Performance Qualification Report of Soft Gelatin Encapsulation Machine (CAP-X-8)

Location	**Soft Gelatin Department**
Area	**Manufacturing Area**

INDEX

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1.0 REPORT 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 (CAP-X-8) has been reviewed and approved by the following persons:

FUNCTION	NAME	DEPARTMENT	SIGNATURE	DATE
PREPARED BY		**QUALITY ASSURANCE**		
REVIEWED BY		**PRODUCTION**		
REVIEWED BY		**QUALITY CONTROL**		
REVIEWED BY		**PROJECTS / ENGINEERING**		
APPROVED BY		**QUALITY ASSURANCE**		

2.0 OVERVIEW:

2.1 OBJECTIVE:

The objective of developing and executing this report is to check and document the performance of the Soft Gelatin Encapsulation Machine (CAP-X-8) in the established/ predetermined operating ranges.

2.2 PURPOSE:

The purpose of this report is to provide the documented evidence that the functions of the Soft Gelatin Encapsulation Machine (CAP-X-8) which affect the product quality, equipment integrity, and safety of operating and maintenance personnel is taken into consideration.

2.3 SCOPE:

The scope of this report shall define the test procedures, documentation and acceptance criteria to establish that the operational parameters of Soft Gelatin Encapsulation Machine (CAP-X-8) is as per the requirement.

2.4 RESPONSIBILITY:

The following shall be responsible:

Quality Assurance Officer/Executive – For preparation of report / execution.

Production Officer /Executive - For execution of report

Quality Control Officer /Executive - For execution of report

Engineering Officer/ Executive - For execution of report

Projects / Engineering Head – For review of report

Production Head – For review of report

Quality Control Head – For review of report

Quality Assurance Head – For adequacy and final approval

2.5 EXECUTION TEAM:

The satisfactory operation of the Soft Gelatin Encapsulation Machine (CAP-X-8) shall be verified by executing the performance qualification studies described in this report of the Soft Gelatin Encapsulation Machine (CAP-X-8). The successfully execution of the instructions mentioned in

the report of the Soft Gelatin Encapsulation Machine (CAP-X-8) documents that the Soft Gelatin Encapsulation Machine (CAP-X-8) is operational and is satisfactorily working.

Execution team is responsible for the execution of performance qualification of the Soft Gelatin Encapsulation Machine (CAP-X-8).

Execution Team comprises of:

NAME	DESIGNATION	DEPARTMENT	SIGNATURE	DATE
		PRODUCTION		
		ENGINEERING		
		QUALITY CONTROL		
		QUALITY ASSURANCE		

3.0 GENERAL CONSIDERATION/PREREQUISITE:

3.1 Approved Standard operating procedure of Soft Gelatin Encapsulation Machine.

3.2 The impact analysis of the equipments shall be recorded in the summary sheet.

3.3 The installation and operational qualification of Soft Gelatin Encapsulation Machine shall be successfully completed before the execution of the performance qualification.

3.4 All the deficiencies and discrepancies related to Soft Gelatin Encapsulation Machine which affects the product quality and corrective action taken shall be recorded in the appropriate section of the report.

3.5 After completion of PQ activities, equipment shall be cleaned as per respective cleaning SOP's and released for manufacturing.

3.6 All the critical parameters shall be challenged.

4.0 REVALIDATION CRITERIA:

The machine shall be requalifies if

- There are any major changes, which affect the performance of the equipment.
- After major breakdown maintenance is carried out.
- As per revalidation 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 13800 to 36000 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 capsules are placed on trays which are then stacked and transferred into the capsule Drying Room for further drying.

5.2 RISK ANALYSIS:

- 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.
- In the event of power failure the system is designed to unload the pressure.
- 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.
- Thermostats and temperature controllers are installed at each spreader box for temperature regulation and controlled by PLC.
- In case of breaking of ribbon the machine will stop and an alarm appeared on the PLC.
- Empty medicament tank shall be acknowledged by a message displayed on the PLC and by the glowing of tower lamp.
- Injection of the medicament in the shell in regulated by the six miniature dosing pump to avoid the weight variation and controlled by separate VFD.

