INSTALLATION QUALIFICATION

PROTOCOL CUM REPORT

FOR

CARTON PACKING MACHINE

EQUIPMENT ID. No.	
LOCATION	**PACKING AREA**
DATE OF QUALIFICATION	
SUPERSEDE PROTOCOL No.	**NIL**

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR CARTON PACKING MACHINE

PROTOCOL CONTENTS

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR CARTON PACKING MACHINE

1.0 PROTOCOL PRE – APPROVAL:

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OPERATING MANAGER (QUALITY ASSURANCE)			
HEAD (ENGINEERING)			
HEAD (PRODUCTION)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR CARTON PACKING MACHINE

2.0 OBJECTIVE:

- To provide documented evidence for the Installation Qualification of Carton Packing Machine in Packing Area.
- To confirm that the equipment and its components are installed as per the Specifications mentioned in the design qualification document and other requirements given by supplier.

3.0 SCOPE:

- The scope of this installation qualification protocol cum report is limited to qualification of Carton Packing Machine (**Make:** ACG Pampac) to be installed in the Packing Area.
- This document provides all the relevant information related to specification, installation checks and acceptance criteria to be required to perform installation qualification activity of Carton Packing area Machine.

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4.0 RESPONSIBILITY:

The Validation Group, comprising of a representative from each of the following departments shall be responsible for the overall compliance of this Protocol cum Report:

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	• Preparation, Review, Authorization and Compilation of the Installation Qualification Protocol cum Report. • Co-ordination with Production and Engineering to carryout Installation Qualification. • Monitoring of Installation Qualification Activity. • Post Approval of Qualification Protocol cum Report after Execution.
Production	• Review & Pre Authorization of Installation Qualification Protocol cum Report. • To Co-ordinate and support for Execution of Qualification study as per Protocol. • Post Approval of Installation Qualification Protocol Cum Report after Execution.
Engineering	• Review & Pre Approval of Installation Qualification Protocol cum Report. • Co-ordination, Execution and technical support in Installation Qualification Activity. • Calibration of Process Instruments. • Responsible for Trouble Shooting (if occurs during execution). • Post Approval of Installation Qualification Protocol Cum report after Execution.

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR CARTON PACKING MACHINE

5.0 EQUIPMENT DETAILS:

Equipment Name	Carton Packing Machine
Equipment ID.	
Manufacturer's Name	ACG-Pampac
Supplier's Name	ACG-Pampac
Model	HICART PLUS
Serial Number	
Location of Installation	Packing Area

6.0 SYSTEM DESCRIPTION:

HI Cart plus is Continuous Motion cartooning Packing machine, Suitable for automatic Cartoning of Product Like Ampoule Bottle Tubes and blister . the Type of Machine meets the Need of The high Volume Production , Giving an Output of up to 180 Carton /minutes Depending upon Application .the Machine Performed following Function .

- Receive unit Product From Up stream machine on Product Chain .
- Storing of pre Broken Carton in flat from in the Carton Magazine .
- Picking Up The carton from Carton Magazine with rotary Pick up System .
- Opening / erecting the Carton
- Rear Side Flaps Folding Before Product Pushing
- Loading Product
- Both side Carton Closing (Front & Rear sides)
- Discharge Either to a Bin or to downstream Machine

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR CARTON PACKING MACHINE

The machine consists of following Main Functional Areas:

A. **Product Chain:** Product Chain transports the Product from Receipt area to the Pushing Area. Product in Feed occurs.

- On a Pair of Roller Supported , Double Transport Chains
- Guided in Plastic Plates.
- With adjusted Product Pockets

Individual Product Pocket can be adapted to the Product Size with an adjustment of Chain . Length of the Chain Extension is depends on application , Upstream integration and Room Layout

Product Chain Extension :

The product chain Extension is additional extension for the Product Chain . the Extension Provides Additional Space Between Transfer and Cartooning Machine for Customer Specific use ei. For Manual Product Insertion Into the Product Chain.

B. **Carton Chain:**

The Carton Chain Transport open Carton from carton Landing to Carton Closing. Following Process take Place on the Carton Chain:

- Transfer and final Erection of the Cartons.
- Insertion of the Product and Leaflet.
- Folding of the side Flaps – front and Rear sides .
- Printing /embossing of the Flap .
- Carton Closing.

The Individual Chain Pocket can be adapted to the Carton Size with an Adjustment of Chain .

