

PROTOCOL No.:

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

Location	Soft Gelatin Department
Area	Manufacturing Area

INDEX



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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		

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PERFORMANCE QUALIFICATION FOR SOFT GELATIN ENCAPSULATION MACHINE

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

PHARMA DEVILS

PERFORMANCE QUALIFICATION FOR SOFT GELATIN ENCAPSULATION MACHINE

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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.



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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 $20^{\circ}\text{C} \pm 2^{\circ}\text{C}$ 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 $60^{\circ}\text{C} \pm 5^{\circ}\text{C}$, 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.



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 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.,	IPQA
	Maximum	100 Caps.	Gelatin Shell Weight, Average Fill Weight, Ribbon Thickness	
Optimum Speed	Full Hopper	100 Caps.	Appearance, Group 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, Group wt.,	IPQA
	At middle stage	100 Caps.	Gelatin Shell Weight,	
	At end stage	100 Caps.	Average Fill Weight,	
			Ribbon Thickness	
	At Regular interval	20 Caps.	Appearance, Group wt.,	IPQA
	(every 2 hours)		Gelatin Shell Weight,	
			Average Fill Weight,	
			Ribbon Thickness	
Tumbling of	After 30 minutes	20 Caps.		IPQA
Capsules	After 60 minutes	20 Caps.	Physical Appearance, Sealing	
	After 90 minutes	20 Caps.	of Capsules	
	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:



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5.4.1	Product Detail of Minimum	n Batch Size:
	Product Name :	
	Product Code :	
	Batch Number :	
	Batch Size	:
	Mfg. Date	:
	Exp. Date	:
	BMR Number	:
5.4.2	Product Detail of Maximus	m Batch Size:
	Product Name :	
	Product Code :	
	Batch Number :	
	Batch Size	:
	Mfg. Date	:
	Exp. Date	:
	BMR Number	:
Infere	nce:	
	wed By	
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)



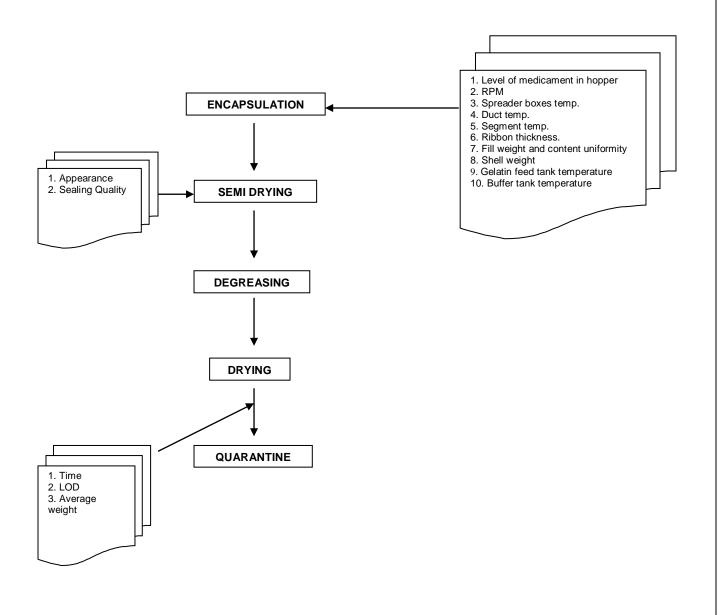
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Reviewed By Sign & Date

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:





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5.6 SET PARAMETERS	5.6	SET	PAR.	AME'	TERS
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Die Roll No.:	
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S.No.	Parameters	Limits
1.	Description	Orange Opaque coloured, Oblong shaped soft gelatin capsules containing oily paste.
2.	Ribbon thickness	0.75 ± 0.05 mm (0.70 mm to 0.80 mm)
3.	Gelatin Shell Weight	$300 \text{ mg} \pm 30 \text{ mg}$ (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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S.No.	Parameters	Limits
1.	Description	Orange Opaque coloured, Oblong shaped soft gelatin capsules containing oily paste.
2.	Ribbon thickness	$0.85 \pm 0.05 \text{ mm}$ (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)	$1250 \text{ mg} \pm 3\%$ (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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Die Roll No.:	

