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1.0   OBJECTIVE

1.1   To lay down a procedure for cleaning and operation of bulk counter Machine (Make:Pharma

Pack) with online camera inspection and rejection system(Make : Jekson Vision).

2.0   SCOPE

2.1   This procedure is applicable for cleaning and operation of bulk counter Machine (Make:Pharma

Pack) with online camera inspection and rejection system in production department.

3.0   RESPONSIBILITY

3.1   Technical Associate   : Cleaning and operation of bulk counter.

3.2   Officer, Executive-production : To prepare recipe and its compliance.

3.3   Officer, Executive-IPQA   : SOP compliance.

3.4   Manager–production   : SOP compliance.

4.0   DEFINITION (S)

4.1   Done By- The activity performed by the Person

4.2   Verified By- Evidence that establish or confirm the accuracy or truth of activity

5.0   PROCEDURE

5.1   **CLEANING**

5.1.1   **TYPE A CLEANING**

Change over from one batch to next batch of the same product and potency.

5.1.1.1   Ensure that all the materials of previous batch are removed from the packing cubicle.

5.1.1.2   Remove "EQUIPMENT STATUS " label and affix "UNDER CLEANING" label on

the machine with date and sign of the production officer.

5.1.1.3   Clean the control panel of machine with dry lint free cloth, Switch 'OFF' all utility supply before

cleaning.

5.1.1.4   Clean the control panel of camera inspection system monitor and wiring panel with dry lint free

cloth.

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5.1.1.5   Clean the top and outer surface of machine with the dry lint free cloth.

5.1.1.6   Open guard and clean inside surface of machine, hopper, hopper plate and its assembly by dry lint free cloth.

5.1.1.7   Clean the product deposit area on top and parts by vacuum cleaning followed by dry lint free cloth.

5.1.1.8   **Machine Dismantling Procedure**:

5.1.1.8.1   Remove the dust collector pipe and S.S guards of machine of front, center, sides and back.

Switch 'OFF' the vibratory lock in PLC to release the vibratory plates In-feeding system.

5.1.1.8.3   Remove hopper, hopper plate, and three level vibratory plate's In-feeding system.

5.1.1.8.4   Switch 'OFF' all the utility supply to machine.

5.1.1.8.5   Remove the individual product rejection assembly from machine.

5.1.1.8.6   Remove the pneumatic connection from the memory flap cylinder assembly.

5.1.1.8.7   Remove the channel divide above the sensor head.

5.1.1.8.8   Remove the air purging nozzle assembly of individual rejection of product by loosing the clump.

5.1.1.8.9   Remove the sensor port from the sensor assembly and small sensor port from memory flap cylinder unit.

5.1.1.8.10 Remove the sensor head carefully above the cover of memory flap cylinder unit.

5.1.1.8.11 Remove the safety cover of memory flap cylinder unit.

5.1.1.8.12 Remove the memory flap cylinder unit from the memory flap support.

5.1.1.8.13 Remove the memory flap support plate and S.S. funnel from main gate cylinder.

5.1.1.8.14 Remove the product feeding nozzle with ring from locking system.

5.1.1.8.15 Remove the base S.S.plate of bulk counter machine to which hopper, vacuum suction pipe, three-level vibratory plates In-feeding system attached.

5.1.1.9   Clean the S.S.guards of machine of center, sides and back, hopper, hopper plate, three-level vibratory plates In-feeding system, memory flap support plate, individual product rejection assembly, SS funnel, product feeding nozzle with ring, base SS plate of hopper and vacuum suction pipe with dry lint free cloth.

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5.1.1.10   Clean the machine surface and product deposit area by dust collector pipe followed by dry lint free cloth.

5.1.1.11   Replace the **"UNDER CLEANING"** status label by "CLEANED" status label on the machine with date and sign of the production officer.

5.1.1.12   Record the cleaning activity in equipment usage log as per SOP.

5.1.1.13   Clean the surrounding area as per SOP.

5.1.2   **"TYPE B" CLEANING**

This is a cleaning procedure for Changeover of product with different actives/color / descending potency/ascending potency and If the same product processed for more than a week or after maintenance.

5.1.2.1   Ensure that all the materials of previous batch are removed from the packing cubicle.

5.1.2.2   Remove "EQUIPMENT STATUS" label and affix "UNDER CLEANING" label on machine with date and sign of the production officer.