Note : Range of Carton Depending on Chain Configuration selected while order Finalization. Machine will be Based on the Customer Need Defined during order FinaliSation.

C. **Carton Loading Magazine :**

The carton Magazine Hold Various Size of Carton .Magazine Parts can be adjusted Easily to Accommodation Various Sizes of Carton With the Help of Numeric scales . For each Type each size/ Type of Carton , Values Can be This Conveyor is Drive Intermittently, Though Unidirectional Bearing and Pneumatic Cylinder . A Pressure plate with a dead Weight put Constant Pressure on the

Carton Stack . two Plunger Cylinder hold the Cartons During Carton Pick up. Two Cylinder are Provided, one another on the Bottom.

D. **Carton Pick up & Transfer System:** The carton are Picked up with pickup arms from the carton Magazine and Then Place it the Carton holder . Pick and Place is done by Vacuum , which is Generated either by air venture or Vacuum pump . Suction cups Mounted at the end of Sucker arm do Main pick up Function .these are Rubber Cups, flexible Enough with Cushioning Action makes Carton Pick up easy up arms driven Through the Main Motor and shaft, Oscillating Movement for pick up arms generated through Linkage in Connection with main Shaft. , Carton Vacuum Can be enabled or disabled from Main Screen of HMI.

An Integrated Carton Pre Breaking system Is provided along with the Carton Pick up System . this unit open /from Carton Before Placing it on the Carton Chain Various Gears along with belt drive Rotates Rotary Pick unit . this Unit rotate Continuously . Sucker arms are mounted on Bracket, which in Turn Mounted on Rotary Pickup unit Through Small Gears.

There are Three Vacuum & air Control Valve used in the Unit. Two Valve are Connected to the Vacuum Lines of the Sucker and one to the Pre- Breaker.

In Run Mode , Whenever the Product is not Present in any Pocket of the Product Chain or the Leaflet is not Released for some Pocket , the Signal is Sent to the Vacuum & air control Valve by a Sensor.

Then the Valve for the Corresponding Sucker Operates , the Vacuum Is Vacuum is Not off and carton is Picked for the product Pocket in which the Product or Leaflet is not Present.

The Valve for the Pre Breakers Operation is Mode .the Position of the Sucker arm for which the vacuum in the Pre Breaker is to be Made on and off are Set.

Thus the operation the Position comes, making the Vacuum in the Pre Breaker On at the start of Pre Pre Braking and Cutting it OFF at the end of Pre Breaking .

Carton pre Breaking unit is Provided to Pre Break the Carton Before Placing Them on the Carton Chain .

E. **Carton Positioning :** The Carton Position unit Consist of a Carton Toward the product Chain From Rear side of the Machine.

The Carton is pushed Forward in the Forward:

- The Carton Partially pushed Forward
- The Carton Pushed Forward Unit Flaps come in the Contact with the Outer surface of the Cell angle along with Their Full Length.

The side Flap Opener Opens the Side Flaps of the carton for Smooth Insertion of the Product from Product Chain Side.

F. **Rear Side Flaps Closing :** The Side Flap Closing Takes Places Between Carton Loading on the Carton Chain and product Pushing . Stationary Guide Close Left Side Flap and Folding Finger closes the Right Side Flap , Folding Finger is Moveable and Driven Through the Same Drives of Carton Positioning.

G. **Product Pushing system:** The Product Pushing system is Provided to Push the Carton. It Consist of Product Pusher That Push the Product and Leaflet into the Carton Pushing Takes Places when Product and Carton Comes to the Insertion point.

Folded Leaflet Gets Release by the Leaflet Clamp at this Station and then Inserted into the Carton with the product.

Pusher assembly Consist of a Pusher With rod and pre Pusher . if Product gets Stuck in Between , due to some Reason , It Operates the Overload Safety switch that Stop the Machine .

H. **Carton Closing :** After Slide Flaps Closing Carton system to Main Flap Closing station . front and Rear Flap Closing Takes Place Simultaneously in 3 step.

Flap Position for Closing is done by Creasing guide and guide Rod. These are arranged to blend locking flap with main flap.

Pre- closing: Pre closing and completed closing is done by tuck in closers. In pre closing , tuck in closer pushes the locking flap to lock the carton.