S.No.	Parameters	Limits
1.	Description	Orange Opaque coloured Oblong
		shaped soft gelatin capsules containing oily paste.
2.	Ribbon thickness	$0.85 \pm 0.05 \text{ mm}$ (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	$20 \pm 2^{\circ}\mathrm{C}$
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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Die Roll No.:	
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S.No.	Parameters	Limits				
1.	Description	Orange Opaque coloured oval shaped soft capsules				
		containing oily paste.				
2.	Ribbon thickness	$0.90 \pm 0.05 \text{ mm}$ (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	$60 \pm 5^{\circ} \text{C}$				

Interence:		

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.



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- ➤ 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 $40 \pm 5^{\circ}$ C.
- > Spreader Box Temperature should be $55 \pm 5^{\circ}$ C.
- \triangleright Cooling drum Temperature should be $10 \pm 3^{\circ}$ C.

5.8 RECORDING OF SAMPLING:

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



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

Inference:			
Reviewed By Sign & Date			



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5.9 **OBSERVATIONS AND RESULTS OF CHALLENGE TESTS:**

						OBSE	RVATI	ON				
Batch Nun	nber:				Di	Die Roll Change Part No.:						
Stage of Sa	ampling:				M	inimum	Speed:		RPI	M		
TESTS					RI	ESULT	S					
Appearanc	e											
Spreader B	ox temp	erature ((°C)		Left: Right:							
	Ribbon Thickness (From ribbon continuously formed) (mm)				Le	ft:				Right:		
Cooling Da	Cooling Drum temperature (°C)											
Gelatin Feed Tank temperature (°C)												
Segment temperature (°C)												
Average Gross Weight Capsules (mg)				ıg)								
		Ir	ndividua	l We	eights of 10 Capsules (mg)						Avg. Net weight	
Gross Wt.												
Shell Wt.												
Net Wt.												
Done By:										D	ate:	
Inference:												
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OBSERVATION												
Batch Numb	er:				Die Roll Change Part No.:							
Stage of San	npling:				Ma	aximum	Speed		RPN	Л		
TESTS					RF	ESULT	S					
Appearance												
Spreader Box temperature (°C)					Let	ft:				Right:		
Ribbon Thickness (From ribbon continuously formed) (mm)				Let	ft:				Right:			
Cooling Drum temperature (°C)												
Gelatin Feed Tank temperature (°C)												
Segment temperature (°C)												
Average Gross Weight Capsules (mg))								
		Ind	ividual V	Veig	ights of 10 Capsules (mg)				Avg. Net weight			
Gross Wt.												
Shell Wt.												
Net Wt.												
Done By:									D	ate:		
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						OBSE	RVAT	ION				
Speed of Enc	capsula	tion Ma	chine		0	ptimum	Speed:			_ RPM		
Batch Number	er:				Die Roll Change Part No.:							
Stage of Sam	npling:				Full Hopper							
TESTS					R	ESULT	S					
Appearance												
Spreader Box temperature (°C)					L	eft:				Right	:	
Ribbon Thickness (From ribbon continuously formed) (mm)				Left: Right:								
Cooling Drum temperature (°C)												
Gelatin Feed	Tank t	emperat	ture (°C)									
Segment tem	peratui	e (°C)										
Average Gro	ss Wei	ght Cap	sules (mg	<u>(</u>)								
		In	dividual \	Wei	ights of 10 Capsules (mg)						Avg. Net weight	
Gross Wt.												
Shell Wt.												
Net Wt.												
Done By:											Date: _	
Inference:												
Reviewed By Sign & Date										_		



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						OBSEI	RVATI	ON				
Speed of E	Encapsula	ation Ma	chine		О	ptimum	Speed:			RPM		
Batch Num	nber:				D	ie Roll C	Change I	Part No	.:			
Stage of Sa	ampling:				Н	alf Hopp	er					
TESTS					R	ESULT	S					
Appearanc	e											
Spreader Box temperature (°C)						eft:				Right:		
Ribbon Thickness (From ribbon continuously formed) (mm)					L	eft:				Right:		
Cooling Drum temperature (°C)												
Gelatin Fee	ed Tank	tempera	ture (°C)									
Segment temperature (°C)												
Average G	ross We	ight Cap	sules (mg	()								
	_	In	dividual V	Wei	ights of 10 Capsules (mg)							Avg. Net weight
Gross Wt.												
Shell Wt.												
Net Wt.												
Done By:										J	Date:	
Inference:												
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PR	OT	$\cap C$	n	N	· n

