InstantGMP-Lite™

Electronic Batch Record Software for GMP Manufacturing

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Manufacturing Problems

- Typical manufacturing companies have too much documentation and too little time
- Managing documents and quality processes are overhead activities that don’t contribute to revenue
- Hard to coordinate integrated work flows with paper based systems

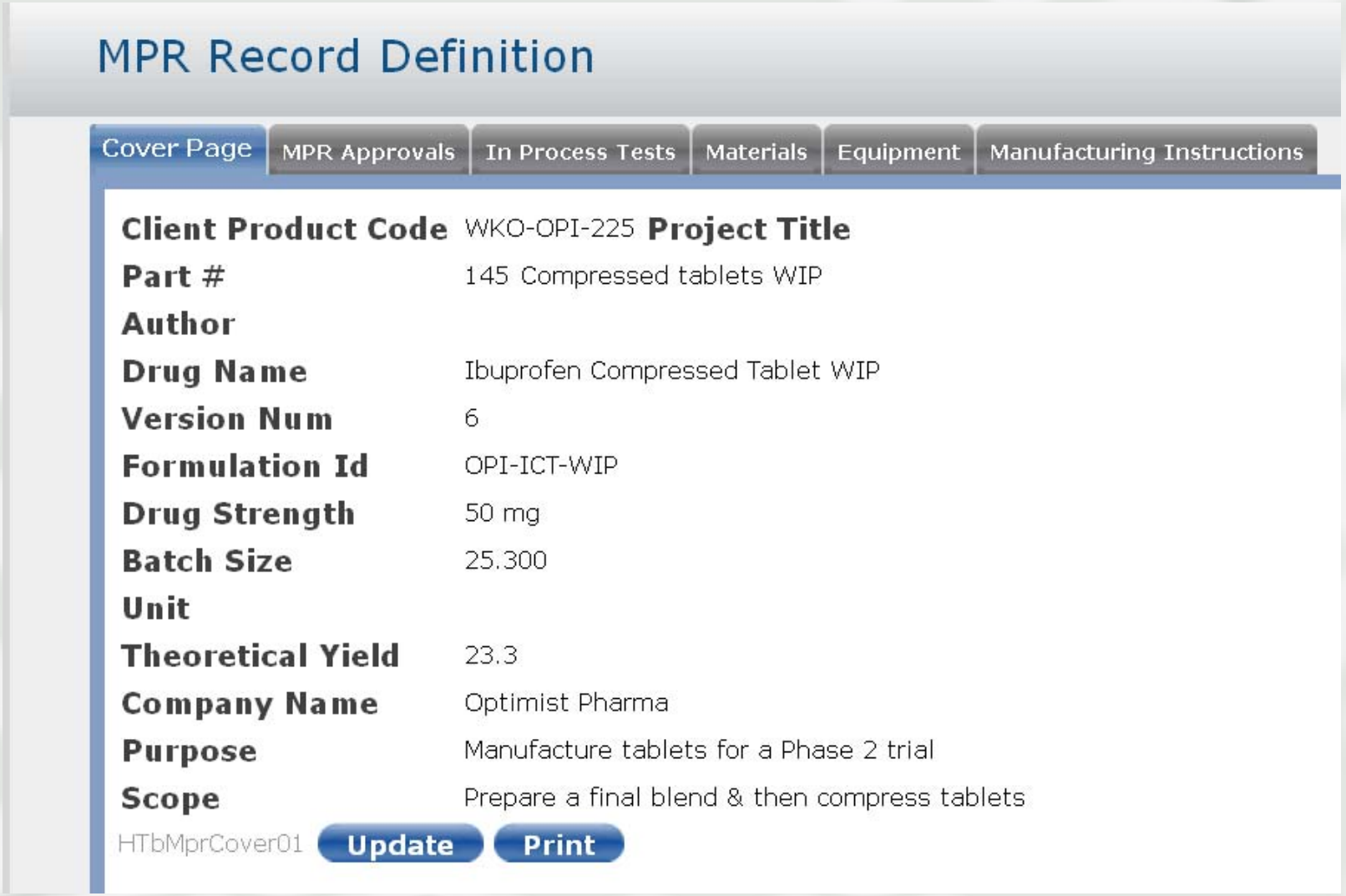
Benefits of Electronic Manufacturing

- More efficient than manual systems
- Shrink or eliminate redundant processes and forms
- Trim time and overhead costs
- Reduce errors, omissions and deviations
- Provide opportunities to reorganize and update processes
- Increases throughput, quality and margins

