
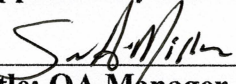
	Standard Operating Procedure		SOP Number B-507	Revision 5
	Encapsulation Machine Model NJP-2000 and NJP-3200		Effective Date <i>05/01/22</i>	Page Page 1 of 28
Written by/ Date <i>Lance Nielsen 04/18/22</i>		Reviewed by/ Date  <i>04/20/22</i>		Approved by/ Date  <i>04/25/22</i>
Title: Maintenance Manager		Title: Production Manager		Title: QA Manager

1.0 Purpose

This procedure defines the process for setup, operation, and cleaning of the encapsulation machine model NJP-2000 and NJP-3200.

2.0 Scope

This procedure applies to the encapsulation machine model NJP-2000 and NJP-3200 in operation at Ion Labs, Inc.

3.0 Responsibility

- 3.1 It is the responsibility of Production (Compression) personnel to follow this procedure.
- 3.2 It is the responsibility of the department supervisor/manager to implement this procedure and to ensure that the procedure is being followed.

4.0 Definitions

- 4.1 **BPR** – Batch Production Record
- 4.2 **QC** – Quality Control

5.0 References

- 5.1 B-103, SOP, Small Parts Cleaning and General Sanitation
- 5.2 B-111, SOP, Cleaning of Manufacturing/Production Areas and Equipment

6.0 Procedure

- 6.1 Machine Preparation

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6.1.1 Machine preparation consists of two steps:

6.1.1.1 Loading the capsules

6.1.1.2 Filling the powder hopper

6.1.2 How to load capsules

6.1.2.1 Ensure that the capsules to be loaded are the correct size for the parts on the machine.

6.1.2.2 Remove the lid from the capsule container.

6.1.2.3 Insert the capsule filler vacuum hose, which will automatically load the machine when capsules are low in the hopper.

6.1.3 How to fill the powder hopper

6.1.3.1 Insert the powder filler vacuum hose, which will automatically load the machine with powder when the hopper is low.

6.1.4 After the capsules are loaded and the powder hopper is filled, the machine is ready for operation.

6.2 Machine Setup

6.2.1 Refer to Attachment 1 Section 5 Operation Instructions for machine setup for the appropriate size capsule change parts. Follow the step-by-step setup instructions directly as the manual states.

6.3 Machine Startup and Operation

6.3.1 Refer to Attachment 1 Section 5 Operation Instructions and Section 6 Startup and Operation of Machine for the basics behind the machine operation. Follow the step-by-step operation instructions directly as the manual states.

6.3.2 Refer to Attachment 1 Section 7 Table: Familiar Malfunction Obviating for Operation Troubleshooting.

6.4 Machine Maintenance and Cleaning

6.4.1 Refer to Attachment 1 Section 6 Maintenance and Cleaning of Machine for the step-by-step instructions for lubrication as stated in the machine manual.

6.4.2 Minor Cleaning

6.4.2.1 Turn of the machine and disconnect the power supply.

6.4.3 Refer to SOP B-103 Small Parts Cleaning and General Sanitation to follow appropriate cleaning steps for small parts.

6.4.4 Refer to SOP B-111 Cleaning of Manufacturing/Production Areas and Equipment to follow the cleaning procedure applicable to this type of equipment.

7.0 Revision History

Revision	Date	Description of Changes	CCR #	By
1	07/15/13	New	-	-
2	11/13/13	Updated SOP to include new machine model	13-1034	S. Grimes
3	02/16/16	Biennial review: Updated SOP format. Changed QA to QC.	16-0149	K. Burris
4	01/28/19	Scheduled review: Removed obsolete definitions. Added references. Revised section 6.4.	19-0103	K. Burris
5	04/15/22	Update procedure to correct model numbers on machines we currently have in-house. Change cleaning section. Update logo and format.	CC-22-0188	J. Mireles

8.0 Attachments

8.1 Attachment 1 -- Machine Manual: Illustrations and Instructions

Attachment 1 – Machine Manual: Illustrations and Instructions

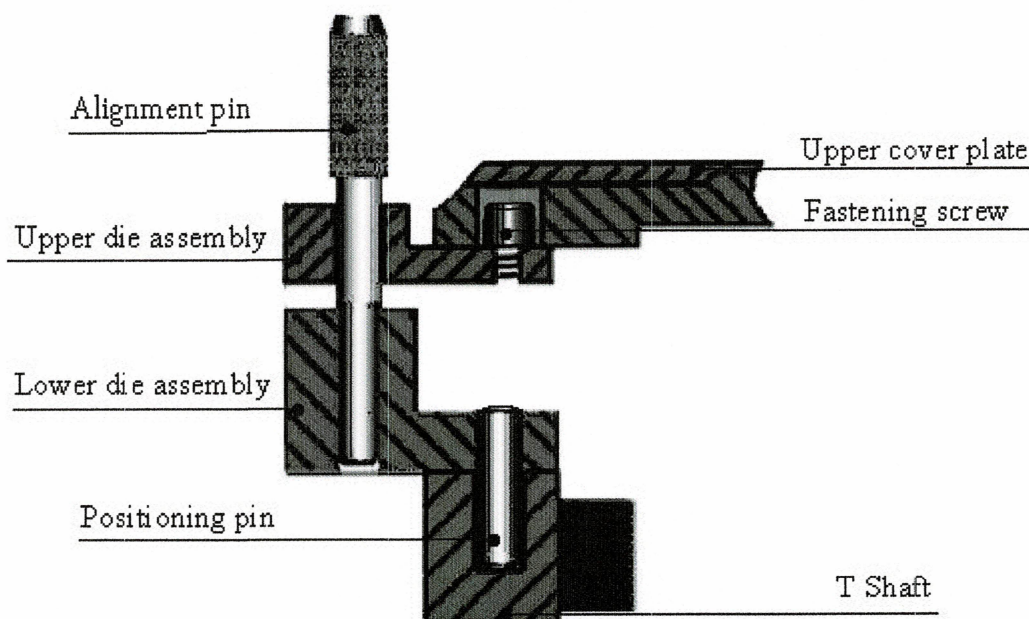
To change the size of capsule, replace corresponding upper and lower segment assemblies, capsule feeding plate, horizontal fork, vertical fork, straightener, filling rod and dosing disk.