						OBSEI	RVAT	ION						
Speed of Encapsulation Machine Optimum S										_ RPM				
Batch Nur	mber:				D	Die Roll Change Part No.:								
Stage of S	ampling	:			E	End Hopper								
TESTS					R	RESULTS								
Appearance	се													
Spreader Box temperature (°C)						eft:				Right:				
Ribbon Thickness (From ribbon continuously formed) (mm)					L	eft:				Right:				
Cooling D	Cooling Drum temperature (°C)													
Gelatin Feed Tank temperature (°C)														
Segment temperature (°C)														
Average C	Gross We	ight Ca	psules (n	ng)										
		I	Individua	l We	eights of 10 Capsules (mg)					Avg. Net weight				
Gross Wt.														
Shell Wt.														
Net Wt.														
Done By: Inference:										Da	te:			
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						OBSEI	RVATIO	ON				
Speed of E	ncapsula	tion Ma	chine		O	ptimum	Speed: _			_ RPM		
Batch Num	ıber:				Die Roll Change Part No.:							
Stage of Sa	ımpling:				Initial Stage							
TESTS					R	ESULT	S					
Appearance												
Spreader Box temperature (°C)					L	eft:				Right:		
Ribbon Thickness (From ribbon continuously formed) (mm)					L	eft:				Right:		
Cooling Drum temperature (°C)												
Gelatin Feed Tank temperature (°C)												
Segment te	mperatu	re (°C)										
Average G	ross Wei	ight Cap	sules (n	ng)								
		In	dividual	Wei	ights of 10 Capsules (mg)							Avg. Net weight
Gross Wt.												
Shell Wt.												
Net Wt.												
Done By: _ Inference:										D	ate:	
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Speed of Encapsulation Machine					Optimum Speed: RPM								
Batch Nur	mber:				Die Roll Change Part No.:								
Stage of S	ampling	; :			Middle Stage								
TESTS					RESULTS								
Appearance	ce												
	D 4		(00)		T C								
Spreader Box temperature (°C) Ribbon Thickness (From ribbon					Left:				Right:				
Ribbon Thickness (From ribbon continuously formed) (mm)					Left:				Right:				
Cooling Drum temperature (°C)													
Gelatin Feed Tank temperature (°C)													
Segment t	Segment temperature (°C)												
Average C	Gross We	eight Ca	psules (1	ng)									
		I	ndividua	al We	eights of 10 Capsules (mg)						Avg. Net weight		
Gross Wt.													
Shell Wt.													
Net Wt.													
Done by:									I	Date:			
Inference:													
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Speed of Encapsulation Machine		Optimum Speed:RPM								
Batch Number:		Die Roll (Change	Part No.	:					
Stage of Sampling:		End Stage								
TESTS		RESULTS								
Appearance										
						1				
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 (m	ng)									
Individual	Weig	ights of 10 Capsules (mg)						Avg. Net weight		
Gross Wt.										
Shell Wt.										
Net Wt.										
Done By:						D	ate:			
Inference:										
Reviewed By						_				



