

<SAMPLE> Master Formulation Record and Compounding Record Template - Product Description (name, strength, volume and dosage form) Product Type (sterile or non-sterile)

Components	Closed System Transfer Device(s) required	Notes
Drug with weight or volume	CSTD 1	i.e. final product should be colorless
Diluent 1 (i.e. sterile water XX mL)	CSTD 2	
Diluent 2 (i.e. dextrose 5% in water XX mL)	CSTD 3	
	CSTD 4	

Compounding Instructions

Label Description (i.e. drug X mg in 50 ml D5W)

• Bullet 1	Attach Sample Label Here
• Bullet 2	
• Bullet 3	
• Bullet 4	
• Bullet 5	
• Bullet 6	
• Bullet 7	
• Bullet 8	
Special Instructions: (i.e. protect from light, non-PVC bag)	

Compounding Record

Date and Time	Drug Manfct	Drug Lot#	Drug Exp	Diluent 1 Manfct	Diluent 1 Lot#	Diluent 1 Exp	Diluent 2 Manfct	Diluent 2 Lot#	Diluent 2 Exp	Process Lot #	Pre-check Initials	Preparer Initials	Post-check Initials	Beyond Use Date and Time2	Quantity	QI Done
08/22/21 1530	Company X	1234567	11/11/22	Company Y	1234567	12/1/23	Company Z	1234567	12/1/22	123456789	RPh 1	Tech 1	RPh 2	08/24/21 1500	X	Yes

CSTD 1 Manufacturer	CSTD 1 Lot#	CSTD 1 Exp	CSTD 2 Manufacturer	CSTD 2 Lot#	CSTD 2 Exp	CSTD 3 Manufacturer	CSTD 3 Lot#	CSTD 3 Exp	CSTD 4 Manufacturer	CSTD 4 Lot#	CSTD 4 Exp

References

1.	
2.	
3.	

Calculations

Deviations from Master Formulation Record - document only if deviation occurred

Production Date	Process Lot#	Deviation

Label requirements

- Product Description
- Final Concentration
- Lot #
- Prep Date
- BUD
- EXP
- Special Instructions
- Barcode

Quality insurance required prior to release:

- No Particulate matter observed
- Color of compound is appropriate
- Clarity - No observed particulates, cloudiness or phase change:
- Container is not damaged or leaking
- All labels are visible and legible
- Final product matches components used
- Label matches compounded product and compounding record
- Label is appropriate, including storage requirements and BUD
- Weight / Volume is correct
- BUD is appropriate based on process and storage time