To facilitate the Agency’s review of XXX DS and DP manufacturing processes, provide the information for all process parameters and controls proposed for routine commercial manufacturing as well as those evaluated during development and validation, in the tabular format provided below. Please provide a separate table for each unit operation. The tables should summarize information from Module 3 and may be submitted Module 3.2.R as a single document. Note that these tables do not replace other parts of Module 3 or impact the nature or amount of information included in those parts of Module 3.

Title: INSERT UNIT OPERATION

| Process Parameter / Operating Parameter / IPC / IPT | Proposed range for commercial manufacturing | Criticality classification | Characterized range from process development | Manufacture range from historical experience | Manufacture range assessed during process validation | Justification of the proposed commercial acceptable range | Comment |
|---------------------------------------------------|---------------------------------------------|---------------------------|---------------------------------------------|-----------------------------------------------|----------------------------------------------------------|-----------------------------------------------|

1. Terminology should be adapted to those used by XXXX.
2. As applicable
3. For example, critical process parameter, non-critical process parameter, as described in Module 3.
4. Manufacturing experience for the DP lots, and associated DS lots, which were used in the clinical studies to establish product safety and efficacy profile (i.e., pivotal clinical studies).
5. Operation ranges, not the acceptance criteria, used during process validation.
6. This could be a brief verbal description (e.g., “development range”, “validation range”, or “historical manufacturing experience”, etc.) or links to the appropriate section of the eCTD
7. Optional