Remark: capsule size 00#~000# also needed replace capsule locking and ejecting pins.

Upper and lower segment alignment (refer to Fig. 6)

Caution: Move the arbor wheel of the main motor with hand crank when replacing the upper and lower segments. Remove the regulating rod before rotating!

First install all of the lower segment assembly including tightening the screws. Then at station 10 install the upper segment assembly to align their concentricity; insert the alignment pins in to the upper and lower segments in the two holes at the outside of the segment; then tighten the screws. Make sure the alignment pin rotates freely in the holes of upper and lower segment assemblies. Then with the alignment pins verify that the other holes are aligned.



Attachment 1 – Machine Manual: Illustrations and Instructions

Replace Capsule-Feeding Unit (refer to Fig. 7, 8)

Disassembly

Loosen two fastening screws on capsule hopper, remove the screws and the hopper;
Move arbor wheel of main motor with hand crank and let capsule-feeding plate go to the highest position;

Loosen four fastening screws on capsule-feeding plate, remove the capsule-feeding plate;

Loosen two fastening screws on straightener, remove the straightener;

Loosen fastening screws on horizontal fork, remove the horizontal fork;

Replacement and Installation

Align two positioning holes of straightener with the pins of casing, and tighten the screw;

Align two grooves of horizontal fork with the pin of lateral sliding plate and install on the sliding plate;
adjust to feeding capsule to the optimum position and tighten screw (generally feed the body of capsule to the outer end surface of straightener);

Align two positioning holes of capsule-feeding plate and rear plate with the pin of straight sliding plate, and tighten screw;

Install capsule hopper and tighten screw (make sure the clearance around square groove and capsule-feeding plate should be uniform);

After replacing capsule feeding parts, put some empty capsules in the hopper and start vacuum pump, open capsule release unit, rotate the machine with hand crank to ensure normal capsule separating.

Attachment 1 – Machine Manual: Illustrations and Instructions

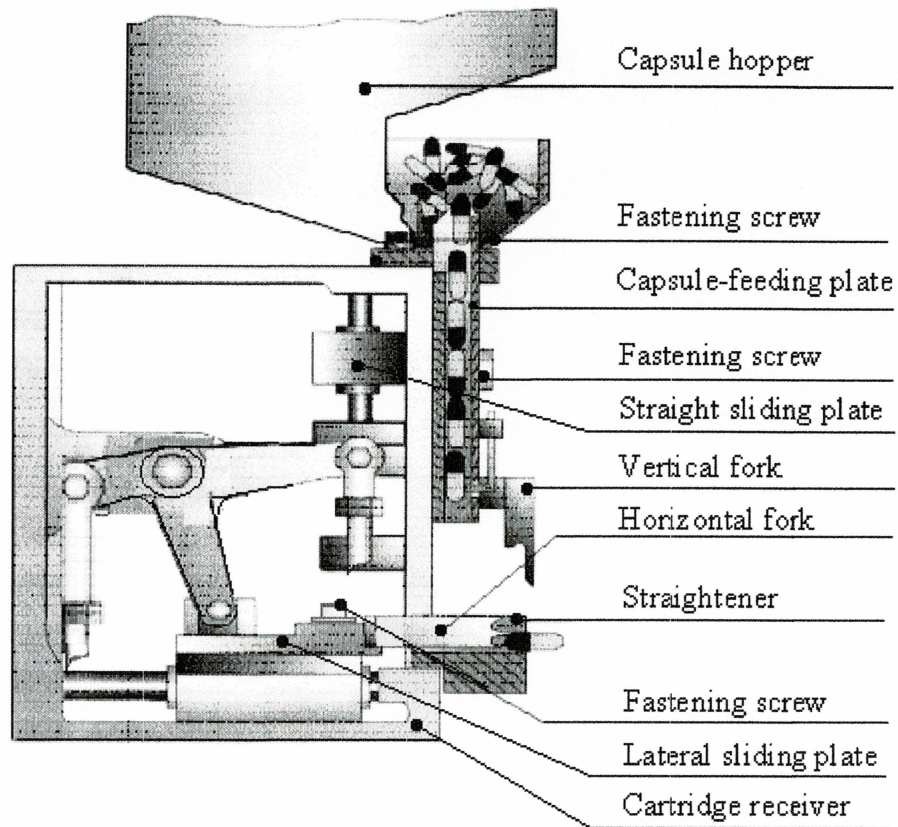


Fig. 7 Capsule-feeding Mechanism

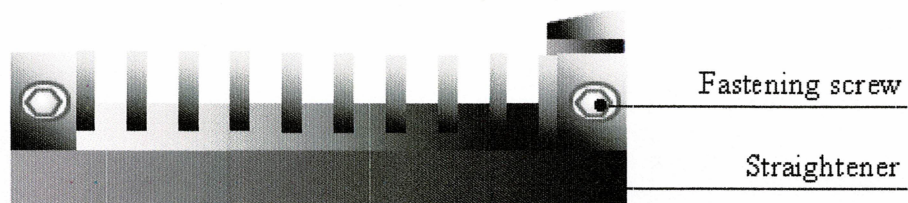


Fig.8 Straightener

Attachment 1 – Machine Manual: Illustrations and Instructions

Replace Dosing Disk and Filling Rod (refer to Fig. 9, 10, 11)