S.No.	Risk identified	Control measures
1.	Power failure	The machine shall unload the pressure.
2.	In case of an emergency stop	The machine shall automatically lift up the segment system.
3.	Temperature fluctuation	Thermostats and temperature controllers are installed at each spreader box for temperature regulation
4.	Unavailability of ribbon	The machine will stop and an alarm appeared on the PLC
5.	Empty medicament tank	A message displayed on the PLC and by the glowing of tower lamp
6.	Weight variation	Dosing of medicament is regulated by the six miniature dosing pump to avoid the weight variation

EVALUATION AND CONCLUSION:

All the risks associated with Soft Gelatin Encapsulation Machine (CAP-X-8) have been evaluated and control/preventive measures have been taken.

5.3 METHODOLOGY:

Methodology of the encapsulation process is as follows:

- Maintain the encapsulation area temperature at 20°C ± 2°C and Humidity 50± 5 %.
- Check the all gaskets and Change Parts.
- PQ batches of minimum (20% of working capacity) and maximum (100% of working capacity) 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 tank temperature 60°C± 5°C, Spreader box temperature at 55°C ± 5°C, Segment temperature at 40°C ± 5°C and cool drum temperature at 10°C ± 3°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 degreasing pan.

5.3.1 QUALIFICATION/ VALIDATION SAMPLING PLAN:

Parameter	Stage/ Time of Sampling	Sample Quantity	Test Required	Responsibility
Speed	Minimum	100 Caps.	Appearance, Group wt., Gelatin Shell Weight, Average Fill Weight, Ribbon Thickness	IPQA
	Maximum	100 Caps.		
Optimum Speed	Full Hopper	100 Caps.	Appearance, Group wt., Gelatin Shell Weight, Average Fill Weight, Ribbon Thickness	IPQA
	Half Hopper	100 Caps.		
	End Hopper	100 Caps.		
Optimum Speed	At initial stage	100 Caps.	Appearance, Group wt., Gelatin Shell Weight, Average Fill Weight, Ribbon Thickness	IPQA
	At middle stage	100 Caps.		
	At end stage	100 Caps.		
	At Regular interval (every 2 hours)	20 Caps.	Appearance, Group 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.		

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 : _____

Inference:

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Sign & Date

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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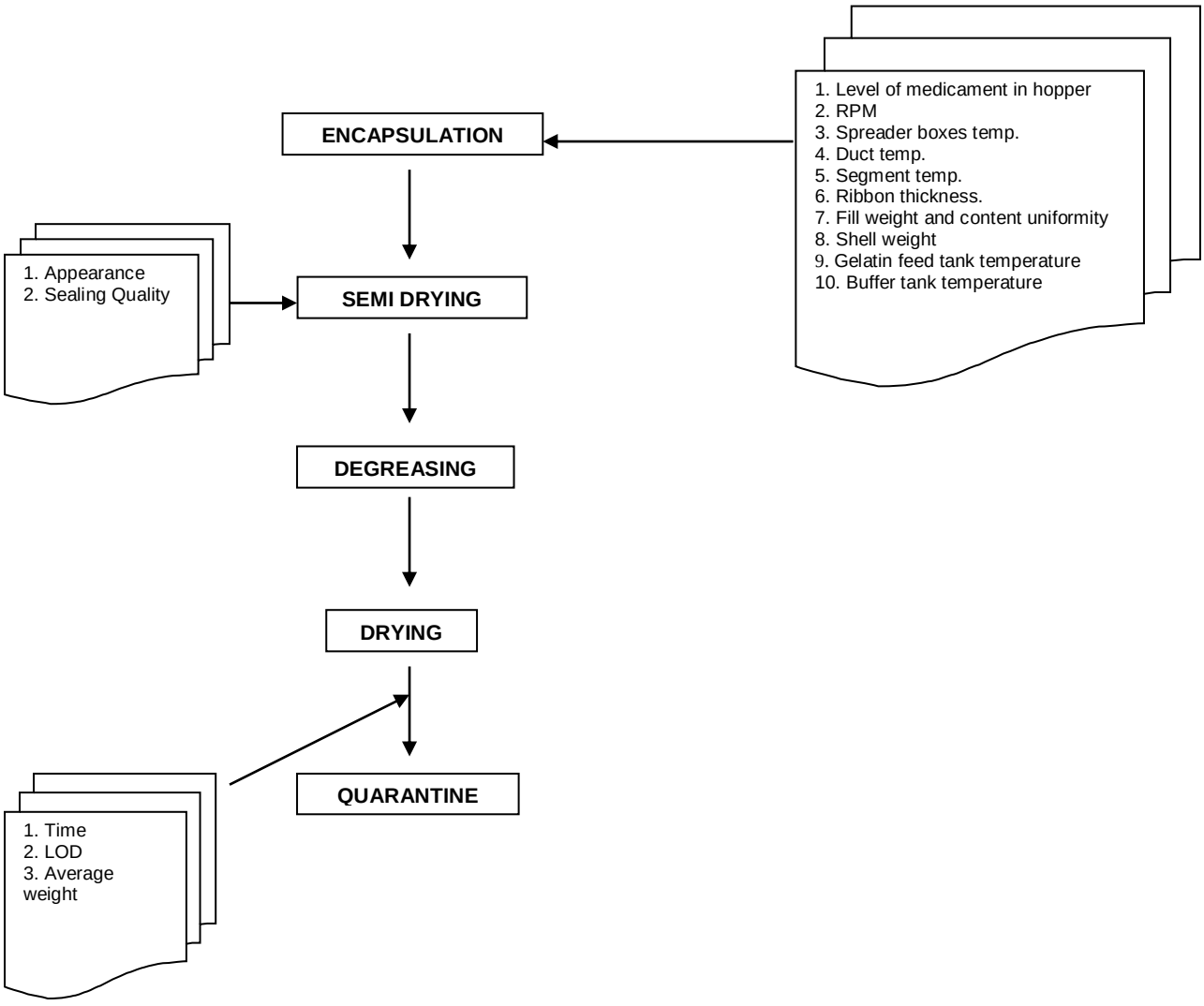
Sign & Date

5.5 Process Flow Diagram with Qualification Parameters of Soft Gelatin Encapsulation Machine (CAP-X-8):

Process flow diagram of Soft Gelatin Encapsulation Machine (CAP-X-8) is mentioned below:



5.6 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 ± 2.0 % (784 to 816 mg)
5.	Gross weight of the Capsule (Individual)	1100± 5%mg (1045 to 1155 mg)
6.	Room Temperature	20 ± 2°C
7.	Segment Temperature	40 ± 5°C
8.	Spreader Box Temperature	55 ± 5°C
9.	Cooling Drum Temperature	10 ± 3°C
10.	Relative Humidity (%)	50 ± 5 %
11.	Buffer Tank Temperature	60 ± 5°C

Inference:

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Sign & Date

PHARMA DEVILS	PERFORMANCE QUALIFICATION FOR SOFT GELATIN ENCAPSULATION MACHINE	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	670 mg ± 70 mg (600 mg to 740 mg)
4.	Weight Variation of Net Content (Individual fill weight)	1250 mg ± 3% (1212.5 – 1287.5 mg)
5.	Gross weight of the Capsule (Individual)	1920 mg ± 5.0% (1824 to 2016 mg)
6.	Room Temperature	20 ± 2°C
7.	Segment Temperature	40 ± 5°C
8.	Spreader Box Temperature	55 ± 5°C
9.	Cooling drum Temperature	10 ± 3°C
10.	Relative Humidity (%)	50 ± 5 %
11.	Buffer Tank Temperature	60 ± 5°C

Inference:

