3.2.S.2.2 DESCRIPTION OF MANUFACTURING PROCESS AND PROCESS CONTROLS [{DRUG SUBSTANCE NAME}, {MANUFACTURER}]

Manufacturing flow and process together with in process controls for {drug substance name} are in compliance with {CEP number}/ {ASMF(DMF) number}

or

3.2.S.2.2.1 Manufacturing Process Flow Diagram

The process flow diagram for the manufacture of {Drug Substance Name} is reported in Figure 1.

Figure 1. Manufacturing process flow diagram for {Drug Substance Name}
{include flow diagram}

1. Diagram of the synthetic process(es) should be provided that includes molecular formulae, weights, yield ranges, chemical structures of starting materials, intermediates, reagents and drug substance reflecting stereochemistry, and identifies operating conditions and solvents.
2. For biotech-should illustrate the manufacturing route from the original inoculum (e.g. cells contained in one or more vials(s) of the Working Cell Bank up to the last harvesting operation. The diagram should include all steps (i.e., unit operations) and intermediates.

3.2.S.2.2.2 Description of the Manufacturing Process

For biotech- information should be provided on the manufacturing process, which typically starts with a vial(s) of the cell bank, and includes cell culture, harvest(s), purification and modification reactions, filling, storage and shipping conditions.

{include a short narrative for each step}

Step 1 – Preparation of {Intermediate 1}
{include a short narrative}

Step 2 – Preparation of {Intermediate 2}
{include a short narrative}

Step 3 – Preparation of {Intermediate 3}
{include a short narrative}

The list of the equipment used in the manufacturing process for {Drug Substance Name} is provided in Table 1.

Table 1: List of Equipment
Only a list with major equipment (details provided in 3.2.A.1)

3.2.S.2.2 Description of Manufacturing process and process Controls
[{Drug Product Name}, {Dosage Form}]

Name/type	Working capacity (where appropriate)

3.2.S.2.2.3 Description of the In-Process Controls

The list of relevant and critical In-Process and Quality Controls performed throughout the manufacture of {Drug Substance Name} is reported in Table 2.

Table 2: In-Process and Quality Controls

Process Step (name)	Parameter	Acceptance Criteria
	{Test performed}	{introduce limit as per product specification}

3.2.S.2.2.4 Reprocessing

No reprocessing of {Drug Substance Name} is performed as per {manufacturer(s) name} procedures.
If reprocessing is performed justification have to be introduced together with supporting data.

Or, where applicable

"In case of unplanned deviations, any drug substance batch or any intermediate batch can be reprocessed in accordance with the ICH Q7A guideline by repeating all or part of the specific manufacturing step"

3.2.S.2.2.5 Batch(es) and scale definition

5.1 Development batches
Applicable to INDs for Phase I and II

5.1.1 Manufacture of batches used in non-clinical studies

Table 3: List of batches for supportive non-clinical studies

Batch No.	Drug Substance Bulk Size	Non-Clinical Study Reference	Process Differences compared to Figure 1
{insert batch number}	{insert drug substance Batch Size}	{insert non-clinical study reference}	{insert process differences short description}

5.1.2 Manufacture of batches used in clinical studies

Table 4: List of Batches for Supportive Clinical Studies

Batch No.	Drug Substance Bulk Size	Clinical Study Reference	Process Differences from Non-clinical Manufacturing
{insert batch number}	{insert Drug Substance Batch Size}	{insert clinical study reference}	{insert process differences between the manufacturing of clinical and non-clinical lots}

5.2 Batch size or batch scale definition

Batch sizes and yield ranges can be reported at the end of the manufacturing process description of each step.

{report batch size or scale definition for all the drug substance manufacturing process steps, including information regarding any pooling of harvests or intermediates. Report also yields for each batch size. If a variability of batch size has been validated within a defined range, it can be stated here}

Table 5: Batch Number Genealogy

Stage	Batch Number
{insert Stage}	{insert number}

5.3 Batch numbering system

The batch number is a unique and non-descriptive sequence of {insert a number} characters that is automatically assigned by a validate enterprise resource planning system.
{Provide an explanation of the batch numbering system. Specify if consecutive numbers correspond to consecutive batches.}

The batch number changes at selected steps of the manufacturing process of {insert drug substance name}, {insert steps name}.

An example of batch numbering system is presented in Figure 3.
Only if available and applicable only if available and applicable