



# Batch Master Record

CLEANOUT:

BATCH NUMBER: 880-CM-624

DATE DATE: 7/20/20

08-20-20

FINISHED GOOD: 2000-00000

PRINT DATE: 8/20/20

AMOUNT TO PRODUCE: 5,450,000 lb

WAREHOUSE: 00-1A

LOT NUMBER: T80-LOT

HRIS RATING: 4- 1 1- 2 0- 1 00- 1

CONTAINER MEASURE (WEIGHT): 100 LB

Remarks: Print on Batch Ticket

## TOTAL RAW MATERIAL REQUIREMENTS:

PRODUCT CODE	PRODUCT NAME / PACKAGE DESCRIPTION	LOT NUMBER/LOC	TOTAL WEIGHT QUANTITY (LBS)	TOTAL VOL. (GALS) USED
700-00000	Whylene Glycol	T80-LOT	2,432,500 lb	35,000.4
	1.00 lb BULK	T80-LOC		
200-20000	Green Dye	T80-LOT	5,450,000 g	0.770
	25.00 lb Can	T80-LOC		
200-00000	Ethyl Alcohol	T80-LOT	877,500 lb	105,500.4
	1.00 lb BULK	T80-LOC		
000-00000	Methanol	T80-LOT	117,000 lb	38,400.7
	1.00 lb BULK	T80-LOC		
000-00000	Ice (A)	T80-LOT	2,345,000 lb	208,000.1
	1.00 lb BULK	T80-LOC		

## STEP BY STEP INSTRUCTIONS

STEP: 1-0000      WORK CENTER: 1-Blending

EQUIPMENT: 10-Blending

MATERIALS:      TOTAL QUANTITY: 5,750,000 lb

2000-00000      2,345,000 lb

Whylene Glycol      2,432,500 g

200-20000      5,450,000 g

Green Dye      877,500 lb

200-00000      2,345,000 lb

Ethyl Alcohol      117,000 lb

000-00000      2,345,000 lb

Ice (A)      117,000 lb

000-00000      117,000 lb

Methanol

INSTRUCTIONS: Unlimited Instructions - Heat, mix for 2 hours. QC, Filter, Package

START TIME: \_\_\_\_\_ STOP TIME: \_\_\_\_\_

INITIALS: \_\_\_\_\_

# Master Batch Production Record Sample

**Léo Pomar**



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**Good Manufacturing Practices for Pharmaceuticals** Joseph D. Nally, 2016-04-19 With global harmonization of regulatory requirements and quality standards and national and global business consolidations ongoing at a fast pace pharmaceutical manufacturers suppliers contractors and distributors are impacted by continual change Offering a wide assortment of policy and guidance document references and interpretations this Sixth Edition is significantly expanded to reflect the increase of information and changing practices in CGMP regulation and pharmaceutical manufacturing and control practices worldwide An essential companion for every pharmaceutical professional this guide is updated and expanded by a team of industry experts each member with extensive experience in industry or academic settings

Practical Pharmaceutical Engineering Gary Prager, 2018-11-28 A practical guide to all key the elements of pharmaceuticals and biotech manufacturing and design Engineers working in the pharmaceutical and biotech industries are routinely called upon to handle operational issues outside of their fields of expertise Traditionally the competencies required to fulfill those tasks were achieved piecemeal through years of self teaching and on the job experience until now Practical Pharmaceutical Engineering provides readers with the technical information and tools needed to deal with most common engineering issues that can arise in the course of day to day operations of pharmaceutical biotech research and manufacturing Engineers working in pharma biotech wear many hats They are involved in the conception design construction and operation of research facilities and manufacturing plants as well as the scale up manufacturing packaging and labeling processes They have to implement FDA regulations validation assurance quality control and Good Manufacturing Practices GMP compliance measures and to maintain a high level of personal and environmental safety This book provides readers from a range of engineering specialties with a detailed blueprint and the technical knowledge needed to tackle those critical responsibilities with confidence At minimum after reading this book readers will have the knowledge needed to constructively participate in contractor user briefings Provides pharmaceutical industry professionals with an overview of how all the parts fit together and a level of expertise that can take years of on the job experience to acquire Addresses topics not covered in university courses but which are crucial to working effectively in the pharma biotech industry Fills a gap in the literature providing important information on pharmaceutical operation issues required for meeting regulatory guidelines plant support design and project engineering Covers the basics of HVAC systems water systems electric systems reliability maintainability and quality assurance relevant to pharmaceutical engineering Practical Pharmaceutical Engineering is an indispensable tool of the trade for chemical engineers mechanical engineers and pharmaceutical engineers employed by pharmaceutical and biotech companies engineering firms and consulting firms It also is a must read for engineering students pharmacy students chemistry students and others considering a career in pharmaceuticals

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methodologies that can serve as a reference point for new formulations the second volume covers uncompressed solids which include formulations of powders capsules powders ready for reconstitution and other similar products Highlights from Uncompressed Solid Products Volume Two include the fundamental issues of good manufacturing **Active**

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Rodríguez-Pérez,2019-05-08 Data integrity is a global mandatory requirement for the regulated healthcare industry It is more than a mere expectation it s a basic element of good documentation practices one of the most fundamental pillars of a quality management system Robustness and accuracy of the data submitted by manufacturers to regulatory authorities when bringing a medical product to market are crucial The purpose of this book is to consolidate existing data integrity principles and expectations from several regulatory sources including the U S Food and Drug Administration World Health Organization and European Medicines Agency into a single and handy document that provides detailed illustrative implementation guidance It serves as a means of understanding regulatory agencies position on good data management and the minimum expectation for how medical product manufacturers can achieve compliance **Handbook of**

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