



PHARMA DEVILS

**PERFORMANCE QUALIFICATION
FOR
SOFT GELATIN ENCAPSULATION MACHINE**

PROTOCOL No.:

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1.0 PROTOCOL APPROVAL:

Signing of this approval page of reports indicates agreement with the qualification approach described in this document. If modification to the qualification approach becomes necessary, an addendum shall be prepared and approved. The report cannot be used for execution unless approved by the following authorities.

This Performance Qualification report of Soft Gelatin Encapsulation Machine has been reviewed and approved by the following persons:

This Performance Qualification protocol of Soft Gelatin Encapsulation Machine has been reviewed and approved by the following signatories:

FUNCTION	NAME	DESIGNATION	DEPARTMENT	SIGNATURE	DATE
PREPARED BY			QUALITY ASSURANCE		
REVIEWED BY			QUALITY ASSURANCE		
			ENGINEERING		
			QUALITY CONTROL		
			PRODUCTION		
APPROVED BY			HEAD OPERATION		
			QUALITY ASSURANCE		



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2.0 OVERVIEW:

2.1 OBJECTIVE:

The objective of developing and executing this protocol is to check and document the performance of equipment in the established/predetermined operating ranges.

2.2 PURPOSE:

The purpose of this protocol is to provide the documented evidence that the functions of the equipment, which affect the product quality, integrity and safety of operating and maintenance personnel is taken into consideration.

2.3 SCOPE:

The scope of protocol shall define the test procedures, documentation and acceptance criteria to establish that the performance of Soft Gelatin Encapsulation Machine installed in soft gel area of

2.4 RESPONSIBILITY:

In accordance with protocol, following functions shall be responsible for the qualification of system.

Execution Team (Comprising members from Production, Quality control , Engineering and Quality Assurance) and their responsibilities are following:

- Prepares the qualification protocol.
- Ensures that the protocol is in compliance with current policies and procedures on system Qualification.
- Distributes the finalized protocol for review and approval signatures.
- Execution of Qualification protocol.
- Review of protocol, the completed qualification data package, and the final report.
- The analysis of sample shall be carried out by quality control department (wherever applicable).
- Engineering department shall support for execution.
- The production operator / supervisor shall carry out the cleaning and operation of machine.

Head – Quality control / Production / Engineering:



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- Review of protocol, the completed qualification data package, and the final report.
- Assist in the resolution of validation deficiencies.

Head – Operation and Quality Assurance:

- Review and approval of protocol, the completed qualification data package, and the final report.

2.5 EXECUTION TEAM:

The satisfactory operation of the Soft Gelatin Encapsulation Machine shall be verified by executing the performance qualification studies described in this report of the Soft Gelatin Encapsulation Machine. The successful execution of the instructions mentioned in the report of the Soft Gelatin Encapsulation Machine documents that the Soft Gelatin Encapsulation Machine is operational and is satisfactorily working.

Execution team is responsible for the execution of performance qualification of the Soft Gelatin Encapsulation Machine.

NAME	DESIGNATION	DEPARTMENT	SIGNATURE	DATE



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3.0 GENERAL CONSIDERATION/PREREQUISITE

- 3.1 Approved Standard operating procedure of the Soft Gelatin Encapsulation Machine shall be available.
- 3.2 The installation and operational qualification of the equipment shall be successfully completed before the execution of the performance qualification.
- 3.3 All the deficiencies and discrepancies related to the equipment which affect the product quality and corrective action taken shall be recorded in the appropriate section of the protocol.
- 3.4 After completion of PQ activities, equipment shall be cleaned as per respective cleaning SOP's and released for manufacturing.

4.0 REVALIDATION CRITERIA:

The machine shall be re-qualified if

- There are any major changes, which affect the performance of the equipment.
- After major breakdown maintenance is carried out.
- As per re-validation date and schedule

5.0 PERFORMANCE QUALIFICATION PROCEDURE

5.1 EQUIPMENT DESCRIPTION:

General Description:

The Automatic Rotary Die Soft Gelatin Encapsulation Machine is designed to perform the process of Encapsulation with different fill weights in different shape and sizes of capsules.