InstantGMP-Lite: Makes GMP Compliance Easy

- Electronic Batch Records Software for GMP Manufacturing
- Seamlessly incorporates everything necessary for GMP manufacturing in one place
- Cloud-based application makes all data visible to everyone at all times
- Uses built-in quality procedures to make GMP compliance easy
- Provides opportunities for more flexibility, visibility and productivity

Master Production Record



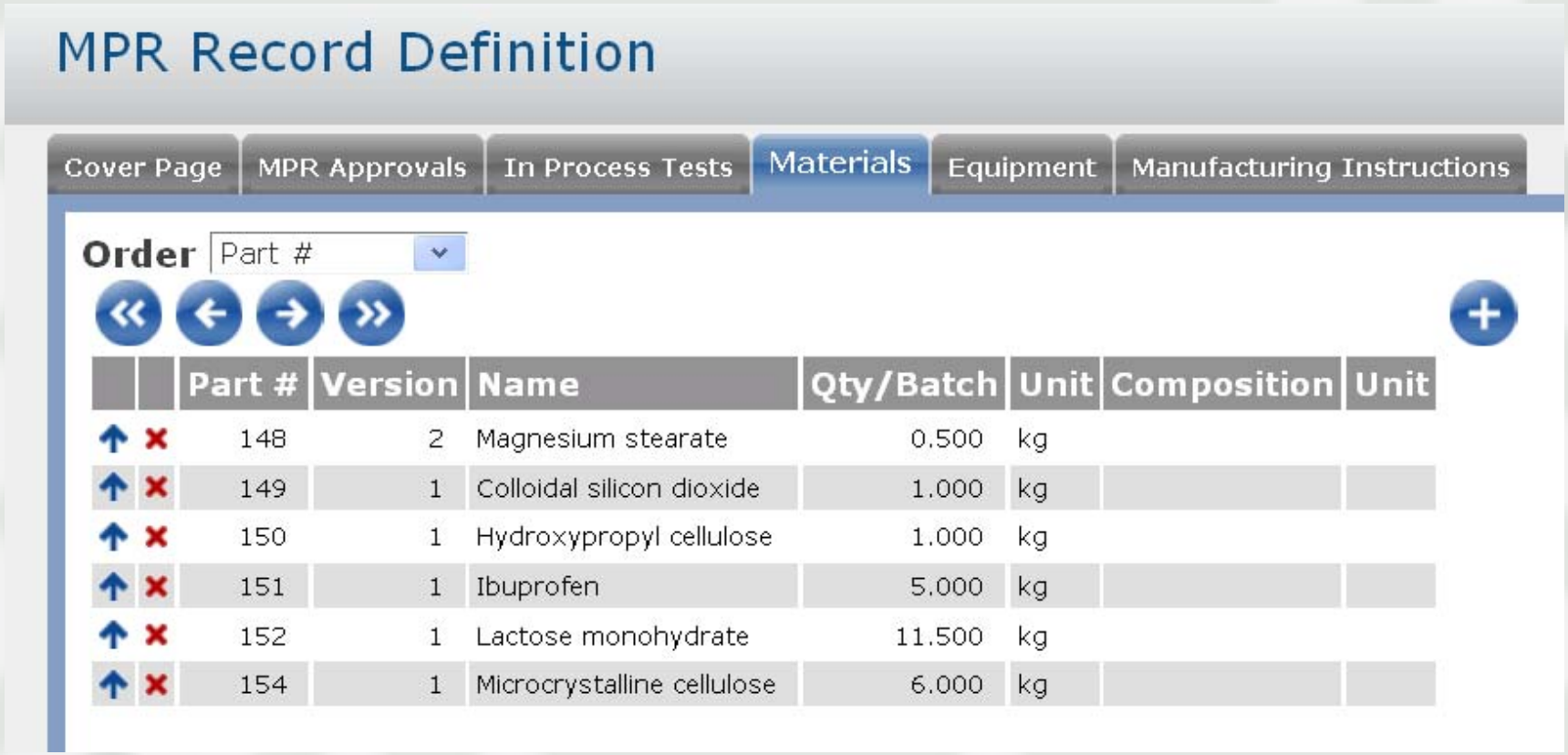
GMPs for Batch Records

- Instructions and procedures are clear and unambiguous