Complete closing : Pre closing and completed closing is done by tuck in closers. In pre closing , tuck in closer pushes the locking flap over the side flap to lock the carton

I. **Carton Discharge**

The closed carton from the carton chain are transferred to the discharge belt. Discharge belt continuously carry these carton to the next point which may be either Collection bin or Line conveyor.

Discharge belt assembly includes two flat belts , driven through the main drive. Speed of both the belts is synchronized and slightly higher than the carton chain speed.

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J. Empty Carton Rejection System

This system is provided to detect and reject the empty carton from the discharge conveyor. A sensor is provided to detect the presence of the product in the carton .If the product is not available in carton , the sensor gives signal to the control system, and it operates an ejection lever, which is operated by a pneumatic cylinder. The rejected carton will then collected in a separate bin.

K. Printing Station

This station has batch code embossing provision. A metallic roller holds embossing letters for coding on the carton flap. Carton flap is passed through the metallic roller and pressure roller to get the impressions of letters on the carton flap.

L. Pre- folded Leaflet Transfer System

This attachment is provided to transfer the folded leaflet into the carton.

Pre folded leaflets are stored in magazine. The leaflets are picked up by the sucker arm and then transferred to the transfer belts. Belts carry these leaflet up to leaflet clamps with rotary turret. Then clamps along with chain carry these leaflets to the pusher station for insertion in the carton.

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7.0 PRE – QUALIFICATION REQUIREMENTS:

7.1 Verification of Documents:

- Executed and approved design qualification document.
- Electrical circuits diagram.
- Technical specification of equipment.

7.1.1 Procedure:

- Verify the above mentioned documents for availability, completeness and approval status.
- If any deviation is observed the same has to be recorded giving reasons for deviation and approved. Deviation should be approved by Authorized person.
- Approved Drawings and supporting documents would form a part of the IQ Protocol cum Report.

7.1.2 Acceptance Criteria:

- All the documents should be available, complete and approved by respective authorities.

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR CARTON PACKING MACHINE

8.0 CRITICAL VARIABLES TO BE MET:

8.1 Installation Qualification Checklist:

INSTALLATION CHECKS	ACCEPTANCE CRITERIA	OBSERVATION (COMPLIES /NOT COMPLIES)	OBSERVED BY (ENGINEERING) SIGN/DATE
Grouting and Mounting	Should be properly grouted and mounted.		
Leveling	Should be properly balanced and leveled.		
Edges of parts	Metal parts should be properly ground without any sharp edges.		
Welding of Joints	Welding of joints should be without any welding burrs.		
Place of Installation	Packing Area, LVP Line 'L' Block		
Room Condition	RH : NMT 55 % TEMP : NMT 25 ºC		
Illumination	NLT 300 Lux		
Working space around the Equipment.	Should be sufficient for easy operation, cleaning, sanitation and maintenance.		

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8.1 VERIFICATION OF UTILITIY REQUIREMENTS:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION (COMPLIES /NOT COMPLIES)	OBSERVED BY (ENGINEERING) SIGN/DATE
Electrical Supply	Voltage : 415 V Phase : 3 Phase Frequency : 50 Hz ± 10%. Power consumption : 6 kW max		
Room Condition	Temperature NMT 25 ºC RH : NMT 55 %		
Compressed Air Consumption	02 CFM for Carton (with Vacuum Pump) 06CFM for Leaflet (with Vacuum Venturi)		
Incoming Cable	5 core x 4 mm ² Copper Cable		
Air Pressure	6 Bar		

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8.2 Installation Checks For Technical Specification:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION (COMPLIES /NOT COMPLIES)	OBSERVED BY (ENGINEERING) SIGN/DATE
Machine Specification			
Machine Type	Continuous motion ,automatic carton packing machine		
Model	HICART PLUS		
Machine Number	HI630001336-10		
Output	Upto 180 cartons/min ,out put of the machine depends on the type of product to be packed, type and size of carton, leaflet/booklet and quality of carton and leaflet/booklets.		
Machine Weight (Net)	2250 kg		
Machine Weight (Gross)	3200Kg.		
Noise Lavel	80 db (approx)		
Recommended Temperature Range	18 – 30 ° C		
Recommended Humidity	45- 60 % RH		
Mechanical components			
Vacuum Pump			
Make	Beaker		
Model	VT 4.40		
Motor			
Make	Rotomotive (90 L-4)		
Model	Rating : 3 Phase , 415 V , 1.5 Kw , 3.5 A, 1400RPM		
Gear Box for Main motor			

