



## Batch Documentation Checklist For Tablet Packing

(Ref. [SOP QMS-075](#); [QMS-085](#); [QMS-090](#))

**Production is to complete Sections 1 & 2**  
**Quality Assurance Department is to complete Section 3**

### SECTION 1

<b>PRODUCT NAME:</b>	<b>BPN:</b>	<b>CODE:</b>
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Tick appropriate boxes	✓
Put a N/A against boxes which are NOT APPLICABLE	N/A

### SECTION 2

**The following manufacturing documents and samples must accompany the checklist:**

	Production ✓	Prod Initial	QA ✓
<b>MI Sheets</b> for all the process phases			
<b>Form-450</b> Deviation Report Form (If any <b>DR</b> raised)			
<b>Form-120</b> Printed Material Sample Sheet/s			
<b>Form-035</b> Bulk Tablet Sampling Form/s ( <b>if applicable</b> )			
<b>Form-160</b> Line Clearance, Opening and Cleaning Form/s			
Finished Good Retention <b>Samples</b>			
<b>Form-055</b> Material Transfer Order Form/s			
<b>Form-175</b> Vacuum Leak Test - Hourly Form			
<b>Form-180</b> Vacuum Leak Test - New Foil and PVC Roll Form			
<b>Form-195</b> In-Process Check - Shipper Form			
<b>Form-200</b> In-Process Check-Blister and Carton form			
<b>Form-125</b> Batch Reconciliation Sheet for Tablet Packing			
<b>Form-145</b> IBC Cleaning Tag/s			
<b>Form-380</b> IBC Identification Label/s			
<b>Form-155</b> Checkweigher Weight Record ( <b>if applicable</b> )			
<b>Form-540</b> Pallet Booking Information			

<b>If any deviation raised write the DR Number/s:</b> (Attach the copy of deviation report/s)		
<b>If any work-order raised during the batch write the order number/s:</b>		
<b>Name of authorised production person (print name):</b>		
<b>Signature of Authorised production person:</b>		<b>Date:</b>
<b>Comments:</b>		



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**SECTION: 3**

<b>PRODUCT NAME:</b>		<b>CODE:</b>	
<b>EXPIRY DATE:</b>		<b>BATCH (BPN) NO:</b>	
<b>DEVIATION REPORT:</b>		<b>PROCESS LINE:</b>	
<b>MANUFACTURING INSTRUCTION:</b>			
All Phases Complete Checked ( <b>MI Sheet Status must be completed and Signed off</b> )		Time / Date Blistering Finished	
		Time / Date Packing Started	
Expiry Date Checked		Time / Date Packing Finished	
Incomplete Entries Checked		Carton % Yield Checked	
PI Sheet Comments Checked		Leaflets % Yield Checked	
Manufacturing Date ( <b>C of A</b> )		/ /	Label % Yield Checked
Time / Date Blistering Started		Tablet % Yield Checked	
Retention Samples & Printed Materials Checked– Product Code, Description, BPN, Expiry Date, Pack Size, Temperature			
Shipper Label Checked – Product Code, Description, BPN, Expiry Date, Pack Size, Temperature,			
<b>QUANTITY</b>		Retention Samples:	Packs to "Quarantine":
Batch Size:		Stability Samples:	
<b>Checklist Checked By</b>	<b>Print Name:</b>		
<b>Signature:</b>		<b>Date:</b>	
<b>Batch Document and QA Inspection Sheet Reviewed By</b>		<b>Initial:</b>	<b>Date:</b>
<b>Name of Authorised QA Person (Print Name):</b>			
<b>Signature of Authorised QA Person:</b>		<b>Release Date:</b>	