

BATCH MANUFACTURING RECORD

Batch Information

Product Name:	Drug XYZ 50 mg Tablets		
Batch Number:	DXYZ-2024-015	Batch in Total:	100,000 tablets
Manufacturing Date:	2024-02-10	Expected Yield:	100,000 tablets
Expiry Date:	2026-02-09	Expiry Date:	2026-02-09

Raw Materials

Material Code	Material Name	Required Qty	Actual Qty	Lot Number	Verified By
RM-001	API XYZ 50 mg	5.0 kg	<input type="checkbox"/>	RM-001-01	<input type="checkbox"/>
RM-002	Lactose Monohydrate	45.0 kg	<input type="checkbox"/>	RM-002-03	<input type="checkbox"/>
RM-003	Microcrystalline Cellulose	35.0 kg	<input type="checkbox"/>	RM-003-02	<input type="checkbox"/>
RM-004	Magnesium Stearate	2.0 kg	<input type="checkbox"/>	RM-004-05	<input type="checkbox"/>

Manufacturing Steps

Step No.	Operation Description	Equipment Used	Time Start	Time End	Performed By
1.	Weigh and dispense raw materials	Weighing Scale			<input type="checkbox"/>
2.	Blend ingredients in a granulator	High-Shear Granulator			<input type="checkbox"/>
3.	Dry the granulation in fluid bed dry	Fluid Bed Dryer			<input type="checkbox"/>
4.	Compress granules into tablets usin	Tablet Press			<input type="checkbox"/>

In-Process Quality Checks

Parameter	Specification	Actual Result	Pass / Fail
Appearance	Uniform, white, round tablets		<input type="checkbox"/>
Weight Variation	±5% of target weight		<input type="checkbox"/>
Disintegration Time	Not more than 15 minutes		<input type="checkbox"/>

Yield & Reconciliation

Theoretical Yield: 100,000 tablets

Actual Yield: _____ tablets

Percentage Yield: _____ %

Deviation Notes:

Prepared by: _____ Date: _____ Approved by: _____ Date: _____

Reviewed by: _____ Date: _____ Approved by: _____ Date: _____

QA Release: _____ Date: _____ QA Release: _____ Date: _____

MASTER PRODUCT CARD

Product Information

Product Name:	Drug XYZ 50 mg Tablets	
Product Code / SKU:	DXYZ-50MG	Batch Size: 100,000 tablets
Batch Size:	100,000 tablets	Unit of Measure: Tablets
Unit of Measure:	Tablets	Expiry Date: 24 months

Specifications

Physical Description:	Uniform, white, round tablets
Dimensions / Weight:	8 mm diameter x 4 mm thickness, 50 mg active ingredient per tablet
Active Ingredients / Composition:	API XYZ 50 mg per tablet, Lactose Monohydrate, Microcrystalline Cellulose, Magnesium Stearate
Storage Conditions:	Store in a cool, dry place below 25°C in well-sealed containers.

Manufacturing Details

Manufacturing Location:	PharmaCorp Facility 1
Equipment Required:	Weighing Scale, High-Shear Granulator, Fluid Bed Dryer, Tablet Press
Quality Control Checkpoints:	Weight Variation, Disintegration Time, Appearance checks during in-process stages

Prepared by: _____ Date: _____ Approved by: _____ Date: _____

Reviewed by: _____ Date: _____ Approved by: _____ Date: _____

QA Release: _____ Date: _____ QA Release: _____ Date: _____