5.1.2.3   Clean the control panel of machine with dry lint free cloth, Switch 'OFF' all utility supply before cleaning.

5.1.2.4   Clean the control panel of camera inspection system monitor and wiring panel with dry lint free cloth.

5.1.2.5   **Machine Dismantling Procedure**

5.1.2.5.1   Remove the dust collector pipe and S.S.guard of machine of front, center, sides and back.

5.1.2.5.2   Switch 'OFF' the vibratory lock in PLC to release the vibratory plates In-feeding system.

5.1.2.5.3   Remove hopper, hopper plate, three-level vibratory Plates In feeding System.

5.1.2.5.4   Switch 'OFF' all the utility supply to machine.

5.1.2.5.5   Remove the individual product rejection assembly from machine.

5.1.2.5.6   Remove the pneumatic connection from the memory flap cylinder assembly.

5.1.2.5.7   Remove the channel divide above the sensor head.

5.1.2.5.8   Remove the air purging nozzle assembly of individual rejection of product by loosing the clump.

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5.1.2.5.9	Remove the sensor port from the sensor assembly & small sensor port from memory flap cylinder unit.
5.1.2.5.10	Remove the sensor head carefully above the cover of memory flap cylinder unit.
5.1.2.5.11	Remove the safety cover of memory flap cylinder unit.
5.1.2.5.12	Remove the memory flap cylinder unit from the memory flap support.
5.1.2.5.13	Remove the memory flap support plate,S.S funnel from main gate cylinder.
5.1.2.5.14	Remove the product feeding nozzle with S.S. ring from the locking system.
5.1.2.5.15	Remove the, vacuum suction pipe, three-level vibratory plates In-feeding system attached.
5.1.2.6	Transfer the S.S.guards of machine of center, sides and back,hopper,hopper plate, three-level vibratory plates In-feeding system, memory flap support plate,SS funnel, feeding nozzle with S.S. ring,dust collector pipe, individual product rejection assembly, S.S.base plate of vacuum suction pipe to washing area in virgin poly bag for cleaning.
5.1.2.7	Flush all change parts with purified water sufficient to remove the powder. To remove the adhered particulate scrub the equipment/parts with nylon brush using purified water. **NOTE** : 2% Sodium Lauryl Sulphate solution shall be used for scrubbing with nylon brush if API is Efavirenz before final rinsing of equipment/parts.
5.1.2.8	Rinse all the change parts with 40-50 litters of purified water.
5.1.2.9	Clean the parts by mopping with dry lint free cloth.
5.1.2.10	Wipe the all parts with 70% v/v IPA solution followed by mopping with dry lint free cloth.
5.1.2.11	Transfer all the parts from washing area to cubicle area in fresh virgin poly bag.
5.1.2.12	Clean the control panel with dry lint free cloth.
5.1.2.13	Clean the surface of the machine with dry lint free cloth using 70% v/v IPA solution.
5.1.2.14	Clean the machine guards with dry lint free cloth.
5.1.2.15	Assemble all the dismantled parts by following 5.1.2.6.1 to 5.1.2.6.15.
5.1.2.16	If machine is idle for 72 hours after cleaning, re-clean the machine by mopping with lint free cloth using 70% v/v IPA solution before use.
5.1.2.17	Replace the ''UNDER CLEANING" status label by "CLEANED" status label on the machine with date and sign of the production officer.
5.1.2.18	Do the cleaning as per Annexure-I Cleaning checklist of Bulk Counter Machine.

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5.1.2.19   Record the cleaning activity in equipment usage log as per SOP.

5.1.2.20   Clean the surrounding area as per SOP.

Note: Visual inspection shall be done for wear and tear of teflon coating on S.S. plate of hopper gate after B type cleaning.

5.2   **Bulk Counter Machine Operation**

5.2.1   Insert the MMI key and 'ON' the MMI.

5.2.2   System shows four type of user login level and have specific rights assignment.

Following table given according to 'USER RIGHT'.

S.No.	Function	Rights assignment			
		Operator (Level-I)	Supervisor (Level-II)	Adminstrator (Production Head) (Level-III)	Engineering (Level IV)
1	To make recipe.	N	N	Y	Y
2	Online change in vibration frequency.	Y	Y	Y	Y
3	Machine setting (Manual setting)e.g. General gate,Product Max./Min. Value,Flap working.	Y	Y	Y	Y

5.2.3   Enter password for different levels.

5.2.4   Level 1 is for operation of the same product.

5.2.5   Start the machine by pressing Green Button on console panel of MMI.

5.2.6   Start the conveyor belt by pressing conveyor start and then press start for staring the machine.

5.3   **For New product setting**

5.3.1   Enter password for level 3

5.3.2   Main screen open.

5.3.3   Start conveyor belt by pressing conveyor start.

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5.3.4	Press Manual button on main screen.
5.3.5	ON any one-vibrator left hand or right hand side.
5.3.6	Go to main screen by pressing Main button on the MMI.
5.3.7	Set counting quantity as per pack size, i.e. tablets quantity for each bottle, by small numeric keyboard.
5.3.8	Start the machine by pressing start.

5.3.9	Press watch button and observe Maximum Length and Minimum Length for 3 to 4 bottles of the selected side vibrator.
5.3.10	Add 1 to 3 values to the Maximum Length and subtract 1 to 3 values from the Minimum Length of respective head enter in respective production.
5.3.11	Press parameter button on main screen.
5.3.12	Start machine and check 3 to 4 bottles for count check.
5.3.13	If any problem persists then adjust the value of Gate delay .By pressing respective gate delay by small numeric keyboard.
5.3.14	Enter Delay parameter.
5.3.15	Enter Filling delay----This parameter stands for time interval (millisecond) for tablet falling from tablet gate to bottle. It is input by small numeric keyboard

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5.3.16	Enter Lock Bottle Delay Time ------.This parameter stands for time interval from the moment when cylinder discharges one bottle to the moment when cylinder clamps the next one. It is input by small numeric keyboard.
5.3.17	Enter No bottle delay----This parameter stands for time interval (millisecond) from the moment when sensor detects fallen bottle to the moment when filling tablets stops. It is input by small numeric keyboard.
5.3.18	Enter Conveyor Speed----It is input by small numeric keyboard.
5.3.19	Enter Feeder nozzle vibration frequency for big tablets switch ON the Nozzle vibration for big tablets.
5.3.20	Enter Rejection parameter.
5.3.21	Enter Remain Time ---- It stands for time interval for rejection valve from pushing out to pulling back. This value can be input by small keyboard.
5.3.22	Enter Reject Switch ---- Select switch for using rejection function or not. This value can be input by small keyboard.
5.3.23	Gate Interval ---- It stands for time interval from the moment when gate opens to the moment when gate closes. The value is larger; the filling is more accurate, while the rejection rate will be larger (150 to 225).
5.3.24	Minimum Gate Closing Tablet Interval ---- It stands for distance between tablets when tablets gate closes. The value is larger; the filling is more accurate, while the rejection rate will be larger (10 to 20).
5.3.25	Adjust the vibration of vibrating plates on main screen.
5.3.26	Save the file in Product management by product name.
5.3.27	Run the machine by calling product file by follow step No.5.3.3.