Loosen fastening screws and raise powder hopper by the resilience of spring;

Absorb residual power in power-store ring with dust collector;

Rotate the arbor wheel of main motor with hand crank until the filling rod holder reaches the highest position;

Loosen and remove acorn nut, rotate knob clockwise (refer to Fig. 21) to uplift and remove press plate and filling retainer;

Loosen the screws on the small press plate with square hole under the retainer and remove the filling rod. After replacing the filling rod, replace the small press plate and fasten the screw;

Loosen the screw on the baffle, then draw out baffle upwards (refer to Fig. 16), loosen two screws on both sides of powder-storing ring cover and remove baffle outside powder-storing ring, loosen four fastening screws of power-storing ring and remove the ring and cover plate from dosing disk gently from the side without removing filling rod holder;

Loosen three fastening screws of dosing disk with special wrench, and remove dosing disk and powder-storing ring.

Clean the powder in the tray and replace alternate dosing disk of another specification. Do not tighten three fastening screws for the time being;

Rotate main motor by hand crank until the filling rod holder reaches the lowest position, insert two regulating rods of dosing disk separately into multiple holes of filling rod holder at different positions. Gently rotate dosing disk so as to insert the regulating rod easily, carefully tighten three screws in turn. Should the regulating rod be unable to insert in dosing disk hole easily, you must re-adjust until the rod can be inserted easily;

Insert powder-storing ring and cover plate to the precise position from the side, rotate the machine with hand crank and fasten four screws of powder-storing ring. If newly replaced dosing disk is thicker than the former one, lift the powder wiper correspondingly.

Fasten screws of cover plate. Carefully examine the clearance (**0.05~0.1 mm**) between powder wiper and dosing disk with feeler gauge, then tighten fastening screws;
Install filling rod and retainer in their original positions and tighten acorn nut;