The production capacity of the machine is 20520 to 37800 capsules per hour @ 3.0 rpm. The capsules are manufactured by passing the gelatin film of uniform thickness over two rotating die rolls of cylindrical form with cavities on periphery. A metering pump forces premeasured injection of fill material through a heated feeder segment placed between two gelatin films into matching die roll cavities. The filled capsules are formed between the two die rolls. Through pressure and heat sealing, the two halves of ribbon get effectively fused. Freshly formed soft gelatin capsules discharged from the machine and pass along a transfer conveyor into Tumbler Drier. On completion of the tumbling, the



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capsules are placed on trays which are then stacked and transferred into the capsule Drying Room for further drying.

5.2 RISK ANALYSIS

- (a) The Automatic Rotary Die Soft Gelatin Encapsulation Machine is designed to perform the process of Encapsulation with different fill weights in different shape and sizes of capsules.
- (b) In the event of power failure the system is designed to unload the pressure.
- (c) The segment lifting system is pneumatically controlled through the PLC. In the event of an emergency it is designed to automatically lift up the segment system.
- (d) Thermostats and temperature controllers are installed at each spreader box for temperature regulation and controlled by PLC.
- (e) In case of breaking of ribbon the machine will stop and an alarm appeared on the PLC.
- (f) Empty medicament tank shall be acknowledged by a message displayed on the PLC and by the glowing of tower lamp.
- (g) Injection of the medicament in the shell is regulated by the six miniature dosing pump to avoid the weight variation and controlled by separate VFD.

Risk identified

Power failure
In case of an emergency stop

Temperature fluctuation

Unavailability of ribbon

Empty medicament tank

Control measures

The machine shall unload the pressure.
The machine shall automatically lift up the segment system.
Thermostats and temperature controllers are installed at each spreader box for temperature regulation
The machine will stop and an alarm appeared on the PLC
A message displayed on the PLC and by the glowing of tower lamp

EVALUTION & CONCLUSION:

All the risks associated with Soft Gelatin Encapsulation Machine have been evaluated and control/preventive measures have been taken.



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5.3 METHODOLOGY:

Methodology of the encapsulation process is as follows:

- Maintain the encapsulation area temperature at $18^{\circ}\text{C}\pm 3^{\circ}\text{C}$ and Humidity $35\pm 5\%$.
- Check the all gaskets and Change Parts.
- PQ batches of minimum and maximum batch sizes shall be encapsulated with all available Die Rolls which shall be used in different products.
- Details of the PQ batches and Die Roll details shall be mentioned under the heading of “**Product Details**”.
- Challenge run mentioned in the Sampling Plan shall be performed with all Die Roll change parts individually and shall be record under the heading of “**Observations and Results of Challenge Tests**”.
- Transfer the Gelatin Holding Tank to Gelatin Feeding Room and connect the feed pipe from Gelatin Holding Tank to spreader box and connect the feed pipe from gelatin holding tank to gelatin Spreader box.
- Maintain gelatin holding tank temperature $60^{\circ}\text{C}\pm 5^{\circ}\text{C}$, Spreader box temperature at $55^{\circ}\text{C}\pm 5^{\circ}\text{C}$, Segment temperature at $40^{\circ}\text{C}\pm 5^{\circ}\text{C}$ and cool drum temperature at $10^{\circ}\text{C}\pm 3^{\circ}\text{C}$.
- Transfer the Medicament tank to Gelatin Feeding Room and connect the feed pipe to the encapsulation machine as per standard procedure and set the parameter as per in process specifications.
- Start the encapsulation process as per the BMR.
- Transfer capsules to tumbler drier and tumble the capsules to strengthening then unload into Ddegreasing pan.