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5.3.28   The setting of nozzle with respect to the container should be such that nozzle shall completely cover the mouth of the container and no gap should be left. Moreover nozzle shall align parllel with the container mouth tip and shall not failitate any gap for leak/fall out of product while filling of the container. Following is the pictorial representation:-

Picture 1:-

Nozzle should cover whole mouth and should not facilitate any gaps or spaces, so that tablet may fall out while filing of tablet.

Picture 2:-

Nozzle with respect to container should be aligned properly.

NOTE: Alarm for piston malfunctioning generated whenever piston malfunctioning observed, in such case alarm will be generated and bottle will be rejected at the rejection point.
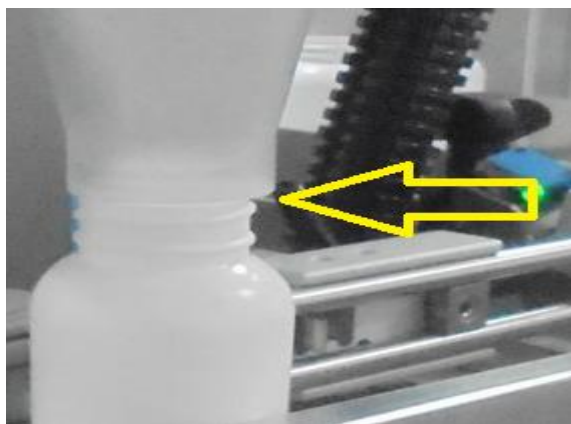
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**Picture 3(wrong alignment and gap):-**

Gap in nozzle and container and allignment of nozzle is not parllel creating chances of product may fall out while filling.

5.4	**Camera Setting Procedure**:
5.4.1	Turn 'ON' the knob given at wiring panel for main power supply and then push the 'push button' given at lower right side of monitor and following first window will be ask for password as:
5.4.2	Now click on 'TIS software' icon then enter the user name and password and press 'enter' in the following screen:
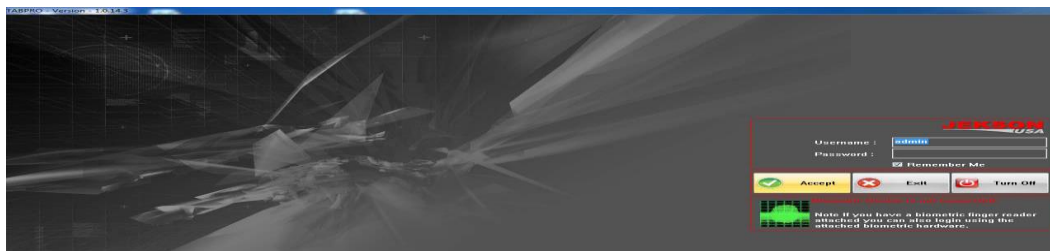
5.4.3	For touch screen monitors, double click on the text boxes to open an on-screen keyboard to enter user name and password.
5.4.4	To start the application, user has to login using user name and password.

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5.4.5   Three different user levels are provided with their different rights assignments as given below:

S.No.	Functions	Level-III (Operator)	Level-II (Supervisor)	Level-I Adminstrator (Production Head)
1	To make recipe.	N	Y	Y
2	Add/remove user & change security policy	N	N	Y
3	Load recipe	Y	Y	Y
4	Tolerance Setting	N	Y	Y
5	Foreign acknowledgement	N	N	Y

5.4.6   Click on the 'accept' button to start application and following image will be displayed:
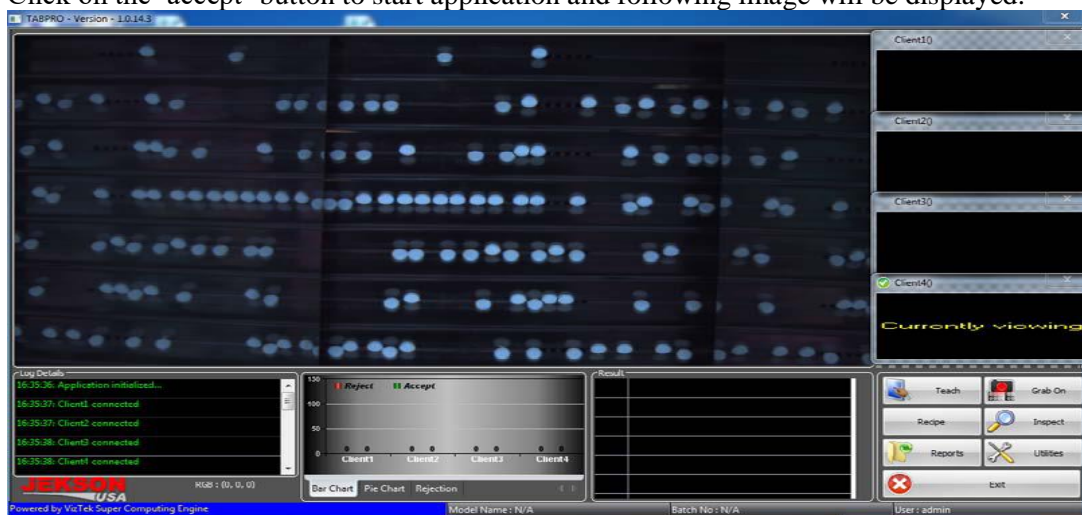
5.4.7   Above image shows the application with single camera, whereas maximum four cameras can be loaded. Each cameras viewing maximum six channels.