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Reviewed By
Sign & Date

PHARMA DEVILS	PERFORMANCE QUALIFICATION FOR SOFT GELATIN ENCAPSULATION MACHINE	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 mg ± 40 mg (580 mg to 660 mg)
4.	Weight Variation of Net Content (Individual fill weight)	1150 mg ± 3% (1115.5 – 1184.5 mg)
5.	Gross weight of the Capsule (Individual)	1770 mg ± 5.0% (1681.5 to 1858.5mg)
6.	Room Temperature	20 ± 2°C
7.	Segment Temperature	40 ± 5°C
8.	Spreader Box Temperature	55 ± 5°C
9.	Cooling drum Temperature	10 ± 3°C
10.	Relative Humidity (%)	50 ± 5 %
11.	Buffer Tank Temperature	60 ± 5°C

Inference:

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Reviewed By
Sign & Date

Die Roll No.: _____

S.No.	Parameters	Limits
1.	Description	Orange Opaque coloured oval shaped soft capsules containing oily paste.
2.	Ribbon thickness	0.90 ± 0.05 mm (0.85mm to 0.95 mm)
3.	Gelatin Shell Weight	600.0 mg ± 60 mg (540 mg to 660 mg)
4.	Weight Variation of Net Content (Individual fill weight)	1875 mg ± 3% (1818.75 – 1931.25 mg)
5.	Gross weight of the Capsule (Individual)	2475.0 mg ± 5.0% (2351.25 to 2598.75mg)
6.	Room Temperature	20 ± 2°C
7.	Segment Temperature	40 ± 5°C
8.	Spreader Box Temperature	55 ± 5°C
9.	Cooling drum Temperature	10 ± 3°C
10.	Relative Humidity (%)	50 ± 5 %
11.	Buffer Tank Temperature	60 ± 5°C

Inference:

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Reviewed By
Sign & Date

5.7 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 ± 5°C**.
- Spreader Box Temperature should be **55 ± 5°C**.
- Cooling drum Temperature should be **10 ± 3°C**.

5.8 RECORDING OF SAMPLING:

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

PHARMA DEVILS	PERFORMANCE QUALIFICATION FOR SOFT GELATIN ENCAPSULATION MACHINE	PROTOCOL No.:

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

Inference:

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Reviewed By
Sign & Date

5.9 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 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: _____**

Inference:

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Reviewed By
Sign & Date

PHARMA DEVILS	PERFORMANCE QUALIFICATION FOR SOFT GELATIN ENCAPSULATION MACHINE	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: _____**

Inference:

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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:	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 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: _____**

Inference:

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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:	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 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: _____**

Inference:

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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 Hopper	
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: _____**

Inference:

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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:	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 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: _____**

Inference:

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Reviewed By
Sign & Date

OBSERVATION

PHARMA DEVILS	PERFORMANCE QUALIFICATION FOR SOFT GELATIN ENCAPSULATION MACHINE	PROTOCOL No.:

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 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: _____**

Inference:

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Reviewed By
Sign & Date

OBSERVATION

PHARMA DEVILS	PERFORMANCE QUALIFICATION FOR SOFT GELATIN ENCAPSULATION MACHINE	PROTOCOL No.:

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 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: _____**

Inference:

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Reviewed By
Sign & Date

OBSERVATION

PHARMA DEVILS	PERFORMANCE QUALIFICATION FOR SOFT GELATIN ENCAPSULATION MACHINE	PROTOCOL No.:

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 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: _____**

Inference:

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Reviewed By
Sign & Date

OBSERVATION

PHARMA DEVILS	PERFORMANCE QUALIFICATION FOR SOFT GELATIN ENCAPSULATION MACHINE	PROTOCOL No.:

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: _____**

Inference:

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Reviewed By
Sign & Date

OBSERVATION

PHARMA DEVILS	PERFORMANCE QUALIFICATION FOR SOFT GELATIN ENCAPSULATION MACHINE	PROTOCOL No.:

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 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: _____**

Inference:

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Reviewed By
Sign & Date

OBSERVATION

PHARMA DEVILS	PERFORMANCE QUALIFICATION FOR SOFT GELATIN ENCAPSULATION MACHINE	PROTOCOL No.:

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 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: _____**

Inference:

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Reviewed By
Sign & Date

OBSERVATION

PHARMA DEVILS	PERFORMANCE QUALIFICATION FOR SOFT GELATIN ENCAPSULATION MACHINE	PROTOCOL No.:

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 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: _____**

Inference:

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Reviewed By
Sign & Date

OBSERVATION

PHARMA DEVILS	PERFORMANCE QUALIFICATION FOR SOFT GELATIN ENCAPSULATION MACHINE	PROTOCOL No.:

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 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: _____**

Inference:

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Reviewed By
Sign & Date

OBSERVATION

PHARMA DEVILS	PERFORMANCE QUALIFICATION FOR SOFT GELATIN ENCAPSULATION MACHINE	PROTOCOL No.:

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 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: _____**

Inference:

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Reviewed By
Sign & Date

OBSERVATION

PHARMA DEVILS	PERFORMANCE QUALIFICATION FOR SOFT GELATIN ENCAPSULATION MACHINE	PROTOCOL No.:

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 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: _____**

Inference:

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Reviewed By
Sign & Date

OBSERVATION

PHARMA DEVILS	PERFORMANCE QUALIFICATION FOR SOFT GELATIN ENCAPSULATION MACHINE	PROTOCOL No.:

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 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: _____**

Inference:

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Reviewed By
Sign & Date

OBSERVATION

PHARMA DEVILS	PERFORMANCE QUALIFICATION FOR SOFT GELATIN ENCAPSULATION MACHINE	PROTOCOL No.:

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: _____**

Inference:

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Reviewed By
Sign & Date

OBSERVATION

PHARMA DEVILS	PERFORMANCE QUALIFICATION FOR SOFT GELATIN ENCAPSULATION MACHINE	PROTOCOL No.:

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 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: _____**

Inference:

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Reviewed By
Sign & Date

OBSERVATION

PHARMA DEVILS	PERFORMANCE QUALIFICATION FOR SOFT GELATIN ENCAPSULATION MACHINE	PROTOCOL No.:

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 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: _____**

Inference:

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Reviewed By
Sign & Date

OBSERVATION

PHARMA DEVILS	PERFORMANCE QUALIFICATION FOR SOFT GELATIN ENCAPSULATION MACHINE	PROTOCOL No.:

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 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: _____**

Inference:

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Reviewed By
Sign & Date

OBSERVATION

PHARMA DEVILS	PERFORMANCE QUALIFICATION FOR SOFT GELATIN ENCAPSULATION MACHINE	PROTOCOL No.:

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 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: _____**

Inference:

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Reviewed By
Sign & Date

OBSERVATION

PHARMA DEVILS	PERFORMANCE QUALIFICATION FOR SOFT GELATIN ENCAPSULATION MACHINE	PROTOCOL No.:

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 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: _____**

Inference:

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Reviewed By
Sign & Date

OBSERVATION

PHARMA DEVILS	PERFORMANCE QUALIFICATION FOR SOFT GELATIN ENCAPSULATION MACHINE	PROTOCOL No.:

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 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: _____**

Inference:

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Reviewed By
Sign & Date

OBSERVATION

PHARMA DEVILS	PERFORMANCE QUALIFICATION FOR SOFT GELATIN ENCAPSULATION MACHINE	PROTOCOL No.:

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 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: _____**

Inference:

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Reviewed By
Sign & Date

OBSERVATION

PHARMA DEVILS	PERFORMANCE QUALIFICATION FOR SOFT GELATIN ENCAPSULATION MACHINE	PROTOCOL No.:

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: _____**

Inference:

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Reviewed By
Sign & Date

OBSERVATION

PHARMA DEVILS	PERFORMANCE QUALIFICATION FOR SOFT GELATIN ENCAPSULATION MACHINE	PROTOCOL No.:

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 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: _____**

Inference:

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Reviewed By
Sign & Date

OBSERVATION

PHARMA DEVILS	PERFORMANCE QUALIFICATION FOR SOFT GELATIN ENCAPSULATION MACHINE	PROTOCOL No.:

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 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: _____**