Attachment 1 – Machine Manual: Illustrations and Instructions

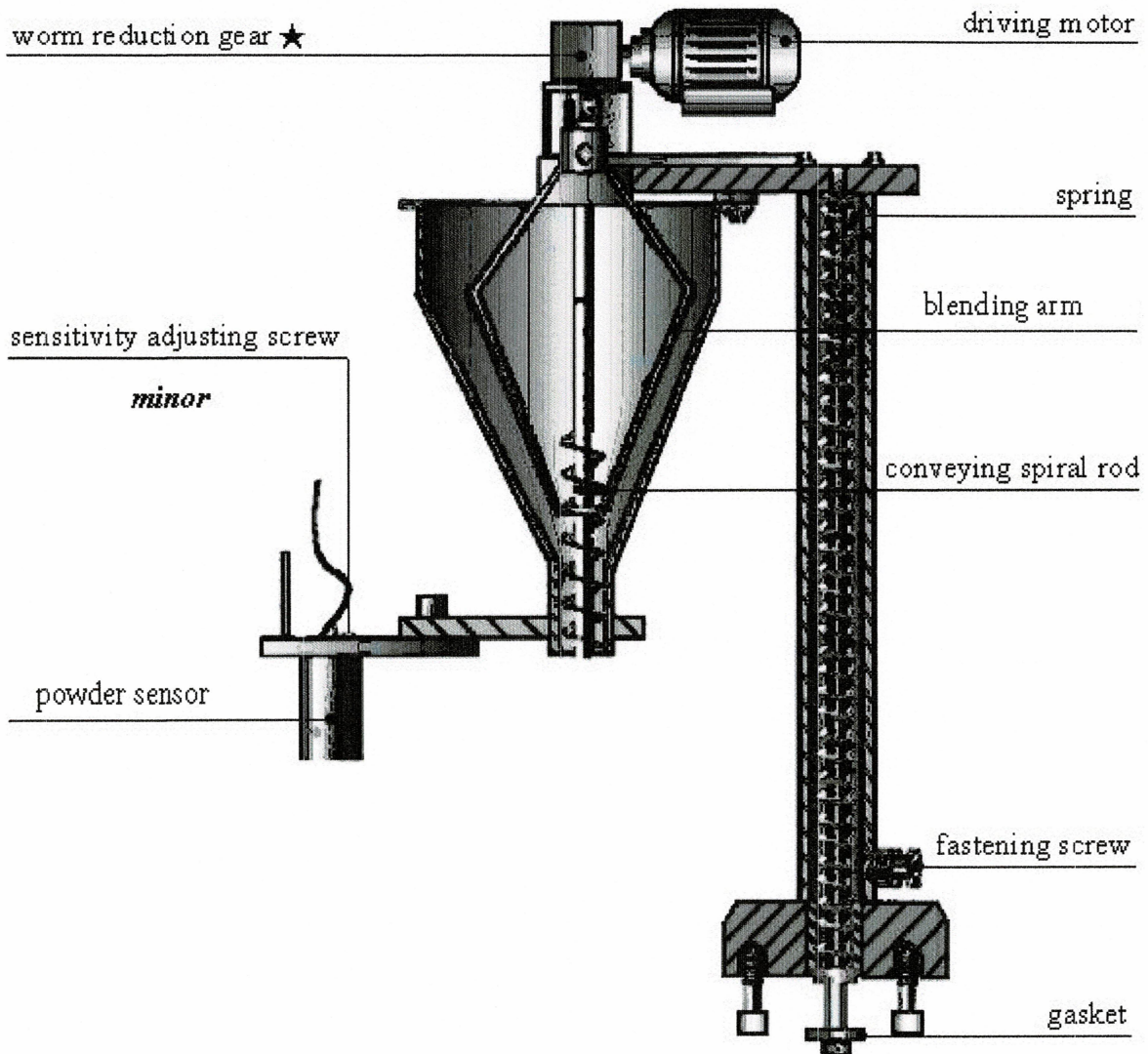


Fig. 9 Powder Feeding Mechanism

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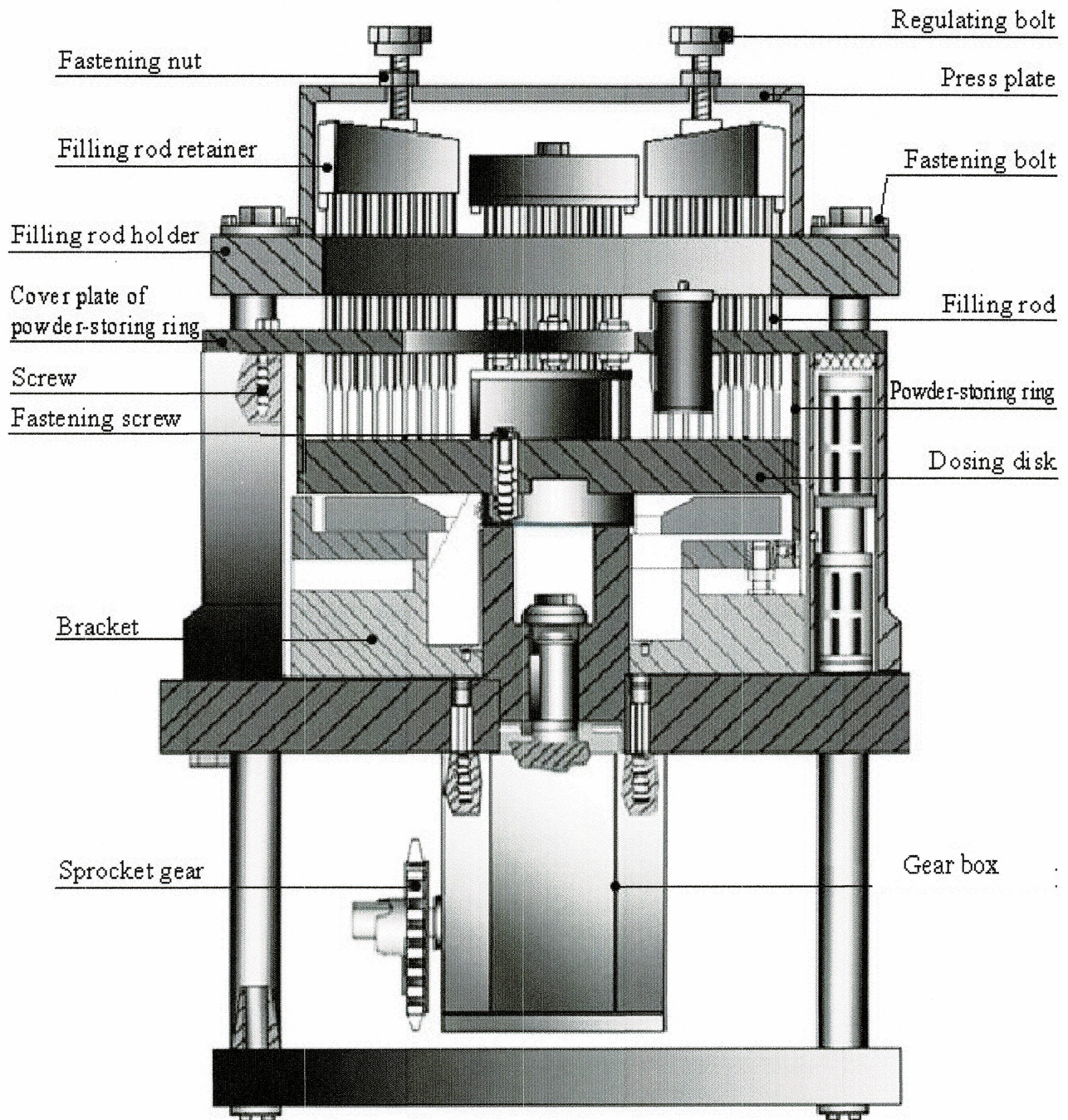