5.4.8   **Camera teaching:**

5.4.8.1   Select the camera1 from the right side of window under point no. 5.4.6 to prepare recipe.

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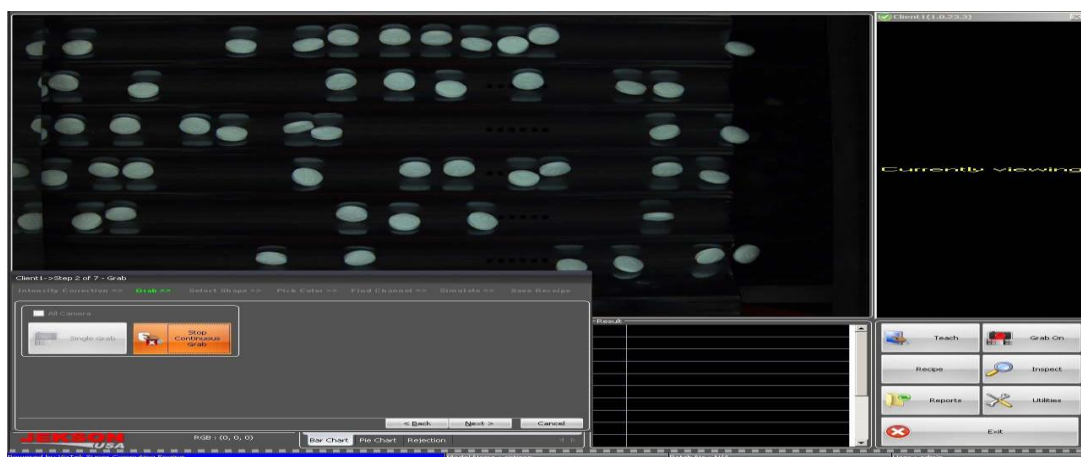| **STANDARD OPERATING PROCEDURE**	
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5.4.8.2   Press 'teach' button (refer to window given in point no. 5.4.6) to prepare a new recipe and following window will be displayed:
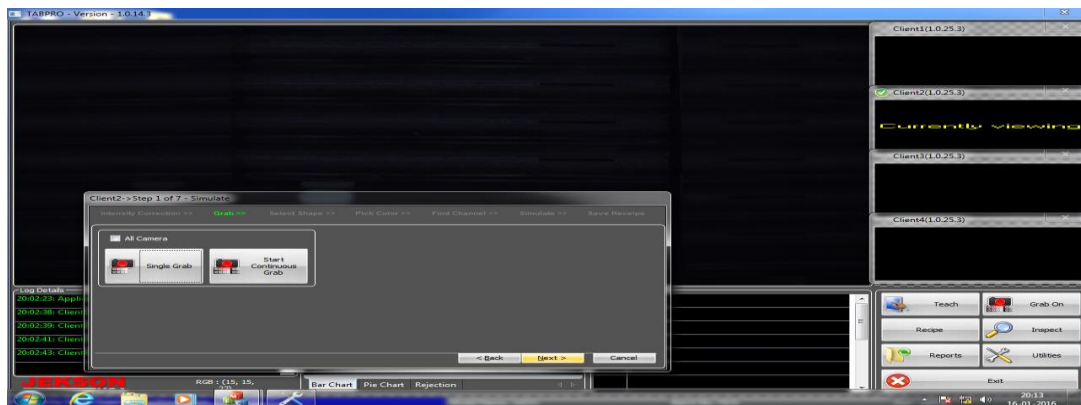
5.4.8.3   Start the machine by loading the good tablets/capsule into hopper.

5.4.8.4   Select the 'start continuous grab' button from above window and following window will be displayed.

5.4.8.5   Grab On:This is a toggle button (Grab ON/OFF), on pressing this button all the attached cameras starts grabbing the images.

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5.4.8.6   Again press the 'start continuous grab' button once all good tablets/capsule are in image of camera (refer to the point no. 5.4.8.4 to get image) and then select 'next' button & following window will be displayed:
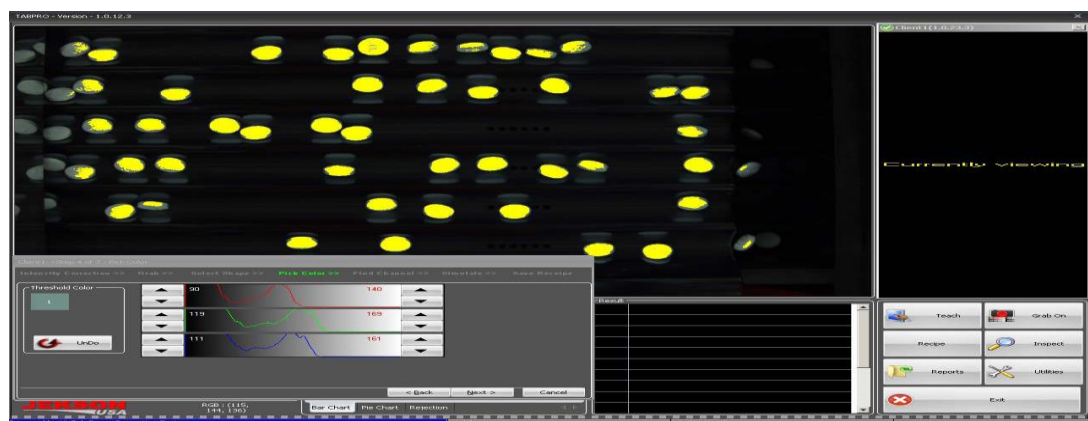

5.4.8.7   There is only option in camera to detect the tablet of round flat top, round bulge top, oval flat top, oval bulge top, capsule flat top, capsule bulge top and capsule (except similar colour of cap & body).

5.4.8.8   Select the type of product shape from the list given at left side of screen and then enter the dimension of tablet/capsule measured in mm as asked in above window.