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5.4 PRODUCT DETAILS:

Product details of minimum and maximum batch size shall be verified from the BMR of the product and record in the following section:

5.4.1 Product Detail of Minimum Batch Size:

Product Name : _____
Product Code : _____
Batch Number : _____
Batch Size : _____
Mfg. Date : _____
Exp. Date : _____
BMR Number : _____

5.4.2 Product Detail of Maximum Batch Size:

Product Name : _____
Product Code : _____
Batch Number : _____
Batch Size : _____
Mfg. Date : _____
Exp. Date : _____
BMR Number : _____

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5.4.3 Die Roll (Capsulator) Details:

S.No.	Die Number	Size of Dies	Number of cavities in a row	Numbers of row in a roll	Done By (Sign. & Date)

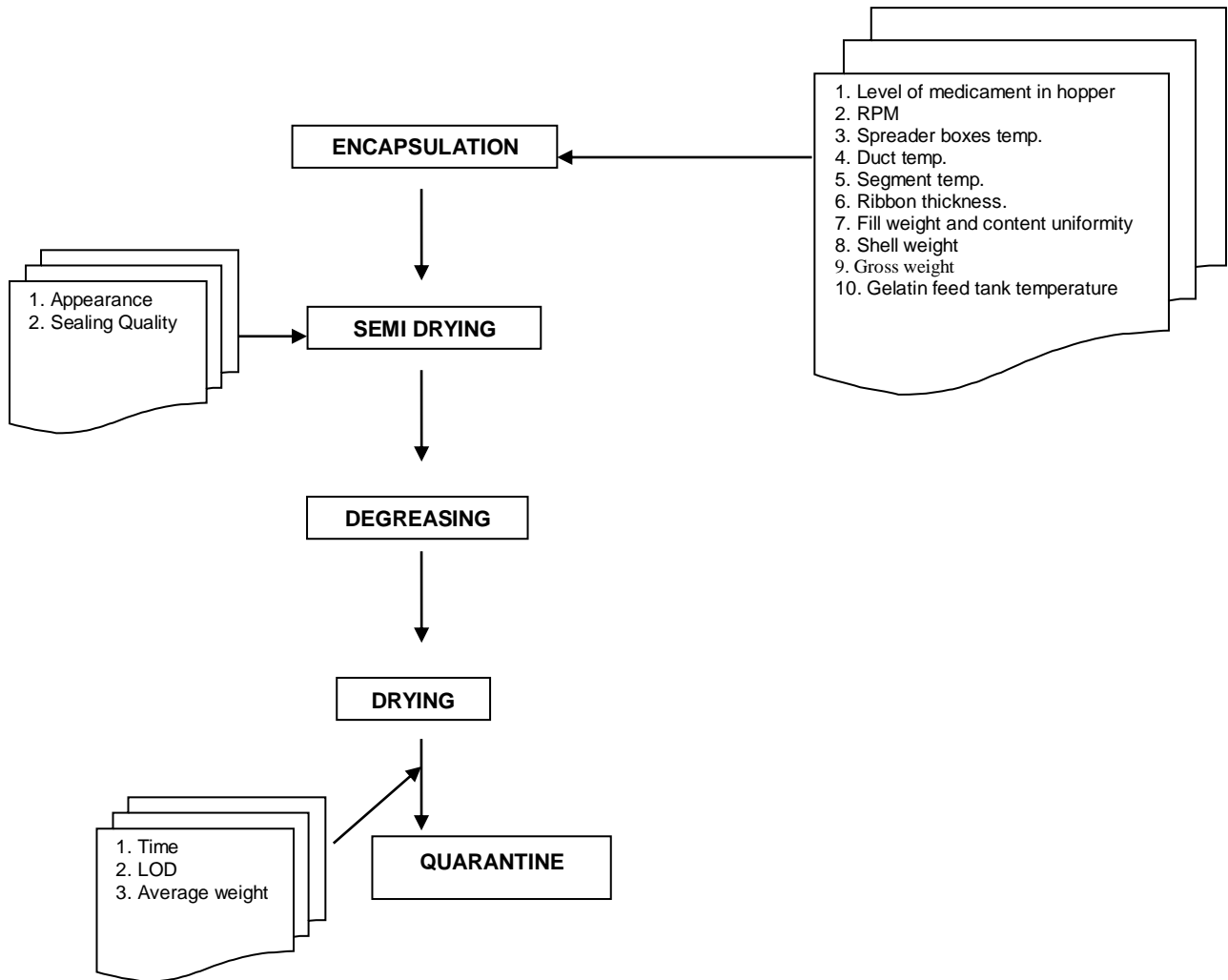
Inference:

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5.5 PROCESS FLOW DIAGRAM WITH QUALIFICATION PARAMETERS OF SOFT GELATIN ENCAPSULATION MACHINE (CAP-X-8):

Process flow diagram of Soft Gelatin Encapsulation Machine is mentioned below:





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5.6 SAMPLING PLAN:

Parameter	Stage/ Time of Sampling	Sample Quantity	Test Required	Responsibility
Speed	Minimum	100 Caps.	Appearance, Gross wt.,	IPQA
	Maximum	100 Caps.	Gelatin Shell Weight, Average Fill Weight, Ribbon Thickness	
Optimum Speed	Full Hopper	100 Caps.	Appearance, Gross wt.,	IPQA
	Half Hopper	100 Caps.	Gelatin Shell Weight,	
	End Hopper	100 Caps.	Average Fill Weight, Ribbon Thickness	
Optimum Speed	At initial stage	100 Caps.	Appearance, Gross wt.,	IPQA
	At middle stage	100 Caps.	Gelatin Shell Weight,	
	At end stage	100 Caps.	Average Fill Weight, Ribbon Thickness	
	At Regular interval (every 2 hours)	20 Caps.	Appearance, Gross wt., Gelatin Shell Weight, Average Fill Weight, Ribbon Thickness	IPQA
Tumbling of Capsules	After 30 minutes	20 Caps.	Physical Appearance, Sealing of Capsules	IPQA
	After 60 minutes	20 Caps.		
	After 90 minutes	20 Caps.		
	After 120 minutes	20 Caps.		
Drying	As per BMR	20 Caps.	LOD	IPQA & Q. C.
		20 Caps.		



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5.7 SET PARAMETERS:

Die Roll No.: _____

S.No.	Parameters	Limits
1.	Description	Orange Opaque coloured, Oblong shaped soft gelatin capsules containing oily paste.
2.	Ribbon thickness	0.75± 0.05mm (0.70 mm to 0.80 mm)
3.	Gelatin Shell Weight	300 mg ± 30 mg (270 – 330 mg)
4.	Weight Variation of Net Content (Individual fill weight)	800 mg ± 5.0 % (760 to 840 mg)
5.	Gross weight of the Capsule (Individual)	1100± 7.5%mg (1017.5 to 1182.5 mg)
6.	Room Temperature	18 ± 3°C
7.	Segment Temperature	40 ± 5°C
8.	Spreader Box Temperature	55 ± 5°C
9.	Cooling Drum Temperature	10 ± 3°C
10.	Relative Humidity (%)	35 ± 5 %

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PROTOCOL No.:

Die Roll No.: _____

S.No.	Parameters	Limits
1.	Description	Orange Opaque coloured Oblong shaped soft gelatin capsules containing oily paste.
2.	Ribbon thickness	0.85 ± 0.05 mm (0.80 mm to 0.90 mm)
3.	Gelatin Shell Weight	$620 \text{ mg} \pm 40 \text{ mg}$ (580 mg to 660 mg)
4.	Weight Variation of Net Content (Individual fill weight)	$1170 \text{ mg} \pm 5.0\%$ (1111.5 – 1228.5 mg)
5.	Gross weight of the Capsule (Individual)	$1790 \text{ mg} \pm 7.5\%$ (1655.75 to 1924.25mg)
6.	Room Temperature	$18 \pm 3^\circ\text{C}$
7.	Segment Temperature	$40 \pm 5^\circ\text{C}$
8.	Spreader Box Temperature	$55 \pm 5^\circ\text{C}$
9.	Cooling drum Temperature	$10 \pm 3^\circ\text{C}$
10.	Relative Humidity (%)	$35 \pm 5^\circ\text{C}$