Fig. 10 Dosing Unit

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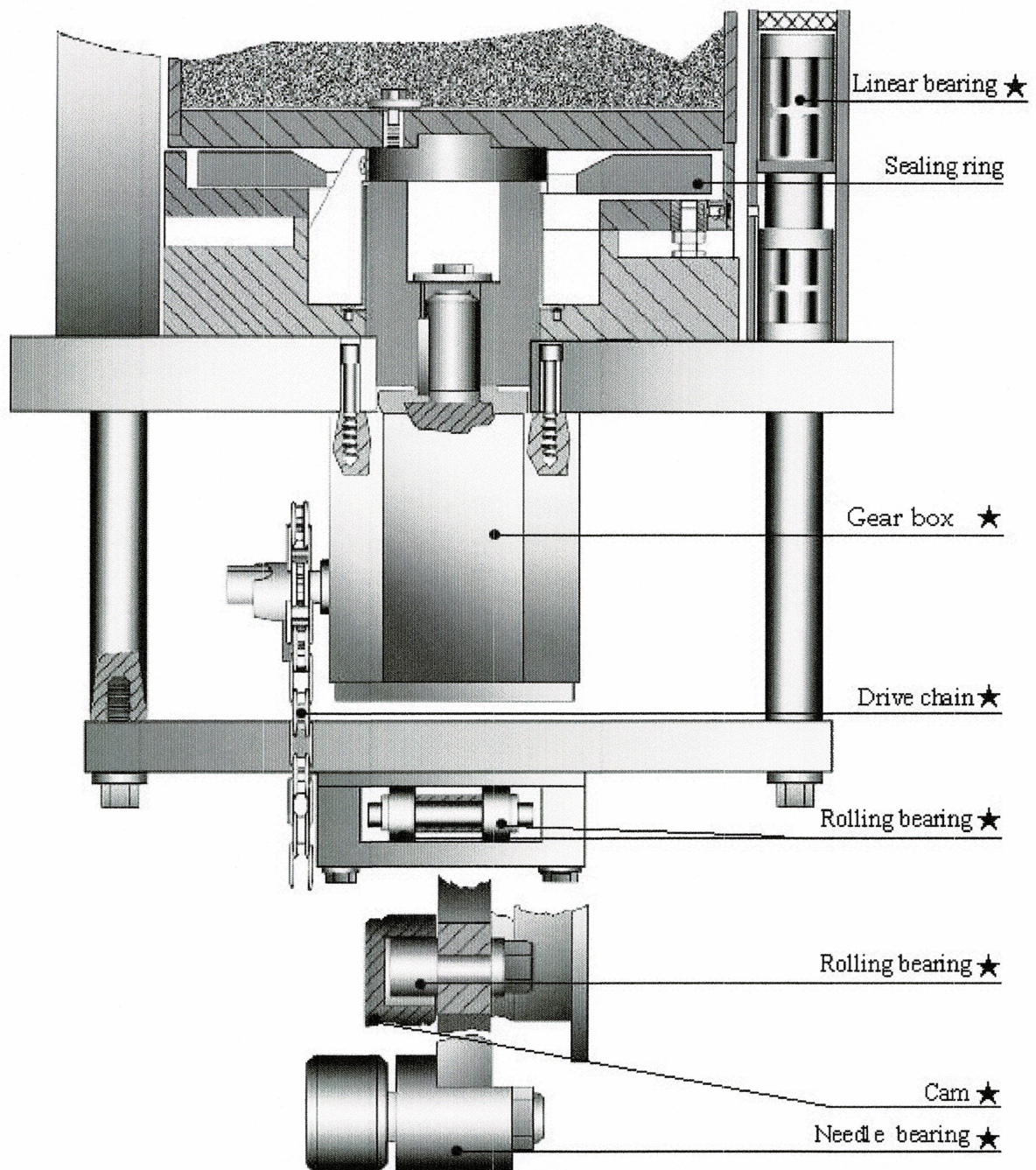


Fig. 11 Driving Mechanism of Dosing Unit

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Adjustment after Replacing Segment Assembly

Whenever replacing the segment assembly, first rotate main motor for 1~2 rotations with hand crank. If anything abnormal happens, stop the machine immediately and locate the problem and fix it.

Adjustment of The Exit of Capsule Hopper (refer to Fig. 12)

The capsule gate installed on the hopper can control the capsule exit by loosening the knob and pulling the baffle up or down According to capsule sizes.

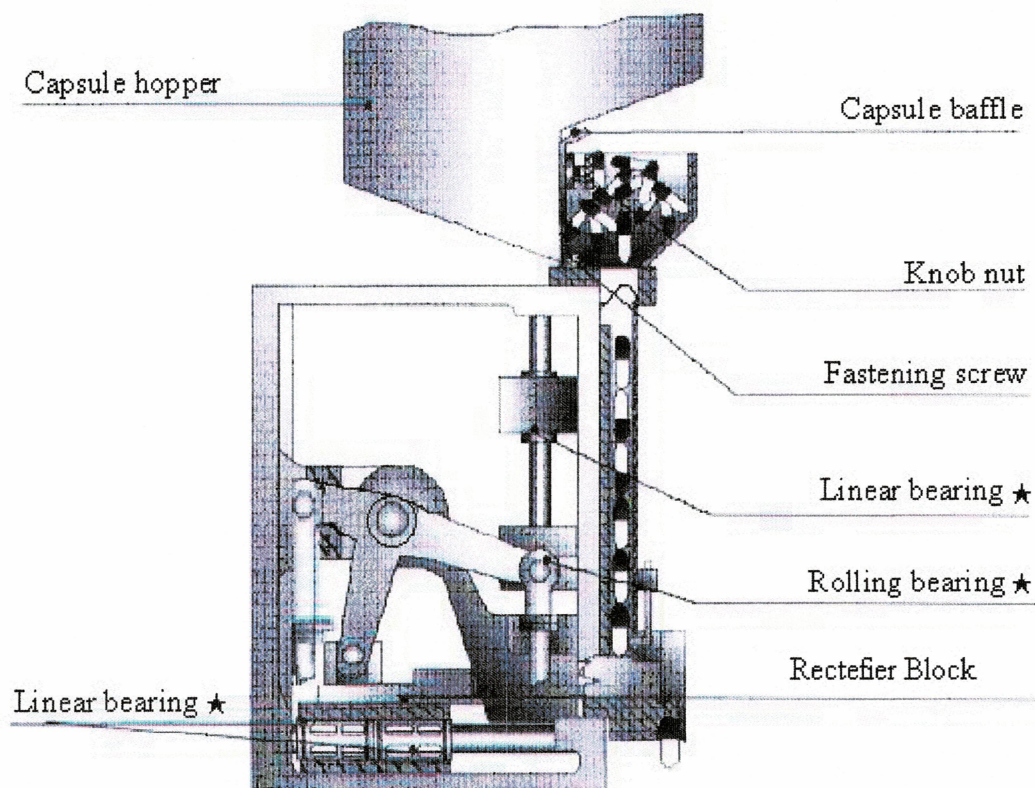


Fig. 12 Feeding Unit

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Adjustment of Capsule-Holding Finger (refer to Fig. 13, 14)