5.4.8.9   Now select the type of product to be detected by camera from right side of above window e.g. Printed capsule, powdered capsule, printed tablets, sandwitch tablet, non coated tablets, none.

5.4.8.10   Press next button from above screen and new window will be displayed:

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5.4.8.11	Above window will ask for 'pick color' and for this select color of tablet/capsule from center of the image.
5.4.8.12	In case of pick colour for capsule select colour of cap and body separately.
5.4.8.13	Tips for color selection is click on center portion of the tablets/capsule where there is less variation in color intensity of its surrounding area of the tablets.
5.4.8.14	Selected color will appear in the 'threshold color' frame. Maximum user can select four different colors of the multi-colored product. If by mistake wrong color is picked, user can click Undo button to remove last picked color from the list .

| 5.4.8.15	As soon as the user picks color of the product, it will be highlighted with yellow color as shown above.
5.4.8.16	User can set appropriate threshold value using histogram Up/Down buttons. The range of the color should be set such that entire product gets highlighted by yellow color(refer to the point no. 5.4.8.8).
5.4.8.17	Certain part of mirror image of the product can also be tolerated in threshold image. If significant amount of mirror image is highlighted with yellow, user needs to fine tune the color range again.
5.4.8.18	Select the 'next' button from the window and new window will be displayed as below:

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5.4.8.19   Again select the 'next' button and new window will be displayed as give below:
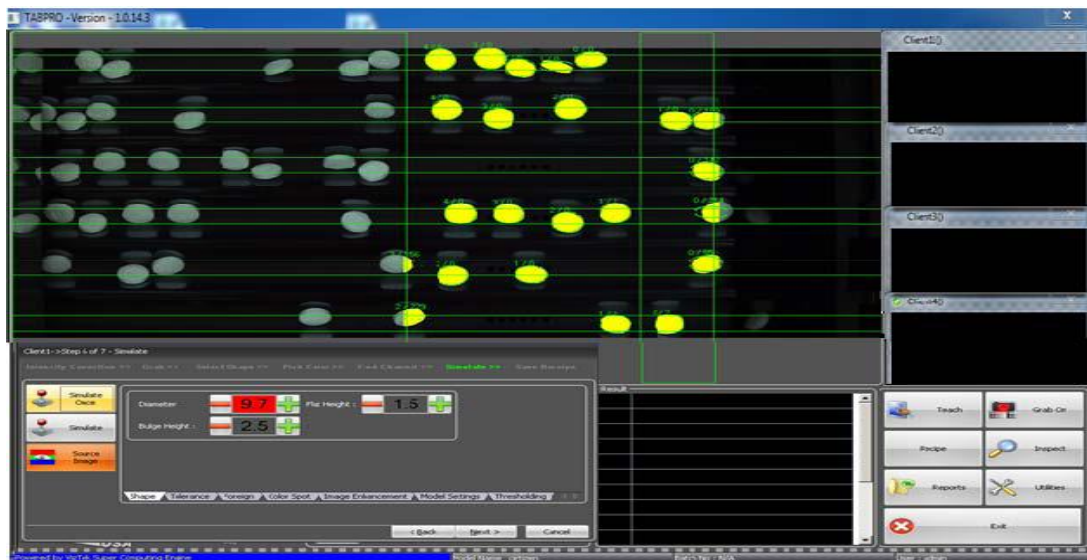
5.4.8.20   This page helps user to simulate taught product for particular camera before saving recipe.

5.4.8.21   Click 'simulate once' button to simulate as given in window and after simulate, each product will be tagged with two numbers separated with '/' i.e. 1/0 . Out of that first number indicated numbering index of the product and second number indicates error in shape of the product compared to the dimension entered by user as:

5.4.8.22   Certain amount of 'dimension fine-tuning' should be done by increasing or decreasing the values against the parameter to minimize error factor in shape, tolerance, foreign, color spot (refer to window given in point no.5.4.8.16)

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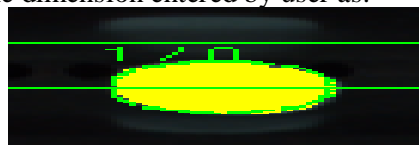| **STANDARD OPERATING PROCEDURE**	
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5.4.8.23	Then select the 'tolerance' from the window (refer to point no. 5.4.8.16) setting shall be done as per 5.4.8.18 :
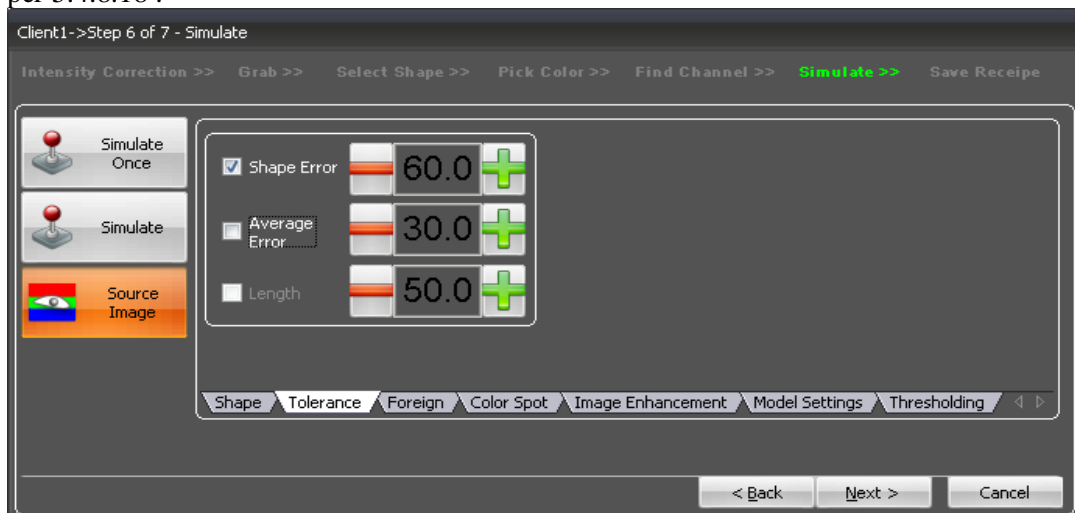
5.4.8.24	**Shape error**: This parameter plays important role in detecting broken,size-variation, shape-variation in products. It works on the principle of 3D shape fitting. Default value of the shape error is 60, this value can be decreased to 10-20 to detect product more precisely.