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Batch Num	Batch Number:						Die Roll Change Part No.:						
Stage of Sa	mpling:				Minin	num	Speed _		_ RPN	1			
TESTS					RESULTS								
Appearance	2												
Spreader Bo	ov tomr	oroturo ((°C)		Left: Right:								
Ribbon Thi	•				Left: Right:								
continuousl		•			Left: Right:								
Cooling Dr	um tem	perature	(°C)										
Gelatin Fee	Gelatin Feed Tank temperature (°C)												
Segment ter													
Average Gr	oss We	ight Cap	sules (m	ng)									
		Ir	ndividua	l Wei	TODIS OF TO CAUSINGS THIS						Avg. Net weight		
Gross Wt.													
Shell Wt.													
Net Wt.													
Done By: _]	Date:		
Inference:													
										_			
	Reviewed By Sign & Date												
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Batch Number:		Die Roll Change Part No.:							
Stage of Sampling:		Maximu	Maximum Speed RPM						
TESTS		RESUL	ΓS						
Appearance									
Spreader Box temperature (°C)		Left:				Right:			
Ribbon Thickness (From ribbon continuously formed) (mm)	continuously formed) (mm)					Right:			
Cooling Drum temperature (°C)									
Gelatin Feed Tank temperature	(°C)								
Segment temperature (°C)									
Average Gross Weight Capsules	(mg)								
Individ	lual We	eights of 10 Capsules (mg)						Avg. Net weight	
Gross Wt.									
Shell Wt.									
Net Wt.									
Done By:	_					D	ate:		
Inference:									
Reviewed By Sign & Date						_			