- Manufacturing processes are clearly defined and controlled
- Operators are trained
- Records demonstrate that all steps were taken
- Master Record for each unique formulation and strength
- Batch Record for each production batch

Master Production Record

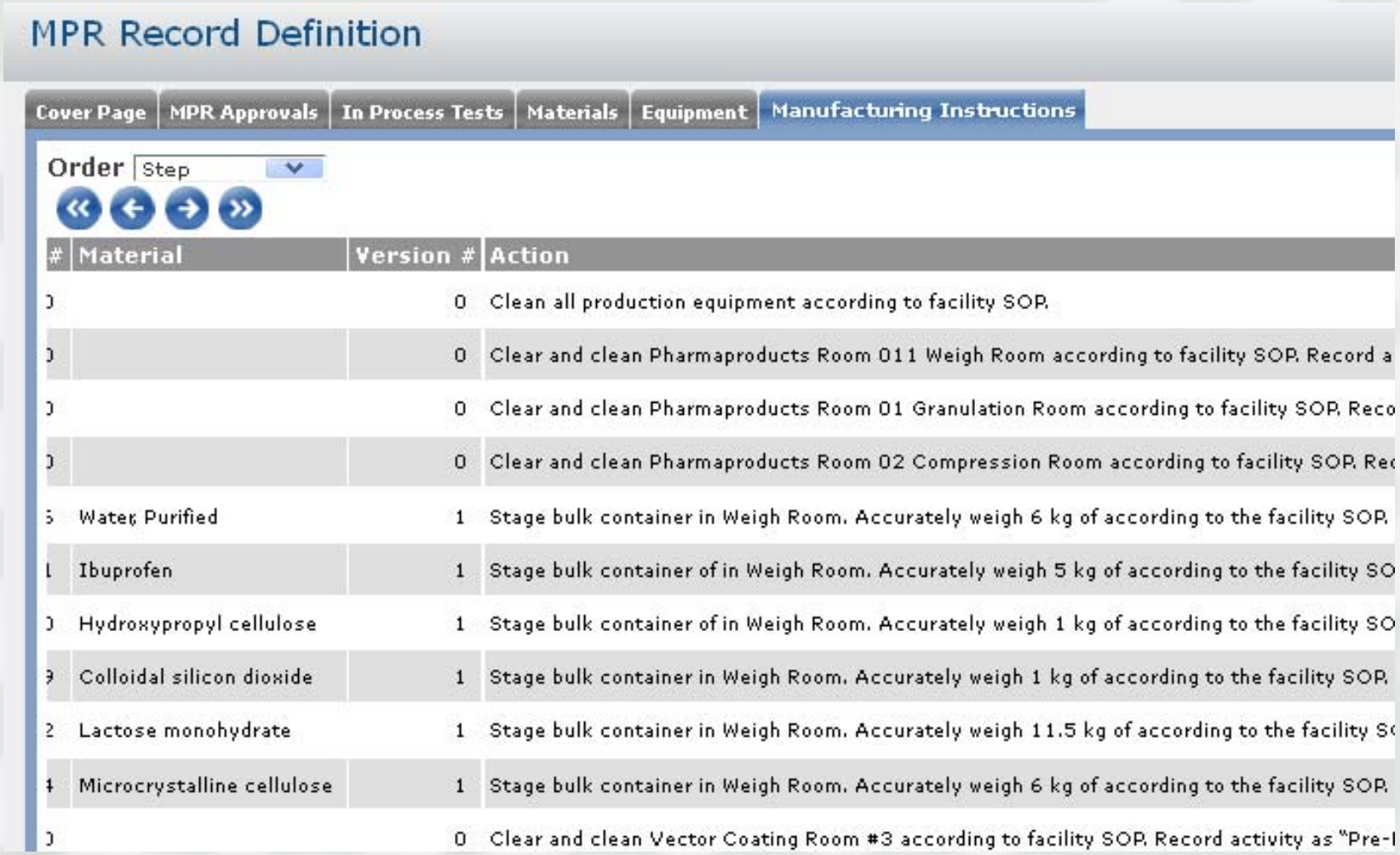
- The MPR must Include:
  - Name and strength of product
  - Description of the product
  - Name, weight or measure of each active and component
  - List of components
  - Theoretical yield
  - Complete manufacturing instructions including sampling, testing and specifications