5.4.8.25	Then select the 'foreign' from the window (refer to point no.5.4.8.20) setting done as per 5.4.8.18 :

5.4.8.26	**Area:** This is the size of the foreign particle/product to be detected. This value is size in pixels.

|	
5.4.8.27	**Image Difference:** This is the intensity difference of foreign product to the base plate. This value can be kept as default during simulate, whereas it can be increased gradually if unwanted foreign detection is observed during inspection. Also it can be decreased if any dark foreign product is not been detected by the camera.

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5.4.8.28	**Product Offset Vertical / Horizontal**: Foreign product is anything other than the tablet/capsule.Now, here if we avoid tablet/cpsule its mirror is also foreign for the camera. But this values are adjusted by software itself according to the dimension of the product.
5.4.8.29	Then select the 'color spot' from the window (refer to point no 5.4.8.22) setting done as per 5.4.8.18:
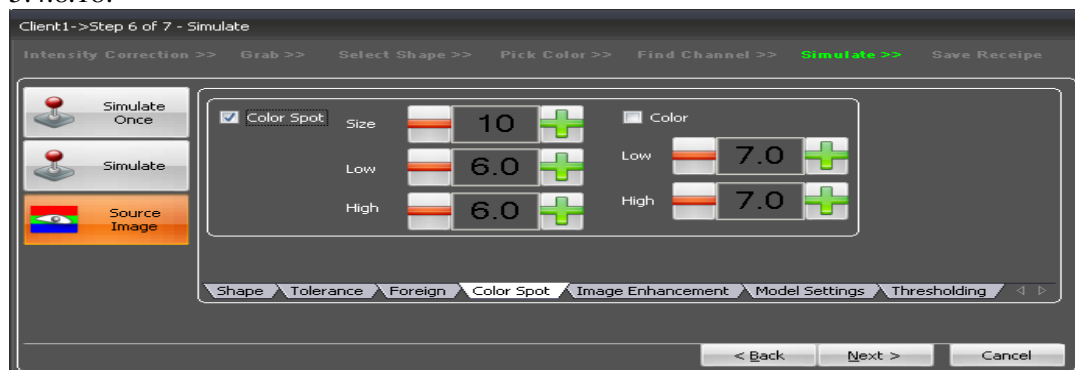
5.4.8.30	**Color Spot- Low :**This parameter is used to inspect dark spot on the product as compared to the actual color of the product
5.4.8.31	**Color Spot-High**: This parameter is used to inspect bright spot/chipping on the product as compared to the actual color of the product.
5.4.8.32	**Color- Low :**This parameter is used to inspect overall drop in intensity of tablet/capsule color.
5.4.8.33	**Color-High:** This parameter is used to inspect overall rise in intensity of tablet/capsule color.
5.4.8.34	Values of Image enhancement, Model setting are automatically set by the software.
5.4.8.35	Then taught all the camera by selecting 'next' button and by following same procedure as mentioned from point no. 5.4.8.1 to 5.4.8.31. All the parameters that user has set for current camera will be carried forward to the next camera for convenience of user.

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5.4.8.36   After teaching the camera 4 , select 'next' from lower right side of screen and new window will open as:

5.4.8.37   Enter the required recipe name in field given against "Recipe Name" and press 'finish' button to save the model.

5.4.9   Now select the 'inspect' from the main window (Refer to point no.5.4.6)as below given:

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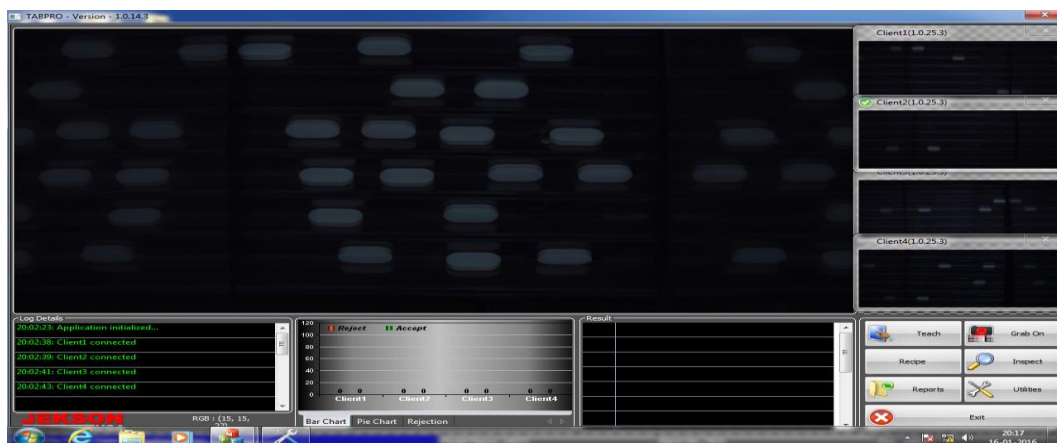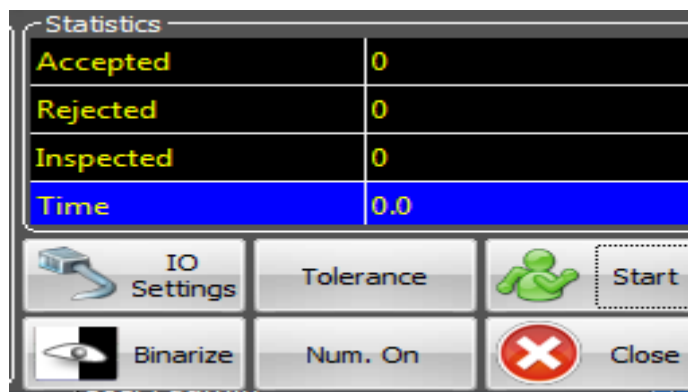|	STANDARD OPERATING PROCEDURE	
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5.4.10   Select the 'inspect' and new window will be displayed with various buttons are provided:

5.4.10.1   **I/O SETTING**: This button is used to configure the timing of air blowing for rejection mechanism. Once this timing is set user need to validate that the timing that is set is working properly for particular product.
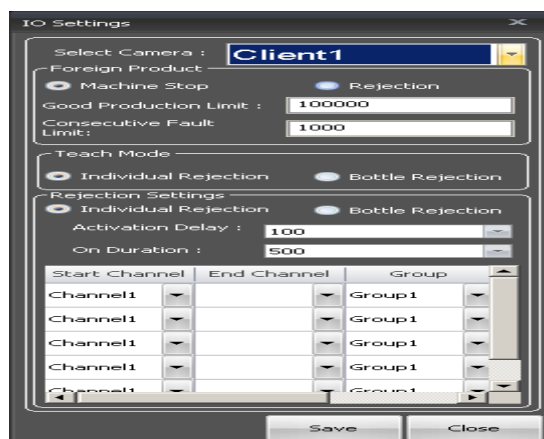
5.4.10.2   **Tolerance** :This button is used to set various defect detection tolerances. This can only be used in inspection stop mode.

5.4.10.3   **Start** :This is a toggle button (Start/Stop) use to start the inspection after entering valid batch number.

5.4.10.4   **Binarize** :This is also a toggle button (Binarize/Source), used to toggle image view from color image to binarize image (black & white).

5.4.10.5   **Background Analysis** :Provides the last 1000 images of the recent inspection tablet/capsules.

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5.4.10.6   **Close** :This button will exit from inspection page and will transfer to the main screen.

5.4.10.7   Now click on the start button following screen will be displayed as given below:
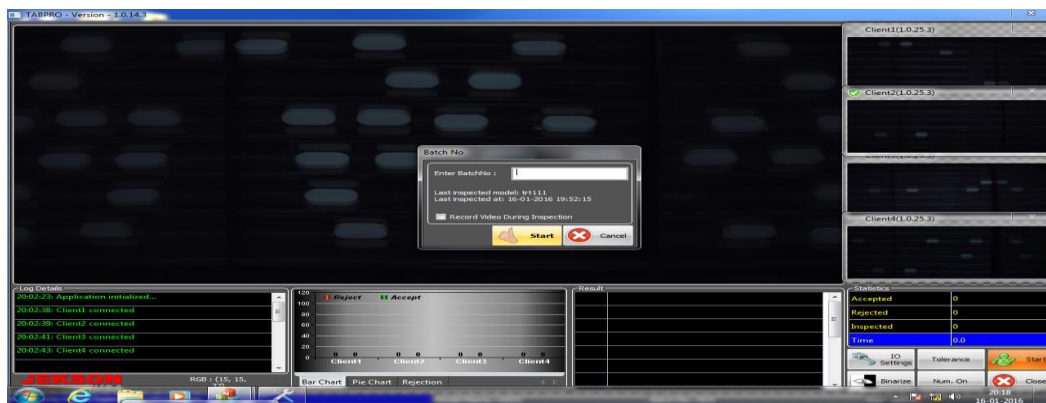
5.4.10.8   Enter the Batch No. in field given against "Batch No." and press start button new window will be displayed as give below:

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5.4.10.9	Now click on view all following screen will be displayed as given below This view is recommended to use during inspection which gives a better visualization to user:
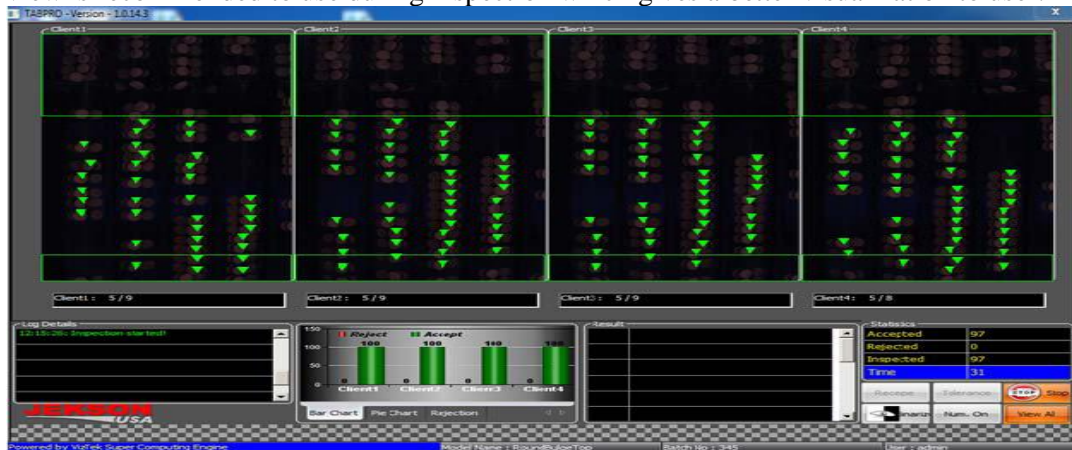
5.4.11	**Digitizer Setting**:This button is used to set camera settings like camera shutter, gain (sensitivity), brightness, red-green-blue balance (white balancing). This setting are stored model/recipe wise.