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Speed of Encap	sulation Machine		Optimum	Speed:			_ RPM			
Batch Number:			Die Roll	Die Roll Change Part No.:						
Stage of Sampl	ing:		Full Hopper							
TESTS			RESULT	RESULTS						
Appearance										
•	emperature (°C)		Left: Right:							
	Ribbon Thickness (From ribbon continuously formed) (mm)						Right:			
Cooling Drum										
Gelatin Feed Ta	C)									
Segment tempe										
Average Gross	Weight Capsules (mg)								
	Individu	al Wei	ights of 10 Capsules (mg)						Avg. Net weight	
Gross Wt.										
Shell Wt.										
Net Wt.										
Done By:							D	ate:		
Inference:										
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Speed of l	Speed of Encapsulation Machine					Optimum Speed: RPM							
Batch Nu	mber:				Die Roll Change Part No.:								
Stage of S	Sampling	•			Half Hopper								
TESTS					RESULTS								
Appearan	ce												
Spreader 1	Box temp	perature	(°C)		Left: Right:								
	Ribbon Thickness (From ribbon continuously formed) (mm)				Left:					Rig	ght:		
Cooling D	Cooling Drum temperature (°C)												
Gelatin Fe	Gelatin Feed Tank temperature (°C)												
Segment temperature (°C)													
Average (Gross We	eight Ca _l	psules (n	ng)									
]	Individua	ıl We	eights of 10 Capsules (mg)						Avg. Net weight		
Gross Wt.													
Shell Wt.													
Net Wt.													
Done By:											Da	te:	
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Speed of I	Speed of Encapsulation Machine					Optimum Speed: RPM					
Batch Nui	mber:				Die Roll	Change	Part No.	:			
Stage of S	ampling	:			End Hopper						
TESTS					RESUL	RESULTS					
Appearance	ce										
Spreader 1	Box temp	perature	(°C)		Left: Right:						
	Ribbon Thickness (From ribbon continuously formed) (mm)				Left:				Right:		
	Cooling Drum temperature (°C)										
Gelatin Fe	Gelatin Feed Tank temperature (°C)										
Segment t	Segment temperature (°C)										
Average (Gross We	eight Ca	psules (mg)							
		I	ndividu	al We	ights of 10 Capsules (mg)						Avg. Net weight
Gross Wt.											
Shell Wt.											
Net Wt.											
Done By:									D	ate:	
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Speed of E	Encapsul	ation Ma	achine		Optimum Speed: RPM						
Batch Nun	nber:				Die Roll Change Part No.:						
Stage of Sa	ampling	:			Initial Stage						
TESTS					RESULTS						
Appearance	e										
Spreader E	Box tem	perature ((°C)		Left: Right:						
Ribbon Th	Ribbon Thickness (From ribbon continuously formed) (mm)				Left:				Right:		
Cooling D	Cooling Drum temperature (°C)										
Gelatin Fe	Gelatin Feed Tank temperature (°C)										
Segment temperature (°C)											
Average G	iross We	eight Cap	sules (mg	g)							
		I	ndividual	Weiş	eights of 10 Capsules (mg)						Avg. Net weight
Gross Wt.											
Shell Wt.											
Net Wt.											
Done By:									Da	ate:	
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Speed of Encapsulation Machine			Optimum Speed: RPM										
Batch Nun	nber:				Die Rol	l Change	Part No	.:					
Stage of Sa	ampling	:			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 to	emperat	ure (°C)											
Average G	iross We	eight Ca _l	psules (1	ng)									
		I	ndividua	al We	eights of 10 Capsules (mg) Avg. Net weight								
Gross Wt.													
Shell Wt.													
Net Wt.													
Done by:					Date:								
Inference:													
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Speed of Encapsulation Machine	Optimum	Optimum Speed: RPM								
Batch Number:		Die Roll	Change 1	Part No	.:					
Stage of Sampling:		End Stage								
TESTS		RESULT	RESULTS							
Appearance										
						1				
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)									
Individu	al We							Avg. Net weight		
Gross Wt.										
Shell Wt.										
Net Wt.										
Done By:						D	ate:			
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Batch Number:			Die	Die Roll Change Part No.:										
Stage of Sa	ampling	:			Mi	Minimum Speed RPM								
TESTS					RF	RESULTS								
Appearance	ce													
Spreader E	Box temp	perature	(°C)		Le	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)														
		I	ndividua	al We	eights of 10 Capsules (mg)								Avg. Net weight	
Gross Wt.														
Shell Wt.														
Net Wt.														
Done By:											Date:			
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Batch Number:				Die Roll Change Part No.:									
Stage of Sar	mpling	:			Maxim	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 Gr	oss We	eight Ca _l	psules (1	mg)									
		I	ndividu	al We	eights of 10 Capsules (mg)						Avg. Net weight		
Gross Wt.													
Shell Wt.													
Net Wt.													
Done By: _					Date:								
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Speed of Enca	Opti	Optimum Speed: RPM									
Batch Number	:		Die	Roll (Change	Part No.	.:				
Stage of Samp	ling:		Full	Full Hopper							
TESTS			RES	RESULTS							
Appearance											
Spreader Box	emperature (°C)	Left	:				Right:			
Ribbon Thickr continuously f	Left	:				Right:					
Cooling Drum											
Gelatin Feed T											
Segment temp											
Average Gross	Weight Cap	sules (mg)									
	In	dividual W	eights o							Avg. Net weight	
Gross Wt.											
Shell Wt.											
Net Wt.											
Done By:			Date:								
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Speed of Encapsulation Machine			Optimum Speed: RPM								
Batch Numb	er:			Die Roll Change Part No.:							
Stage of San	npling:			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 Gro	oss Weight Ca	psules (n	ng)								
]	Individua	l Wei	ights of 10	Capsule	s (mg)				Avg. Net weight	
Gross Wt.											
Shell Wt.											
Net Wt.											
Done By: Inference:								D	ate:		
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Speed of Encapsulation Machine			Optii	mum	Speed:			R	PM				
Batch Nur	nber:				Die F	Roll C	Change	Part No.	:				
Stage of S	ampling	:			End 1	End Hopper							
TESTS					RES	ULT	S						
Appearance	ce												
										1			
Spreader Box temperature (°C)			Left:					Ri	ght:				
Ribbon Thickness (From ribbon continuously formed) (mm)			Left:					Ri	ght:				
Cooling Drum temperature (°C)													
Gelatin Fe	ed Tank	tempera	iture (°C	5)									
Segment to	emperat	ure (°C)											
Average C	Gross We	eight Cap	osules (n	ng)									
		I	Índividua	al We	eights o	of 10	Capsul	es (mg)					Avg. Net weight
Gross Wt.													
Shell Wt.													
Net Wt.													
Done By:											Da	te:	
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Speed of Encapsulation Machine			Optimum Speed: RPM									
Batch Nur	nber:				Die F	Roll (Change	Part No	.:			
Stage of S	ampling	:			Initial Stage							
TESTS					RES	ULT	S					
Appearance	ce											
Spreader I	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 C	Gross We	eight Ca _l	psules (r	ng)								
		I	ndividua	al We	ights o	of 10	Capsul	es (mg)				Avg. Net weight
Gross Wt.												
Shell Wt.												
Net Wt.												
Done By:										D	ate:	
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Speed of Er	ncapsulation Ma	chine	Optimum	Optimum Speed: RPM						
Batch Num	ber:		Die Roll	Change l	Part No.:					
Stage of Sar	mpling:		Middle S	Middle Stage						
TESTS			RESULT	ΓS						
Appearance	2									
Spreader Bo	ox temperature (°C)	Left:		Right:					
Ribbon Thickness (From ribbon continuously formed) (mm)			Left:				Right:			
Cooling Drum temperature (°C)										
Gelatin Fee	ed Tank temperat	ture (°C)								
Segment ter	mperature (°C)									
Average Gr	coss Weight Cap	sules (mg)								
	In	dividual We	eights of 10	Capsule	s (mg)			Avg. Net weight		
Gross Wt.										
Shell Wt.										
Net Wt.										
Done by: _							Date	:		
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Speed of Encapsulation Machine					Optimum Speed: RPM							
Batch Num	nber:				Die Ro	oll Chan	ge Part N	o.:				
Stage of Sa	ampling	:			End Stage							
TESTS					RESU	RESULTS						
Appearance	e											
Spreader B	ox temp	perature	(°C)		Left: Right:							
Ribbon Thickness (From ribbon continuously formed) (mm)				Left:				Right:				
Cooling Drum temperature (°C)												
Gelatin Fee	ed Tank	tempera	ature (°C)								
Segment temperature (°C)												
Average G	ross We	eight Ca _l	psules (m	ıg)								
		I	ndividua	l We	ights of	10 Caps	sules (mg))		_	Avg. Net weight	
Gross Wt.												
Shell Wt.												
Net Wt.												
Done By:									D	ate:		
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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 We	ights of 10 Capsules (mg)	Avg. Net weight						
Gross Wt.								
Shell Wt.								
Net Wt.								
Done By:	Date:							
Inference:								
Reviewed By Sign & Date								