Master Production Record
Bill of Materials



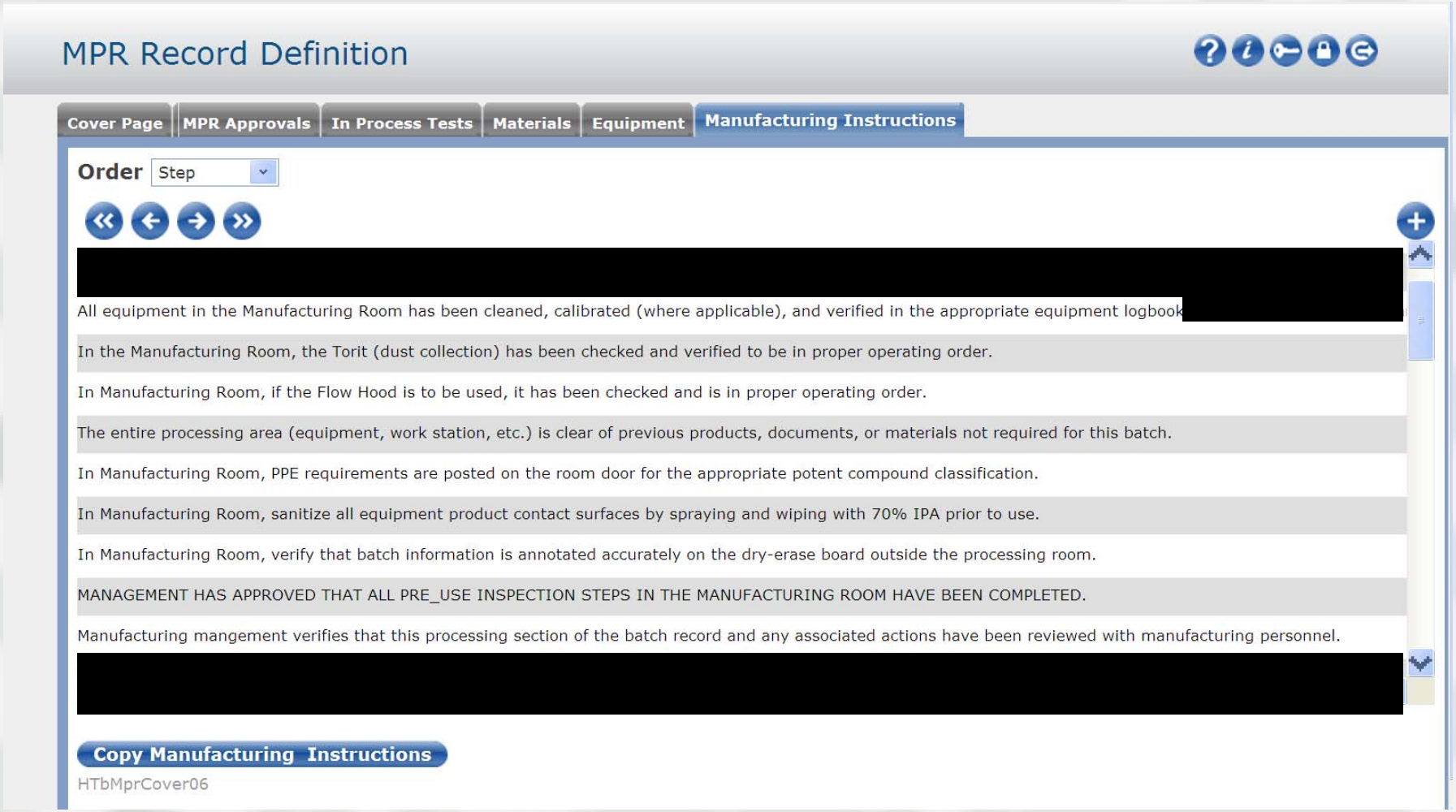
		Part #	Version	Name	Qty/Batch	Unit	Composition	Unit
↑	✖	148	2	Magnesium stearate	0.500	kg		
↑	✖	149	1	Colloidal silicon dioxide	1.000	kg		
↑	✖	150	1	Hydroxypropyl cellulose	1.000	kg		
↑	✖	151	1	Ibuprofen	5.000	kg		
↑	✖	152	1	Lactose monohydrate	11.500	kg		
↑	✖	154	1	Microcrystalline cellulose	6.000	kg		