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5.8 ACCEPTANCE CRITERIA:

The test will be considered failed if the actual test results do not correspond to the expected results as following:

- Description should be match with the specification.
- Ribbon thickness should be within the specified limit as mentioned in respective Die Roll Set Parameter.
- Gelatin Shell Weight should be within the specified limit as mentioned in respective Die Roll Set Parameter.
- Individual fill Weight should be within the specified limit as mentioned in respective Die Roll Set Parameter.
- Gross weight of the Capsule should be within the specified limit as mentioned in respective Die Roll Set Parameter.
- Segment Temperature should be $40 \pm 5^{\circ}\text{C}$.
- Spreader Box Temperature should be $55 \pm 5^{\circ}\text{C}$.
- Cooling drum Temperature should be $10 \pm 3^{\circ}\text{C}$.

5.9 RECORDING OF SAMPLING:

S.No.	Date	Batch No.	Die No.	Stage Details	Quantity	Sampled By (Sign. & Date)

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5.10 OBSERVATIONS AND RESULTS OF CHALLENGE TESTS:

Observations and results of challenge tests of **minimum and maximum batch size** are as follows:

OBSERVATION											
Batch Number:				Die Roll Change Part No.:							
Stage of Sampling:				Minimum Speed: _____ RPM							
TESTS						RESULTS					
Appearance											
Spreader Box temperature (°C)				Left:				Right:			
Ribbon Thickness (From ribbon continuously formed) (mm)				Left:				Right:			
Cooling Drum temperature (°C)											
Gelatin Holding Tank temperature (°C)											
Segment temperature (°C)											
Average Gross Weight Capsules (mg)											
Individual Weights of 10 Capsules (mg)										Avg. Net weight	
Gross Wt.											Avg. Net weight
Shell Wt.											
Net Wt.											

Done By: _____

Date: _____

Inference:

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PROTOCOL No.:

OBSERVATION													
Batch Number:						Die Roll Change Part No.:							
Stage of Sampling:						Maximum Speed _____ RPM							
TESTS						RESULTS							
Appearance													
Spreader Box temperature (°C)						Left:				Right:			
Ribbon Thickness (From ribbon continuously formed) (mm)						Left:				Right:			
Cooling Drum temperature (°C)													
Gelatin Feed Tank temperature (°C)													
Segment temperature (°C)													
Average Gross Weight Capsules (mg)													
Individual Weights of 10 Capsules (mg)											Avg. Net weight		
Gross Wt.													
Shell Wt.													
Net Wt.													

Done By: _____

Date: _____

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PROTOCOL No.:

OBSERVATION											
Speed of Encapsulation Machine				Optimum Speed: _____ RPM							
Batch Number:				Die Roll Change Part No.:							
Stage of Sampling:				Full Hopper							
TESTS				RESULTS							
Appearance											
Spreader Box temperature (°C)				Left:			Right:				
Ribbon Thickness (From ribbon continuously formed) (mm)				Left:			Right:				
Cooling Drum temperature (°C)											
Gelatin Holding Tank temperature (°C)											
Segment temperature (°C)											
Average Gross Weight Capsules (mg)											
Individual Weights of 10 Capsules (mg)										Avg. Net weight	
Gross Wt.											
Shell Wt.											
Net Wt.											

Done By: _____

Date: _____

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PROTOCOL No.:

OBSERVATION											
Speed of Encapsulation Machine				Optimum Speed: _____ RPM							
Batch Number:				Die Roll Change Part No.:							
Stage of Sampling:				Half Hopper							
TESTS						RESULTS					
Appearance											
Spreader Box temperature (°C)				Left:				Right:			
Ribbon Thickness (From ribbon continuously formed) (mm)				Left:				Right:			
Cooling Drum temperature (°C)											
Gelatin Holding Tank temperature (°C)											
Segment temperature (°C)											
Average Gross Weight Capsules (mg)											
Individual Weights of 10 Capsules (mg)										Avg. Net weight	
Gross Wt.											
Shell Wt.											
Net Wt.											