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Batch Num	Batch Number:						Die Roll Change Part No.:							
Stage of Sa	mpling	:			Ma	aximum	Speed _		_ RPM	[
TESTS					RF	ESULT	S							
Appearance	e													
Spreader B		•			Left: Right:									
Ribbon Thi continuous					Left: Right:									
Cooling Dr														
Gelatin Fee	ed Tank	tempera	ature (°C)										
Segment te	mperat	ure (°C)												
Average G	ross We	eight Cap	psules (n	ng)										
		I	ndividua	ıl We	eight	s of 10	Capsule	s (mg)				Avg. Net weight		
Gross Wt.														
Shell Wt.														
Net Wt.														
Done By:										Da	ate:			
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Speed of E	Speed of Encapsulation Machine					Optimum Speed:RPM						
Batch Nun	nber:				Die Roll	Change	Part No	.:				
Stage of S	ampling	:			Full Hop	per						
TESTS					RESULTS							
Appearance	ce											
Spreader F	Box temp	perature	(°C)		Left: Right:							
	Ribbon Thickness (From ribbon continuously formed) (mm)					Left: Right:						
Cooling Drum temperature (°C)												
Gelatin Fe	ed Tank	tempera	ature (°C)									
Segment to	emperati	ure (°C)										
Average G	Gross We	eight Ca _l	psules (mg	g)								
		I	ndividual	Wei	ights of 10 Capsules (mg)						Avg. Net weight	
Gross Wt.												
Shell Wt.												
Net Wt.												
Done By:									Da	te:		
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Speed of E	Speed of Encapsulation Machine					Optimum Speed: RPM					
Batch Nur	nber:				Die Rol	1 Change	e Part No	.:			
Stage of S	ampling	:			Half Ho	pper					
TESTS					RESUI	LTS					
Appearance	ce										
Spreader I	•				Left:				Right:		
Ribbon Th					Left: Right:						
Cooling D	rum tem	perature	e(°C)								
Gelatin Fe	ed Tank	tempera	iture (°C	<u>'</u>)							
Segment to	emperati	ure (°C)									
Average C	Gross We	eight Ca _l	osules (r	ng)							
		I	ndividua	al We	ights of 1	0 Capsu	iles (mg)				Avg. Net weight
Gross Wt.											
Shell Wt.											
Net Wt.											
Done By:									Da	ıte:	
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Speed of E	Encapsul	ation Ma	achine		Optimum Speed: RPM						
Batch Nun					Die Roll						
Stage of Sa	ampling	:			End Hop	per					
TESTS					RESULT	ΓS					
Appearance	ee										
Spreader E	Box temp	perature	(°C)		Left:				Right:		
Ribbon Th		`			Left: Right:						
Cooling Drum temperature (°C)											
Gelatin Fe	ed Tank	tempera	ture (°C)							
Segment to	emperati	are (°C)									
Average G	iross We	eight Cap	osules (n	ng)							
		I	ndividua	ıl We	ights of 10) Capsule	es (mg)				Avg. Net weight
Gross Wt.											
Shell Wt.											
Net Wt.											
Done By:									Da	nte:	
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Speed of E	Speed of Encapsulation Machine					Optimum Speed: RPM						
Batch Nun	nber:				Die	Roll (Change	Part No	.:			
Stage of Sa	ampling	:			Initi	al Sta	ge					
TESTS					RES	SULT	'S					
Appearance	ee											
Spreader E	Box temp	perature	(°C)		Left	:				Right:		
Ribbon Th		•			Left: Right:							
Cooling D	rum tem	perature	(°C)									
Gelatin Fe	ed Tank	tempera	iture (°C	5)								
Segment to	emperati	ure (°C)										
Average G	iross We	eight Cap	osules (n	ng)								
		I	ndividua	ıl We	ights	of 10	Capsul	es (mg)				Avg. Net weight
Gross Wt.												
Shell Wt.												
Net Wt.												
Done By:										D	ate:	
Inference:												
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Speed of Encapsulation Machine					Optimum Speed: RPM								
Batch Numbe	er:				Die Roll	Change	Part No	.:					
Stage of Samp	pling:				Middle S	tage							
TESTS					RESULT	RESULTS							
Appearance													
									1				
Spreader Box	_				Left: Right:								
Ribbon Thickness (From ribbon continuously formed) (mm)					Left:				Right:				
Cooling Drum temperature (°C)													
Gelatin Feed	Tank t	empera	ature (°	C)									
Segment temp	peratur	e (°C)											
Average Gros	ss Weig	ght Ca	psules (mg)									
		I	ndividu	al We	ights of 10	Capsul	es (mg)				Avg. Net weight		
Gross Wt.													
Shell Wt.													
Net Wt.													
Done By:									Γ	Date:			
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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 We	ights of 10 Capsules (mg)	Avg. Net weight			
Gross Wt.					
Shell Wt.					
Net Wt.					
Done By:	Da	ite:			
Inference:					
Reviewed By Sign & Date					