Master Production Record – Manufacturing Instructions



#	Material	Version #	Action
)		0	Clean all production equipment according to facility SOP.
)		0	Clear and clean Pharmaproducts Room 011 Weigh Room according to facility SOP. Record a
)		0	Clear and clean Pharmaproducts Room 01 Granulation Room according to facility SOP. Reco
)		0	Clear and clean Pharmaproducts Room 02 Compression Room according to facility SOP. Rec
5	Water, Purified	1	Stage bulk container in Weigh Room. Accurately weigh 6 kg of according to the facility SOP.
1	Ibuprofen	1	Stage bulk container of in Weigh Room. Accurately weigh 5 kg of according to the facility SO
)	Hydroxypropyl cellulose	1	Stage bulk container of in Weigh Room. Accurately weigh 1 kg of according to the facility SO
9	Colloidal silicon dioxide	1	Stage bulk container in Weigh Room. Accurately weigh 1 kg of according to the facility SOP.
2	Lactose monohydrate	1	Stage bulk container in Weigh Room. Accurately weigh 11.5 kg of according to the facility SO
4	Microcrystalline cellulose	1	Stage bulk container in Weigh Room. Accurately weigh 6 kg of according to the facility SOP.
)		0	Clear and clean Vector Coating Room #3 according to facility SOP. Record activity as "Pre-I

Example of Workflow in MPR



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Batch Production Record

- Batch
  - Specific quantity of a product that is uniform
  - Intended to meet full set of specifications
  - Made on a single batch production record during one manufacturing cycle
- Batch Number
  - Lot or control number which refers to complete manufacturing history of batch
- BRP must have complete manufacturing history
- Must be a BPR for each unique batch

Batch Production Record

- Must Include:
  - Unique identifier for each batch
  - Identity and weight of each component
  - Identity of equipment and processing lines
  - Inspection of manufacturing areas before and after use
  - Date and time of equipment maintenance and cleaning
  - Statement of actual and % theoretical yield

Batch Production Record

- Must include:
  - Operators signature on each step (Initials or digital signature OK)
  - Supervisors signature on each significant step
  - In-process results or references to actual data
  - An label, or reference to the physical location
  - Documentation that finished product meets specifications
  - Any investigations of deviations

Batch Production Record – Manufacturing Instructions

Batch Production Record – Manufacturing Instructions

BPR Instructions

ProductCode	Name	Strength	Batch #	Version
AAA	Phase 2 Clinical Trials		0145-02-007	3

Step 1050.00

Material Water, Purified

Action Stage bulk container in Coating Room. Accurately weigh 6 kg of according to the facility SOP. Record amount weig product name (Ibuprofen 50 mg tablet) and this batch record number in "Purpose" field.

Unit cm

Equipment (None)

Result

Comments

Deviation Comment

Deviation Approved ☐ Approve 0 | / / 12:00 AM |

Performer Required ☐ Approve **Approved By** 0 | / / 12:00 AM |

Verifier Required ☐ Approve **Approved By** 0 | / / 12:00 AM |

Inventory

TBPRManufacturingInstructions

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Find more videos on GMP Manufacturing in the Resource Center at

www.instantgmp.com

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