5.4.12	**Add : Ons**: This is used to enable some additional settings like Event-Logger for recording every user events done in TABPRO.
5.4.13	**I/O Setting** : This button is used to change various I/O settings e.g. output duration of solenoid valve.
5.4.14	**21CFR** : This button opens 21CFR utility of use management
5.4.15	**Closer**: It takes user back to main screen.
5.4.16	**Exit** :This button exits the application after accepting confirmation from the user.
5.4.17	**Recipe Loading:**

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5.4.17.1   Select the 'recipe' option from the main window as :

5.4.17.2   All the list of recipes will be displayed on screen and touch the desired recipe from the window and then touch the 'select' option from main window.

5.4.17.3   Now select the 'inspect' option from main window and new window will be displayed as:

5.4.17.4   Select the 'start' from the above window and new window will be ask for batch number as per point no.5.4.10.7.

5.4.17.5   Enter the desired batch number and press 'ok'.

5.4.17.6   Now machine will be ready for running.

5.4.18   Camera inspection system shall inspect following defects for tablets:

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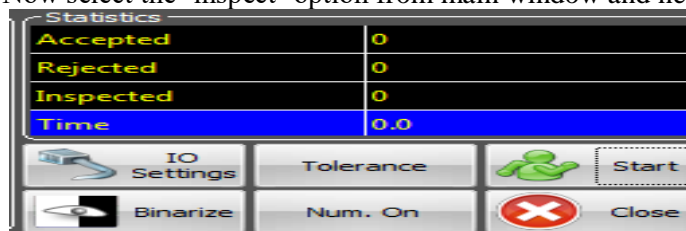|		
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5.4.18.1	Broken tablets.
5.4.18.2	Diameter/length variation.
5.4.18.3	Shape variation.
5.4.18.4	Colour spot on the tablets
5.4.18.5	Chipping in coated tablets
5.4.18.6	Foreign products/objects
5.4.18.7	Colour variation tablets
5.4.18.8	In case of capsules:
5.4.18.9	Foreign products/objects/missing body capsule.

5.4.19	**Camera Challenge Test :**
5.4.19.1	**Challenge Test For Broken Tablet:**
5.4.19.1.1	Pass the good tablets from all the four cameras one by one.
5.4.19.1.2	All the camera must pass all good tablets.
5.4.19.1.3	Record the observation in Annexure-I.
5.4.19.1.4	Pass the broken tablet from all the four cameras one by one.
5.4.19.1.5	All the camera shall pass challenge test if broken tablets detected and rejected by the rejection mechanism at the rejection point.
5.4.19.1.6	Record the observation in Annexure-I.
5.4.19.1.7	Record the number of tablets taken and destroyed during challenge test in Annexure-I.

5.4.19.2	**Challenge Test For Capsule:**
5.4.19.2.1	Pass the good capsule from all the four cameras one by one.
5.4.19.2.2	All the camera must pass all good capsules.
5.4.19.2.3	Record the observation in Annexure-I.
5.4.19.2.4	Pass cap part (capsule without body) of capsule from all the four cameras one by one.
5.4.19.2.5	All the camera shall pass challenge test if cap part of capsule detected and rejected by the rejection mechanism at the rejection point.
5.4.19.2.6	Record the observation in Annexure-I.

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5.4.19.2.7   Record the number of capsule taken and destroyed during challenge test in Annexure-I.

5.4.20   White color teflon coated vibration plates beneath the camera will be used for facillating the teaching of products having teaching related hindrance due to superimposed image of product on vibration plate.

6.0   ABBREVIATION (S)

6.1   SOP - Standard Operating Procedure

6.2   MMI – Man Machine Interface

6.3   S.S- Stainless Steel

6.4   V/V – volume/volume

6.5   IPA- Isopropyl alcohol

6.6   SLS- Sodium Lauryl Sulphate.

7.0   REFERENCES (S):

7.1   SOP: Making entries in equipment usage and cleaning log sheet.

7.2   SOP: Cleaning of production area.

8.0   ANNEXURE:

Annexure no.	Tittle of Annexure	Format no.	Mode of Execution
Annexure-I	CHALLENGE TEST FOR CAMERA INSPECTION SYSTEM (JEKSON VISION)		Control copy

9.0   DISTRIBUTION (S)

9.1   **Master Copy**   : Quality Assurance

9.2   **Controlled copy (S) :** Production department,(02) QA department(01)

9.3   **Reference copy (S) :** Production department (03)

10.0   REVISION HISTORY:

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S.No.	Version No.	Change control No.	Reason (s) for Revision	Details of Revision	Effective Date

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ANNEXURE I

CHALLENGE TEST FOR CAMERA INSPECTION SYSTEM(JEKSON VISION) AT BULK COUNTER MACHINE

Frequency : At start, after every four hours and at end of operation.													
		CHALLENGE TEST										RESULT OK/NOT OK	Done BY	VERIFIED BY
		* For good tablet / capsule				# For Broken Tablet / For missing body capsule								
DATE	TIME	* Camera 1	* Camera 2	* Camera 3	* Camera 4	# Camera 1	# Camera 2	# Camera 3	# Camera 4	Number of Tablets/capsule	Number of Tablets/capsule destroyed			

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 * Mark **''OK''** in observation if tablet / capsule **'pass'** by camera and mark **''Not OK''** in observation if tablet / capsule rejected by camera.
 # Mark **''OK'''** in observation if tablet / missing body of capsule **'rejected'** by camera and mark **''Not OK''** in observation if tablet / missing body of capsule **'pass'** by camera.