

3.2.P.3. Manufacture [{Drug Product Name}], {Dosage Form}]

3.2.P.3.3 DESCRIPTION OF MANUFACTURING PROCESS AND PROCESS CONTROLS [{DRUG PRODUCT NAME}], {DOSAGE FORM}]

Flow diagram, description of manufacturing process and process controls are described hereafter.

3.2.P.3.3.1. Manufacturing Process Flow Diagram

A flow diagram for entire manufacturing process including packaging processes for {Drug Product Name} is provided in Figure 1.

Figure 1: Manufacturing Process Flow Diagram

{A schematic representation of the process starting from preparation of ingredients (active and excipients) (e.g. dispensing, weighing, sieving, thawing, etc..) finishing with secondary packaging}

3.2.P.3.3.2 Manufacturing Process Description

{A short narrative for each manufacturing step. View job aid for examples.}

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

Table 1: List of Equipment

Name/type	Working capacity (where appropriate)

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3.2.P.3.3.3 Description of the In-Process Controls

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

Table 2: In-Process and Quality Controls

Process Step (name)	Parameter	Acceptance Criteria
	{Test performed See job aid for examples}	{introduce limit as per product specification}

2.3.P.3.3.4 Reprocessing

If reprocessing is performed justification have to be introduced together with supporting data.

No reprocessing of {Drug Product Name} is performed as per {manufacturer(s) name} procedures.