC validation documents (IQ, OQ, PQ), and completion dates.	



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4.2	Provide current facility changeover procedures for cross-contamination control (cleaning and changeover) of the FBDS and BMN 270 DP manufacturing areas.	
4.3	Provide the Equipment Cleaning Validation Master Plan. Also, include the cleaning validation and/or verification protocols/reports for the FBDS and BMN 270 DP equipment.	
4.4	SOP(s) for use, maintenance, and (b) (4) decontamination of the (b) (4) [redacted]; SOP(s) for (b) (4) [redacted] (b) (4) testing.	
4.5	List of all equipment used for the manufacture of (b) (4) (b) (4) [redacted] and the finished drug product, with corresponding qualification document numbers (IQ, OQ, PQ) and completion dates. Include if equipment is considered product contact or non-product contact, shared or dedicated, and method of cleaning (e.g., manual, Clean-in-Place (CIP)). This list should include all secondary equipment such as equipment washing machines, and autoclaves.	
5. Materials		
5.1	List of raw materials used in manufacturing and associated vendors. Provide a description of the Supplier Qualification Program.	
5.2	Provide your program and SOPs for materials management including for material receipt, storage, distribution, and quarantine.	
6. Laboratory		
6.1	List of all laboratory equipment used for QC testing with corresponding qualification document numbers (IQ, OQ, PQ) and completion dates.	
6.2	List of deviations/non-conformances/OOS during QC laboratory testing (including re-tests) and during validation of analytical release assays. Please include deviation reports for deviations observed during validation of analytical release assays. Highlight all failed and/or invalid	



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	results for CCI, bioburden, endotoxin, and sterility release and stability testing.	
7. Packaging and Labelling		
7.1	Provide a list of all temperature related OOS investigations during either packaging or labelling. Include lot number, status, dates of occurrence, initiation, and (where applicable) closure, and any associated CAPA. Please provide this information in an organized and easily reviewable and accessible format.	