The time of opening and closing capsule-holding fingers ensures that only single capsule should be discharged out of capsule-feeding plate each time. To adjust the timing, loosen the fastening bolts and move the block down or up to allow only single capsule to be discharged each time. Then detain the capsule to be discharged at the position as illustrated below:

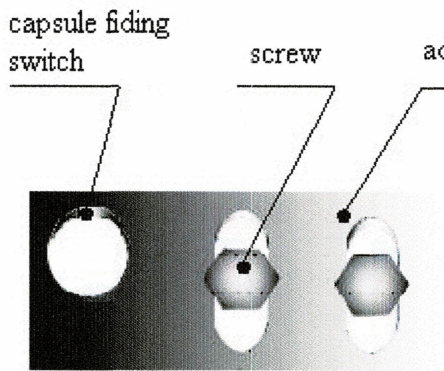


Fig. 13 Adjusting Block

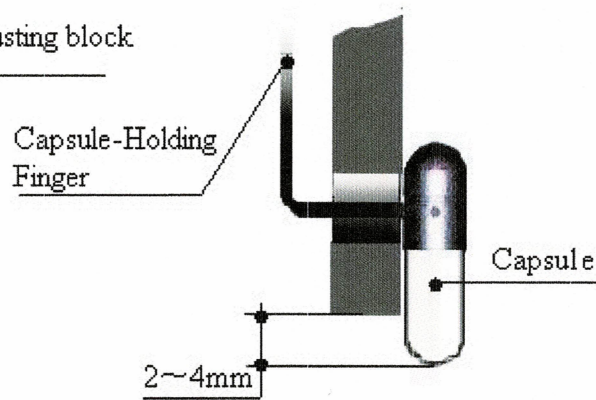


Fig. 14 Capsule-holding finger

Attachment 1 – Machine Manual: Illustrations and Instructions

Adjustment of Vacuum shoe (refer to Fig. 15)

Whenever the machine runs by a station, vacuum shoe goes upwards and downwards; no adjustment is needed in most common case. Should any adjustment is needed, rotate arbor wheel of main motor with hand crank until the vacuum separator reaches the highest position, loosen fastening nuts (left and right thread) on both sides of regulating rod under machine bench, rotate regulating rod to adjust vacuum separator height (**clearance between upper surface of separator and the lower surface of lower die assembly is 0~0.03mm**), and then fasten the nuts. Recheck for several times until proper status is met. Place empty capsules in the capsule-feeding unit and start vacuum pump, rotate machine with hand crank to verify capsule are being separated.

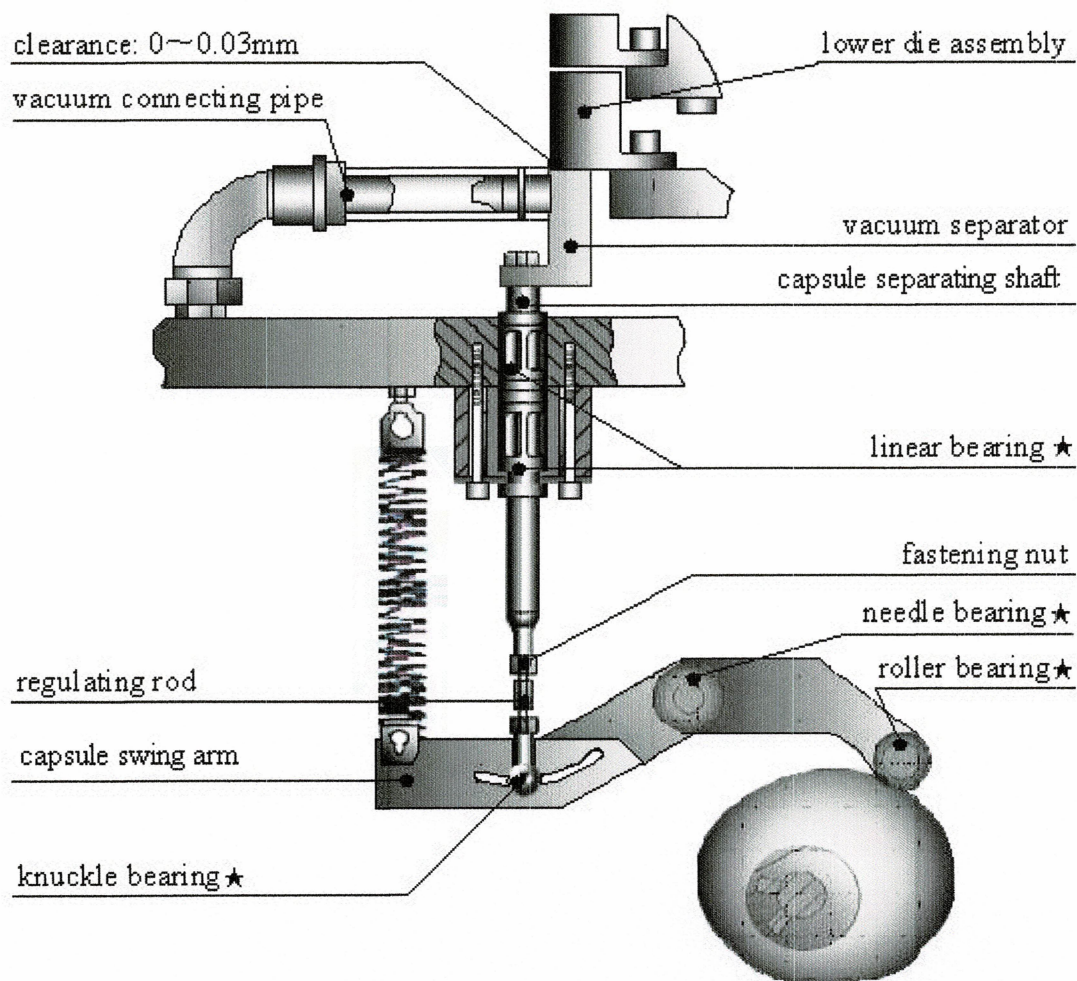


Fig. 15 Adjustment of height of vacuum separator

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Adjustment of The Clearance between Dosing Disk and Sealing Ring (refer to Fig. 16, 17)