Done By: _____

Date: _____

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PROTOCOL No.:

OBSERVATION											
Speed of Encapsulation Machine				Optimum Speed: _____ RPM							
Batch Number:				Die Roll Change Part No.:							
Stage of Sampling:				End Hopper							
TESTS						RESULTS					
Appearance											
Spreader Box temperature (°C)				Left:				Right:			
Ribbon Thickness (From ribbon continuously formed) (mm)				Left:				Right:			
Cooling Drum temperature (°C)											
Gelatin Holding Tank temperature (°C)											
Segment temperature (°C)											
Average Gross Weight Capsules (mg)											
Individual Weights of 10 Capsules (mg)										Avg. Net weight	
Gross Wt.											
Shell Wt.											
Net Wt.											

Done By: _____

Date: _____

Inference:

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PROTOCOL No.:

OBSERVATION										
Speed of Encapsulation Machine				Optimum Speed: _____ RPM						
Batch Number:				Die Roll Change Part No.:						
Stage of Sampling:				Initial Stage						
TESTS				RESULTS						
Appearance										
Spreader Box temperature (°C)				Left:			Right:			
Ribbon Thickness (From ribbon continuously formed) (mm)				Left:			Right:			
Cooling Drum temperature (°C)										
Gelatin Holding Tank temperature (°C)										
Segment temperature (°C)										
Average Gross Weight Capsules (mg)										
Individual Weights of 10 Capsules (mg)										Avg. Net weight
Gross Wt.										
Shell Wt.										
Net Wt.										

Done By: _____

Date: _____

Inference:

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PROTOCOL No.:

OBSERVATION											
Speed of Encapsulation Machine						Optimum Speed: _____ RPM					
Batch Number:						Die Roll Change Part No.:					
Stage of Sampling:						Middle Stage					
TESTS						RESULTS					
Appearance											
Spreader Box temperature (°C)						Left:			Right:		
Ribbon Thickness (From ribbon continuously formed) (mm)						Left:			Right:		
Cooling Drum temperature (°C)											
Gelatin Holding Tank temperature (°C)											
Segment temperature (°C)											
Average Gross Weight Capsules (mg)											
Individual Weights of 10 Capsules (mg)											Avg. Net weight
Gross Wt.											
Shell Wt.											
Net Wt.											

Done By: _____

Date: _____

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OBSERVATION											
Speed of Encapsulation Machine				Optimum Speed: _____ RPM							
Batch Number:				Die Roll Change Part No.:							
Stage of Sampling:				End Stage							
TESTS						RESULTS					
Appearance											
Spreader Box temperature (°C)				Left:				Right:			
Ribbon Thickness (From ribbon continuously formed) (mm)				Left:				Right:			
Cooling Drum temperature (°C)											
Gelatin Holding Tank temperature (°C)											
Segment temperature (°C)											
Average Gross Weight Capsules (mg)											
Individual Weights of 10 Capsules (mg)										Avg. Net weight	
Gross Wt.											
Shell Wt.											
Net Wt.											

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OBSERVATION											
Batch Number:				Die Roll Change Part No.:							
Stage of Sampling:				Minimum Speed _____ RPM							
TESTS				RESULTS							
Appearance											
Spreader Box temperature (°C)				Left:				Right:			
Ribbon Thickness (From ribbon continuously formed) (mm)				Left:				Right:			
Cooling Drum temperature (°C)											
Gelatin Holding Tank temperature (°C)											
Segment temperature (°C)											
Average Gross Weight Capsules (mg)											
Individual Weights of 10 Capsules (mg)										Avg. Net weight	
Gross Wt.											
Shell Wt.											
Net Wt.											