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

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

Inference:			
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5.11 DRYING OF CAPSULES:

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

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

Inference:			
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PROTOCOL No.:

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

Batch No.:			Machine S	Speed:	RPM		
Date	Time	Change Part No.	Appearance	Gross weight (mg)	Colotin Shall	Avg. Weight (mg)	Ribbon Thickness (mm)
T. C.							
Inferen	ce:						
							
Review							

Sign & Date



PROTOCOL No.:

Batch I	No.:				Machine S	RPM	
Date	Time	Change Part No.	Appearance	Gross weight (mg)	Gelatin Shell Weight (mg)	Fill Weight (mg)	Ribbon Thickness (mm)
Inferen	ce:						
Review Sign &	ed By Date						



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3.13 ENVIRONMENTAL MONTORING PORTIO CALGULE PRITIN	5.13	ENVIRONMENTAL	MONITORING DURING	CAPSULE DRYING
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Temperature : ±°C Relative Humidity : ±RH%					RH%
Date	Time	Batch Number	Temperature(°C)	Relative Humidity (%)	Remark
ference:					
eviewed B					



PROTOCOL No.:

Temperature	: ±°C	Relative Humidity : ±	_RH%
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Date Time Batch		Temperature(°C) Relative Humidity (%) R			
		Number	1		
nference:					



PROTOCOL No.:

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:
	Corrective Action(s) taken:
	Reviewed By Sign & Date
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7.2	CONCLUSION

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		