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CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION (COMPLIES /NOT COMPLIES)	OBSERVED BY (ENGINEERING) SIGN/DATE
Make	Rotomotive		
Model	ROBUS 21 (Ratio = 1:10)		
Servo Motor for Carton Positioning and Rear Flap			
Make	Mitsubishi Electric		
Model	HG –KN23 Input : 3AC .119V, 1.3 A Output : 0.91 Kg , 3000 RPM, 200 W		
Gear box carton Positioning and Rear Flap			
Make	Shimpo- Nidec		
Model	EVB-060-8-K4-14BK14		
Carton Chain Cluch			
Make	Comintec		
Model	1.90 DSR/FAMS		
Gear Box in front Truck in Unit			
Make	KMT		
Model	1:2 90-5332		
Gear Box in Rear Truck in Unit			
Make	KMT		
Model	1:2 90-5332		
Leaflet Transfer System			
Gear Box Leaf let Drive			
Make	KMT		
Model	1:1-120-5330		
Gear Box Leaf let Drive			
Make	KMT		
Model	1:4-120-5331		
ELECTRONIC COMPONENT			

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CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION (COMPLIES /NOT COMPLIES)	OBSERVED BY (ENGINEERING) SIGN/DATE
HMI			
Make	Weintek Labs.		
Model	MT 8071 IE		
Power Supply			
Make	Omron		
Model	S8VK-C12024		
PLC For Machine			
Make	Mitsubishi Electric		
Model	FX 2N -16EX		
PLC Card For Input			
Make	Mitsubishi Electric		
Model	FX2N-16EX.		
PLC Card For Output			
Make	Mitsubishi Electric		
Model	FX2N-16EYT		
Single Phase Preventer			
Make	Omron		
Model	K8AK-PM		
Tower Lamp			
Make	Schnedier		
Model	XVGB3S		
Encoder			
Make	Kubler		
Model	8.5000.835A.3600.0050		
Drive for Main Motor			
Make	Danfoss		
Model	(VLT Micro Drive)		
Specification	Rating 1.5 kw, 2.0 HP		

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CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION (COMPLIES /NOT COMPLIES)	OBSERVED BY (ENGINEERING) SIGN/DATE
Servo Drive For Carton Positioning And Rear Flap Servo Motor			
Make	Mitsubishi Electric		
Model	MR-JE-20A		
Pneumatic Component			
Air pressure switch			
Make	Festo		
Model	SPAN-PIOR-G18M-PN-PN-L1		
Carton holding Actuator on , Magazine			
Make	Festo		
Model	DSR-16-180-P		
Pusher Diverter Actuator			
Make	Festo		
Model	DSR-12-180-P		
Pneumatic Cylinder For Empty Carton rejection			
Make	Festo		
Model	DSN-12-100-P		
Pneumatic Cylinder Carton Top Support Cylinder (02 Nos.)			
Make	Festo		
Model	DSBC-32-100-PPVA-N3		
Vacuum Venturi For Leaflet Pickup			
Make	Festo		
Model	VN-20-H-T6-PQ4-VQ5-RO2-M		
Sensor			
Main motor home position check			
Make	Pepperl & Fuch		
Model	NBB5-180GM50-E2		

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CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION (COMPLIES /NOT COMPLIES)	OBSERVED BY (ENGINEERING) SIGN/DATE
Carton Low Level Check in Magazine			
Make	Pepperl & Fuch		
Model	NBB4-12GM50-E2		
Leaflet Low level Check			
Make	IFM		
Model	OJ5148		
Leaflet Check Sensor			
Make	IFM		
Model	OJ5148		
Handwheel Out Check			
Make	Pepperl & Fuch		
Model	NBB4-12GM50-E2		
Carton Check			
Make	IFM		
Model	OJ5148		
Product Pusher Loading Safety			
Make	Pepperl & Fuch		
Model	NBB4-12GM50-E2		
Sucker Arm Home Position Check			
Make	Pepperl & Fuch		
Model	NBB5-18GM50-E2		
Half Product Insertion Check			
Make	IFM		
Model	OJ5148		
Empty Carton Rejection Check			
Make	IFM		
Model	KB5004		

