

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

2. BATCH FORMULA [{DRUG PRODUCT NAME}, {DOSAGE FORM}]

A batch formula should be provided that includes a list of all components of the dosage form to be used in the manufacturing process, their amounts on a per batch basis, including overages, and a reference to their quality standards.

Table 1: Batch Formula Table

Core Tablet		
Component	Quality Standard	Amount (kg) per batch
Drug Substance	In-House Standard	500
Excipient X	USP/NF	310
Excipient Y	USP/NF	280
Excipient Z	In-House Standard	50
Magnesium Stearate	NF	15 (range 14.5 to 15.5)
Purified Water	USP	(200) ^a
Total Batch Size		X
Film Coat Solution^b		
Hydroxy Methylcellulose	USP	10
Purified Water	USP	(200) ^a
Color Red	DMF Holder Y Standard	10
Color White	DMF Holder Z Standard	1.5
Total Batch Size		Y
Print Ink Solution		
Colorant		0.15
Solvent		10
Total Batch Size		Z

^a Water is removed during processing

^b Film coat weight variability is 80 - 120% or target