Inference:

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Reviewed By
Sign & Date

OBSERVATION

PHARMA DEVILS	PERFORMANCE QUALIFICATION FOR SOFT GELATIN ENCAPSULATION MACHINE	PROTOCOL No.:

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 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: _____**

Inference:

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Reviewed By
Sign & Date

OBSERVATION

PHARMA DEVILS	PERFORMANCE QUALIFICATION FOR SOFT GELATIN ENCAPSULATION MACHINE	PROTOCOL No.:

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 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: _____**

Inference:

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Reviewed By
Sign & Date

OBSERVATION

PHARMA DEVILS	PERFORMANCE QUALIFICATION FOR SOFT GELATIN ENCAPSULATION MACHINE	PROTOCOL No.:

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 (ºC)	Left:	Right:
Ribbon Thickness (From ribbon continuously formed) (mm)	Left:	Right:
Cooling Drum temperature (ºC)		
Gelatin Feed Tank temperature (°C)		
Segment temperature (ºC)		
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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Reviewed By
Sign & Date

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 (ºC)	Left:	Right:
Ribbon Thickness (From ribbon continuously formed) (mm)	Left:	Right:
Cooling Drum temperature (ºC)		
Gelatin Feed Tank temperature (°C)		
Segment temperature (ºC)		
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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Reviewed By
Sign & Date

5.10 TUMBLING OF CAPSULES:

PHARMA DEVILS	PERFORMANCE QUALIFICATION FOR SOFT GELATIN ENCAPSULATION MACHINE	PROTOCOL No.:

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:

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Reviewed By
Sign & Date

5.11 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:

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Reviewed By
Sign & Date

5.12 IN PROCESS CHECKS DURING ENCAPSULATION (AT OPTIMUM SPEED):

Batch No.: **Machine Speed: _____ RPM**

Date	Time	Change Part No.	Appearance	Gross weight (mg)	Gelatin Shell Weight (mg)	Avg. Weight (mg)	Ribbon Thickness (mm)

Inference:

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Reviewed By
Sign & Date

PHARMA DEVILS	PERFORMANCE QUALIFICATION FOR SOFT GELATIN ENCAPSULATION MACHINE	PROTOCOL No.:

Batch No.: **Machine Speed: _____ RPM**

Date	Time	Change Part No.	Appearance	Gross weight (mg)	Gelatin Shell Weight (mg)	Fill Weight (mg)	Ribbon Thickness (mm)

Inference:

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Reviewed By
Sign & Date

5.13 ENVIRONMENTAL MONITORING DURING CAPSULE DRYING:

Temperature : _____ ± ___℃ Relative Humidity : _____ ± ___ RH%

Date	Time	Batch Number	Temperature(°C)	Relative Humidity (%)	Remark

Inference:

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Reviewed By
Sign & Date

PHARMA DEVILS	PERFORMANCE QUALIFICATION FOR SOFT GELATIN ENCAPSULATION MACHINE	PROTOCOL No.:

Temperature : _____ ± ___℃ Relative Humidity : _____ ± ___ RH%

Date	Time	Batch Number	Temperature(°C)	Relative Humidity (%)	Remark

Inference:

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Reviewed By
Sign & Date

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

If any deficiency shall be identified record their detail in the report and their corrective actions taken in consultation with the validation team.

Description of deficiency:

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Corrective Action(s) taken:

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Reviewed By
Sign & Date

7.0 PERFORMATION QUALIFICATION FINAL REPORT:

7.1 SUMMARY

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7.2 CONCLUSION

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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 (CAP-X-8) 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 repot (If applicable).

Signature in the block below indicate that all items in the qualification report of Soft Gelatin Encapsulation Machine (CAP-X-8) have been reviewed and found to be acceptable and that all variations or discrepancies (if any) have been satisfactorily resolved.

NAME	DESIGNATION	DEPARTMENT	SIGNATURE	DATE
		PRODUCTION		
		QUALITY CONTROL		
		PROJECTS / ENGINEERING		
		QUALITY ASSURANCE		