

## V5 FORMULA SYSTEM

### *ELEVATE YOUR BATCH MANUFACTURING*

Paperless Lot Traceability



Product Consistency



Reduced Batch Production Time



Allergen, Safety & Recipe Messaging



Simple Real Time ERP Integration



## Description

1. Follow recipe as instructed
2. Set capsule Filler to 850mg
3. When complete, hit GREEN button to begin the transfer to capsule filler
4. Package into Product Formula P101 (240 x 800mg)



TYP	DESCRIPTION	TARGET	ACHIEVED	DONE
1 Weigh	Microcrystalline Cellulose	110.00	110.00	✓
2 Weigh	Maize Starch	90.00	90.00	✓
3 Weigh	Silicon Dioxide	120.00	120.00	✓
4 Weigh	Stearic Acid	180.00	180.00	✓
5 Question	Pass the Medi-101 Base through a 40 to 50 mesh sieve prior to weigh stage	0.00		✓
6 Weigh	Aspirin Powder (USP)	325.00	325.00	✓
7 Question	Combine and triturate the ingredients to form a homogeneous powder bl...	0.00		✓
8 Question	Pass the homogeneous powder blend through a 40 to 50 mesh sieve	0.00		✓



LOTS MANUAL FORMULA ACTIONS

Com Desc: Microcrystalline Cellulose Job: 032621-0001 Usage: 0.00 kg  
 Com Code: IP106 Bl Stock: 9999.01 kg Batch: 50001638 Stop Usage: 0.00 kg  
 Lot No: 10001222 Location: GEN Location: PHARMA1 Gross Weight: 0.00 g

## Empowering Excellence in Batch Manufacturing & 21 CFR Part 11 Compliance

Welcome to V5 Traceability, your ultimate partner in achieving unparalleled precision, compliance, and innovation within the realm of pharmaceutical batch manufacturing.

The advanced solutions offer a comprehensive approach to quality control, paperless lot tracking, and seamless ERP integration, ensuring your operations remain aligned with the stringent standards of 21 CFR Part 11.

Embark on a transformative journey with V5 Traceability that redefines excellence and eliminates Manual Batch Records.

## Pioneering Batch Manufacturing with V5 Traceability

- **Complete Batch Visibility:** Unlock the potential of end-to-end batch manufacturing visibility, overseeing each stage of the process to maintain peak quality standards.
- **Data Integrity:** Uphold data authenticity and integrity with state-of-the-art electronic signatures and fortified data management that strictly adhere to 21 CFR Part 11.
- **Regulatory Confidence:** Seamlessly generate comprehensive audit trails, electronic records, and impeccable reports, ensuring smooth regulatory compliance inspections.
- **Enhanced Efficiency:** Bid farewell to archaic paper-based workflows, as we reduce errors, elevate efficiency, and expedite your manufacturing endeavors.




## Seamless Integration for Enhanced Productivity

- **ERP Integration:** Effortlessly integrate V5 Traceability with your existing ERP system using our robust API capabilities, ushering in a new era of harmonized data management.
- **Warehouse Management:** Extend your batch traceability to the warehouse floor with our Warehouse Management System (WMS), ensuring meticulous end-to-end visibility.

- Laboratory Information Management System (LIMS): Elevate your quality control standards with our optional LIMS module, which empowers streamlined sample management and analysis.
- Enhanced Efficiency: Bid farewell to archaic paper-based workflows, as we reduce errors, elevate efficiency, and expedite your manufacturing endeavors.

R101 (Aspirin Tablets)			50001637
IP106	Microcrystalline Cellulose	110.00g	100012
IP107	Maize Starch	90.00g	100012
IP108	Silicon Dioxide	120.00g	100012
IP109	Stearic Acid	180.00g	100012
IP110	Aspirin Powder (USP)	325.00g	100012

	Job Number:	032621-0001	825.00g
	Produced:	04/07/21	Expiry: 03/08/23
	COMPLETE		



## V5 Traceability's Comprehensive Solutions

- Paperless Lot Tracking: Transition from cumbersome paper trails to agile digital records, securing complete lifecycle traceability with precision.
- Electronic Signatures: Mitigate compliance risks by employing secure and verifiable electronic signatures, in full alignment with the exacting standards of 21 CFR Part 11.
- Audit Trails: Generate meticulous audit trails that capture each action taken, forming an immutable record that attests to the integrity of your manufacturing processes.
- Real-time Monitoring: Gain a competitive edge with real-time monitoring of critical parameters, preempting deviations and cementing consistent quality.
- Laboratory Integration: Revolutionize your quality control measures by seamlessly managing samples, tests, and results through our integrated LIMS module, ensuring uncompromised accuracy.