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Batch Number:				Die Roll Change Part No.:							
Stage of Sampling:				Maximum Speed _____ RPM							
TESTS				RESULTS							
Appearance											
Spreader Box temperature (°C)				Left:				Right:			
Ribbon Thickness (From ribbon continuously formed) (mm)				Left:				Right:			
Cooling Drum temperature (°C)											
Gelatin Holding Tank temperature (°C)											
Segment temperature (°C)											
Average Gross Weight Capsules (mg)											
Individual Weights of 10 Capsules (mg)										Avg. Net weight	
Gross Wt.											
Shell Wt.											
Net Wt.											

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OBSERVATION											
Speed of Encapsulation Machine				Optimum Speed: _____ RPM							
Batch Number:				Die Roll Change Part No.:							
Stage of Sampling:				Full Hopper							
TESTS				RESULTS							
Appearance											
Spreader Box temperature (°C)				Left:			Right:				
Ribbon Thickness (From ribbon continuously formed) (mm)				Left:			Right:				
Cooling Drum temperature (°C)											
Gelatin Holding Tank temperature (°C)											
Segment temperature (°C)											
Average Gross Weight Capsules (mg)											
Individual Weights of 10 Capsules (mg)										Avg. Net weight	
Gross Wt.											
Shell Wt.											
Net Wt.											

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Batch Number:				Die Roll Change Part No.:							
Stage of Sampling:				Half Hopper							
TESTS				RESULTS							
Appearance											
Spreader Box temperature (°C)				Left:				Right:			
Ribbon Thickness (From ribbon continuously formed) (mm)				Left:				Right:			
Cooling Drum temperature (°C)											
Gelatin Holding Tank temperature (°C)											
Segment temperature (°C)											
Average Gross Weight Capsules (mg)											
Individual Weights of 10 Capsules (mg)										Avg. Net weight	
Gross Wt.											
Shell Wt.											
Net Wt.											

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Speed of Encapsulation Machine				Optimum Speed: _____ RPM							
Batch Number:				Die Roll Change Part No.:							
Stage of Sampling:				End Hopper							
TESTS						RESULTS					
Appearance											
Spreader Box temperature (°C)				Left:				Right:			
Ribbon Thickness (From ribbon continuously formed) (mm)				Left:				Right:			
Cooling Drum temperature (°C)											
Gelatin Holding Tank temperature (°C)											
Segment temperature (°C)											
Average Gross Weight Capsules (mg)											
Individual Weights of 10 Capsules (mg)										Avg. Net weight	
Gross Wt.											
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Net Wt.											

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PROTOCOL No.:

OBSERVATION											
Speed of Encapsulation Machine				Optimum Speed: _____ RPM							
Batch Number:				Die Roll Change Part No.:							
Stage of Sampling:				Initial Stage							
TESTS				RESULTS							
Appearance											
Spreader Box temperature (°C)				Left:				Right:			
Ribbon Thickness (From ribbon continuously formed) (mm)				Left:				Right:			
Cooling Drum temperature (°C)											
Gelatin Holding Tank temperature (°C)											
Segment temperature (°C)											
Average Gross Weight Capsules (mg)											
Individual Weights of 10 Capsules (mg)										Avg. Net weight	
Gross Wt.											
Shell Wt.											
Net Wt.											

Done By: _____

Date: _____

Inference:

**Reviewed By
Sign & Date**



PHARMA DEVILS

**PERFORMANCE QUALIFICATION
FOR
SOFT GELATIN ENCAPSULATION MACHINE**

PROTOCOL No.:

OBSERVATION											
Speed of Encapsulation Machine				Optimum Speed: _____ RPM							
Batch Number:				Die Roll Change Part No.:							
Stage of Sampling:				Middle Stage							
TESTS						RESULTS					
Appearance											
Spreader Box temperature (°C)				Left:				Right:			
Ribbon Thickness (From ribbon continuously formed) (mm)				Left:				Right:			
Cooling Drum temperature (°C)											
Gelatin Holding Tank temperature (°C)											
Segment temperature (°C)											
Average Gross Weight Capsules (mg)											
Individual Weights of 10 Capsules (mg)										Avg. Net weight	
Gross Wt.											
Shell Wt.											
Net Wt.											

