3.2.P.2.2 Drug Product [{Drug Product Name}, {Dosage Form}]

3.2.P.2.2.1 Formulation Development

1 3.2.P.2.2.1.1 Formulation history

{insert a brief narrative considering the following:

- Drug product description including difference or similarity between the drug product and reference product, if applicable
- Propose route of administration (include any dilution or reconstitution necessary)
- Choice of manufacturing process, explain choice if alternative process could have been applicable (e.g. aseptic processing instead of terminal sterilization, direct compression instead of granulation). If different processes were used for different formulation highlight and explain differences, refer at 3.2.P.2.3. If no change in the process occurred refer to 3.3.P.3.3 and avoid duplication data.}

The intended quality target product profile (QTPP) for the formulated drug product is presented in the section 3.2.P.2.3 Manufacturing process development.

The differences in the manufacturing process used for bioequivalence batches and for commercial batches of the {drug product name} are presented in section 3.2.P.2.3 Manufacturing process development

1.1

The formulations used during {drug product name} development are included in Table 1

1.2 Table 1 Formulation history for {drug product name}

Formulation Identifier	Composition	Change	Development phase
{insert internal identifier}	{insert composition}	{include change performed}	{include development stage when the formulation was used}

{if necessary, explain in separate paragraphs changes of the formulation (included in the above table), including explanation for each ingredient/quantity of an ingredient change, emphasizing ingredient role and change reason/effect}

2 3.2.P.2.2.1.2 Formulation Development Studies

Include all studies, including robustness and comparability (clinical and commercial formulation)

Summary of the formulation developmental studies conducted are provided in Table 2.

2.1 Table 2: Formulation Development Studies

Study	Formulation identifier	Objective	Quality attribute evaluated	Study design	Study result
{include study name/ type}		{include short description of the study objective}	{insert CQA}	{include short description of the design}	{insert reference to the table showing study results}

2.2 1.2.1 {study name}

Multiply as necessary

{If necessary, describe study design}

Data obtained during {study name} is presented in table 1.2.1.1

2.3 Table 1.2.1.1 Results for {formulation identifier} {study name} study

2.4 1.2."n" {study name}

{If necessary, describe study design}

Data obtained during {study name} is presented in table 1.2."n".1

2.5 Table 1.2.“n”.1 Results for {formulation identifier} {study name} study

3 3.2.P.2.2.1.3 Conclusion

{insert a narrative showing how studies and or process results determined the choice of the final commercial formulation. Refer at M4 and M5 if/or where applicable}

3.2.P.2.2.2 Overages

There are no overages used in the formulation of {Drug Product Name}, {Strength}

or

{include narrative to explain overage presented in the section 3.2.P.1}
If the overage is required to make up for a validated loss during the manufacturing process (e.g. loss during vacuum transfer) or to fill void space (e.g. excess coating solution to fill the tubing) it should be presented along with justification and supporting data for the necessity and quantity of the overage.

3.2.P.2.2.3 Physicochemical and Biological Properties

{insert a short narrative considering:

- Product properties with cross reference to other dossier sections as 3.2.P.5.1 Consider parameters relevant to the performance of the drug product, such as pH, ionic strength, dissolution, redispersion, reconstitution, particle size distribution, aggregation, polymorphism, rheological properties, biological activity or potency, and/or immunological activity
- Any properties which are not included in the product specification, with explanation of parameter control and relevant studies. If applicable refer to relevant compendia monograph}

4

3.2.P.2.2.4 Summary for Risk Assessment of Elemental Impurities in Drug Product

For new drug products submitted under an NDA or ANDA