## V5 Traceability Advantage

Unparalleled Expertise: Harness the depth of our domain knowledge in batch manufacturing and regulatory nuances, delivering solutions that address your unique challenges.

Innovative Solutions: Stay one step ahead with our cutting-edge technologies, designed to not only meet but exceed evolving industry benchmarks.

Global Compliance: Rest easy knowing that our solutions transcend international borders, aligning with regulatory standards across diverse regions.

Proven Impact: Embrace a transformative journey that has propelled industry leaders towards elevated compliance, exceptional efficiency gains, and unmatched product quality.

### Electronic Batch Record



Report generated on 07:57:36 Wed 16 Feb 2022

Formula	R101	Formula Approved By	SG User
Description	Aspirin Tablets	Produced Qty	824,890 g
Version	31	Scheduled Qty	825,000 g
Batch No.	50001790	Start Date/Time	02/16/2022 07:46:37
Job Number	021622-0002	End Date/Time	02/16/2022 07:54:32
Batch Reference		Batch Time	00:06:33
Production Location	Pharmaceutical Line 1	Stock Location	GEN
Created By	Henry Waits	Status	Completed
Accuracy	99.99%		
Expiry Date	01/17/2024		
Allergens		Custom Lot #	

Step Types	Target Qty	Quantity	Lot #	Stock Location	Bag #	User	Terminal	Date/Time
HAZARDS ACKNOWLEDGED : Safety Mask								
Commodity : IP106 (Microcrystalline Cellulose)								
Weigh	110,000 g	109,980 g	10001222	GEN		Henry Waits	Weigh-Room	02/16/2022 07:47:03
	<b>110,000 g</b>	<b>109,980 g</b>						<b>99.98%</b>
Commodity : IP107 (Maize Starch)								
Weigh	90,000 g	89,950 g	10001225	GEN		Henry Waits	Weigh-Room	02/16/2022 07:47:14
	<b>90,000 g</b>	<b>89,950 g</b>						<b>99.94%</b>
Commodity : IP108 (Silicon Dioxide)								
Weigh	120,000 g	119,990 g	10001230	GEN		Henry Waits	Weigh-Room	02/16/2022 07:47:29
	<b>120,000 g</b>	<b>119,990 g</b>						<b>99.99%</b>
Commodity : IP109 (Stearic Acid)								
Weigh	180,000 g	179,990 g	10001231	GEN		Henry Waits	Weigh-Room	02/16/2022 07:48:55
	<b>180,000 g</b>	<b>179,990 g</b>						<b>99.99%</b>
Question :	Pass the Medi-RDT Base through a 40 to 50 mesh sieve prior to weigh stage							
Answer :	Confirm Process Step							
						Henry Waits	Weigh-Room	02/16/2022 07:51:12
Commodity : IP110 (Aspirin Powder (USP))								
Weigh	325,000 g	324,980 g	10001234	GEN		Henry Waits	Weigh-Room	02/16/2022 07:52:09
	<b>325,000 g</b>	<b>324,980 g</b>						<b>99.99%</b>
Question :	Combine and triturate the ingredients to form a homogeneous powder blend							
Answer :	Confirm Process Step							
						Henry Waits	Weigh-Room	02/16/2022 07:53:18
Question :	Pass the homogeneous powder blend through a 40 to 50 mesh sieve							
Answer :	Confirm Process Step							
						Henry Waits	Weigh-Room	02/16/2022 07:53:24
<b>Total</b>	<b>825,000 g</b>	<b>824,890 g</b>						<b>99.99%</b>

#### Q & A

Date/Time	Event	User	Question	Answer
02/16/2022 07:46:45	Batch Start	Henry Waits	CCP1 - Is the area clean and free of hazardous materials?	Yes

Batch Signed Off By	Sam Hawkins (Supervisor)	
Date/Time	02/16/2022 07:54:31	
Comments	Batch reviewed & accepted	

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