Done By: _____

Date: _____

Inference:

**Reviewed By
Sign & Date**



PHARMA DEVILS

**PERFORMANCE QUALIFICATION
FOR
SOFT GELATIN ENCAPSULATION MACHINE**

PROTOCOL No.:

OBSERVATION											
Speed of Encapsulation Machine				Optimum Speed: _____ RPM							
Batch Number:				Die Roll Change Part No.:							
Stage of Sampling:				End Stage							
TESTS						RESULTS					
Appearance											
Spreader Box temperature (°C)				Left:				Right:			
Ribbon Thickness (From ribbon continuously formed) (mm)				Left:				Right:			
Cooling Drum temperature (°C)											
Gelatin Holding Tank temperature (°C)											
Segment temperature (°C)											
Average Gross Weight Capsules (mg)											
Individual Weights of 10 Capsules (mg)											Avg. Net weight
Gross Wt.											
Shell Wt.											
Net Wt.											

Done By: _____

Date: _____

Inference:

**Reviewed By
Sign & Date**



PHARMA DEVILS

**PERFORMANCE QUALIFICATION
FOR
SOFT GELATIN ENCAPSULATION MACHINE**

PROTOCOL No.:

5.11 TUMBLING OF CAPSULES:

MINIMUM BATCH SIZE						
S.No.	Die No.	Sampling Time	Sample Quantity	Result		Done By
				Physical Appearance	Sealing of Capsules	

MAXIMUM BATCH SIZE						
S.No.	Die No.	Sampling Time	Sample Quantity	Result		Done By
				Physical Appearance	Sealing of Capsules	

Inference:

**Reviewed By
Sign & Date**



PHARMA DEVILS

**PERFORMANCE QUALIFICATION
FOR
SOFT GELATIN ENCAPSULATION MACHINE**

PROTOCOL No.:

5.12 DRYING OF CAPSULES:

MINIMUM BATCH SIZE				
S.No.	Sampling Time	Sample Quantity	Result	Compiled By

MAXIMUM BATCH SIZE				
S.No.	Sampling Time	Sample Quantity	Result	Compiled By

Inference:

**Reviewed By
Sign & Date**



PHARMA DEVILS

**PERFORMANCE QUALIFICATION
FOR
SOFT GELATIN ENCAPSULATION MACHINE**

PROTOCOL No.:

6.0 DEFICIENCY AND CORRECTIVE ACTION(S) REPORT(S)

Following deficiency was verified and corrective actions taken.

Description of deficiency:

Corrective action(s) taken :

**Deviation accepted by
(Sign/Date)**

**Deviation Approved by
Sign/Date)**



PHARMA DEVILS

**PERFORMANCE QUALIFICATION
FOR
SOFT GELATIN ENCAPSULATION MACHINE**

PROTOCOL No.:

7.0 PERFORMANCE QUALIFICATION FINAL REPORT:

7.1 SUMMARY:

7.2 CONCLUSION :

**Prepared By
Sign/Date**

**Checked By
Sign/Date**



PHARMA DEVILS

**PERFORMANCE QUALIFICATION
FOR
SOFT GELATIN ENCAPSULATION MACHINE**

PROTOCOL No.:

7.3 FINAL REPORT APPROVAL

The final report shall be signed after verifying that all the tests required in the qualification report of Soft Gelatin Encapsulation Machine are completed, reconciled and attached to the Qualification report or included in the qualification summary report and also verified that all amendments and discrepancies are documented, approved and attached to respective report (If applicable).

Signature in the block below indicate that all items in the qualification report of Soft Gelatin Encapsulation Machine have been reviewed and found to be acceptable and that all variations or discrepancies (if any) have been satisfactorily resolved.

FUNCTION	NAME	DESIGNATION	DEPARTMENT	SIGNATURE	DATE
REVIEWED BY			QUALITY ASSURANCE		
			PROJECTS / ENGINEERING		
			QUALITY CONTROL		
			PRODUCTION		
APPROVED BY			HEAD OPERATION		
			QUALITY ASSURANCE		