The clearance between dosing disk and sealing ring should be preferably 0.03~0.08 mm. With larger particles, the clearance may be adjusted wider. Too narrow of clearance may increase the resistance between dosing disk and sealing ring. Should too much powder leakage or resistance occur in the operation, adjustment the clearance. To adjust the clearance, loosen and remove five screws on the baffle, and loosen fastening screw and nut, even rotate the five regulating bolts carefully one by one to adjust the height of sealing ring, and check the clearance on 3~5 points, ensure every value is the same and five adjusting sleeve connect with sealing ring. After checking, tighten fastening screw at first, then tighten fastening nut; check the clearance again and verified, install the baffle with screw.

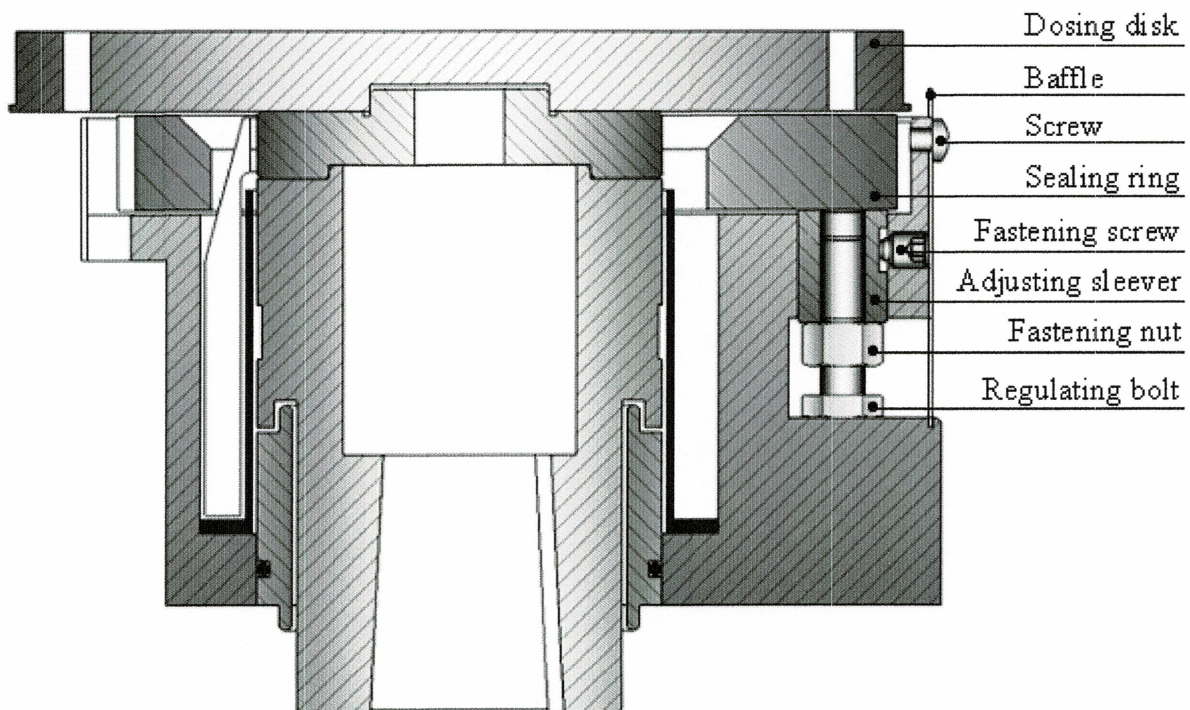


Fig. 16 Structure of Dosing Disk and Sealing Ring

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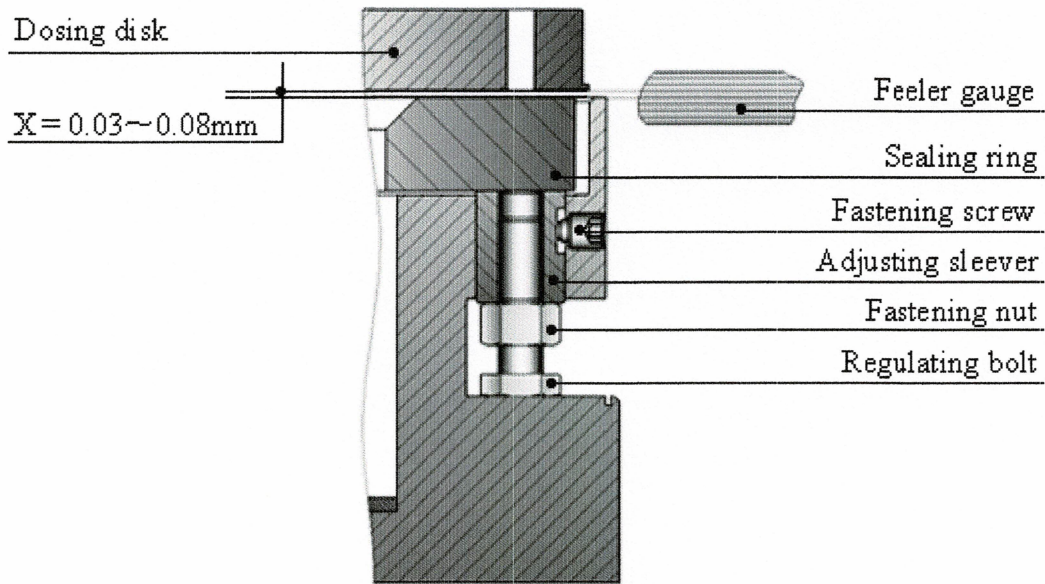


Fig. 17 Adjusting Unit of Dosing Disk

Adjustment of powder wiper clearance (refer to Fig. 18)

Adjust the clearance after replacing dosing disk each time. The clearance should be preferably 0.05~0.1 mm. To adjust the clearance, loosen the fastening nut and rotate adjusting screw to raise or lower the powder wiper. Measure the clearance with feeler gauge and tighten the fastening nut.