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CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION (COMPLIES /NOT COMPLIES)	OBSERVED BY (ENGINEERING) SIGN/DATE
Carton Chain Clutch			
Make	Pepperl & Fuch		
Model	NBB4-12GM50-E2		
Carton Rear pusher home position check			
Make	Pepperl & Fuch		
Model	NBB4-12GM50-E2		
Guard Switches (04 Nos.)			
Make	Telemecanique		
Model	XCJ-110		

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8.2 MATERIAL OF CONSTRUCTION:

Parts Name	ACCEPTANCE CRITERIA	OBSERVATION (complies /not complies)	OBSERVED BY (ENGINEERING) SIGN/DATE
Chain	MS		
Pockets Wall	Plastic		
Pusher	MS Hardened rods		
Drive and guide assembly	MS		
Magazine assembly	SS304, MS, EN9		
Carton chain and Flap folding assembly	MS, SS304 and alluminum		
Tuck in assembly	MS, SS304 and EN8		
Carton discharge assembly	MS, PU, SS304 and aluminum		
Interconnection assembly	PU belt and Aluminum section		

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INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR CARTON PACKING MACHINE

8.3 SAFETY FEACHURE & ALARM :

Description of Test	Message Displayed on HMI	Result of the Test	Observation Complies /Not Complies)
Emergency Switch pressed on HMI	Emergency Stop at Console	Machine should stop immediately	
Emergency switch pressed on Discharge end	Emergency stop at discharge end	Machine should stop immediately	
Emergency switch pressed on Infeed end	Emergency stop at infeed	Machine should stop immediately	
Low Air Pressure	Air Pressure Below as per Set Limit	The Machine Should not start unless set set air Pressure is Available	
Carton Vacuum Off	Carton Vacuum Key is Off	Machine should not start	
Leaflet Vacuum Key Off from HMI	Leaflet Vacuum off	Machine should not start	
Hand wheel Out	Hand wheel out	Machine should not start	
Product Not sensed	Product not sensed by sensor	The Leaflet will not picked up	
Leaflet not Sensed	Leaflet not sensed by sensor	The Machine Should Stop as per Preset Count.	
Carton Not sensed	Carton not sensed by sensor	Product Pusher will Get Diverted	
Product as per set count in HMI not present	No Continuous Product	The Machine should stop as per set count	
Leaflet as per set count in HMI not present	No Continuous leaflet	The Machine should stop as per set count	

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INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR CARTON PACKING MACHINE

Description of Test	Message Displayed on HMI	Result of the Test	Observation Complies /Not Complies)
Cartons as per set count in HMI not present	No Continuous Cartons	The Machine should stop as per set count	
Low Level carton	Carton Level is Low	Machine Should stop as per set count	
Leaflet Low Level	Leaflet Low Level detected by Sensor	The Machine Should Stop as per Preset Count.	
Half product insertion	Product is not Completely Pushed in the Carton	Machine should Stop immediately	
Carton Chain Cluch Overload	Carton Chain Clutch Overload	Machine should Stop immediately	
Pusher Loading Safety	Loading Safety at Pusher	The Machine should Stop Immediately	
Guard Open	Should be properly balanced and leveled.	Machine should Stop	

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9.0 REFERENCES:

- Design Qualification
- Vendor Documents

10.0 DOCUMENTS TO BE ATTACHED:

- Calibration certificates.
- Any other relevant documents.

11.0 DEVIATION FROM PRE-DEFINED SPECIFICATION IF, ANY:

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12.0 CHANGE CONTROL, IF ANY:

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13.0 REVIEW (INCLUSIVE OF FOLLOW UP ACTION, IF ANY):

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INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR CARTON PACKING MACHINE

14.0 CONCLUSION:

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15.0 RECOMMENDATION:

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INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR CARTON PACKING MACHINE

16.0 ABBREVIATIONS:

cGMP	:	Current Good Manufacturing Practice
CPM	:	Carton Packing Machine
HP	:	Horse Power
Hz	:	Hertz
IQ	:	Installation Qualification
MCB	:	Miniature circuit breaker
mm	:	Millimeter
NLT	:	Not less than
NMT	:	Not More Than
RH	:	Relative Humidity
RPM	:	Revolution per minute
SS	:	Stainless steel

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17.0 PROTOCOL POST- APPROVAL:

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OPERATING MANAGER (QUALITY ASSURANCE)			
HEAD (ENGINEERING)			
HEAD (PRODUCTION)			

APPROVED BY:

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HEAD (QUALITY ASSURANCE)			