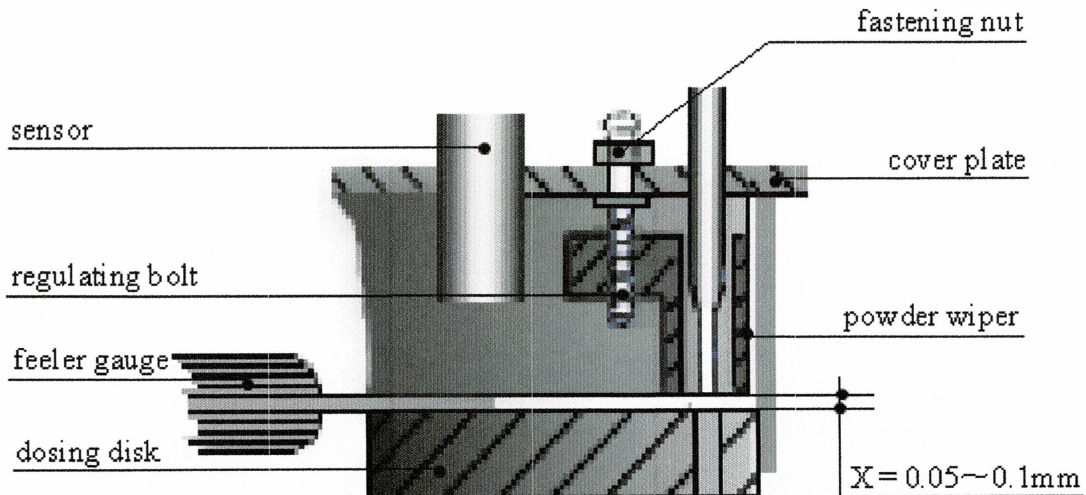


Fig. 18 Clearance between Powder Wiper and Dosing Disk

Attachment 1 – Machine Manual: Illustrations and Instructions

Attachment 1 – Illustrations and Instructions (Cont'd)

Adjustment of The Height of Filling Rod Retainer (refer to Fig. 19, 20, 21)

The density and volume of powder column change with the height of the filling rod. Appropriate adjustment of filling rod height leads to precise volume of powder filling. The depth that filling rod enters dosing disk may be decided upon the reference table and not be too deep. When filling rod holder is at the lowest position, the “0” scale line of retainer represents that the lower surface of filling rod is at the same level as the lower surface of dosing disk, i.e., the numerical reading aligned with the work position line of sight glass is the very height of the lower end surface of filling rod from sealing ring. To adjust the height, loosen the fastening screw on adjusting rod, rotate the knob on the screw stem counterclockwise so as to raise the filling rod, and then rotate the knob clockwise to lower it to desired height, finally tighten the fastening nut. That is to say, adjustment shall be made in the order from high to low.

(The data as follow when the thickness of dosing disk is 18mm)

Station	1	2	3	4	5
Depth into dosing disk	9	5	3	2	0.5

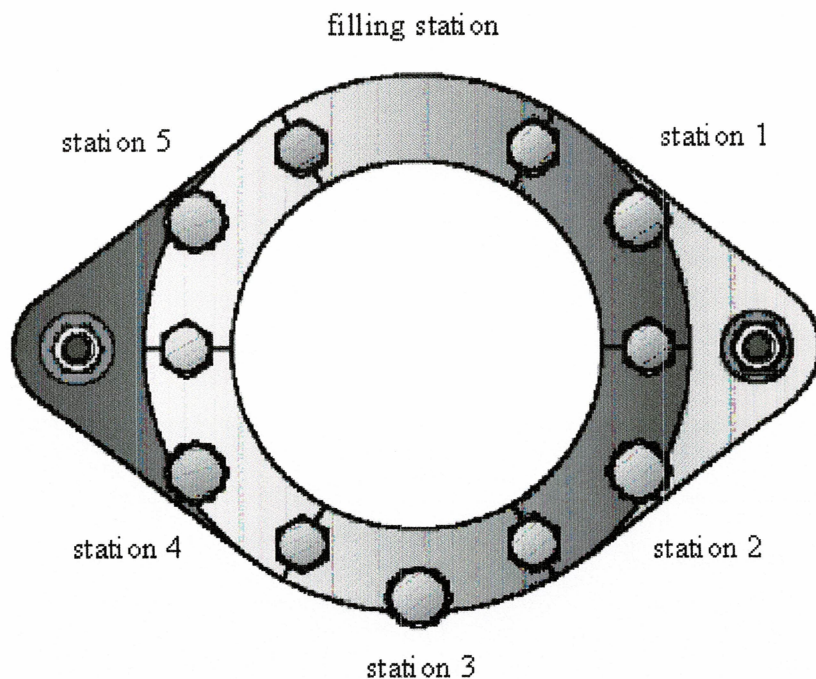


Fig. 19 Layout of Six Stations in Filling Unit

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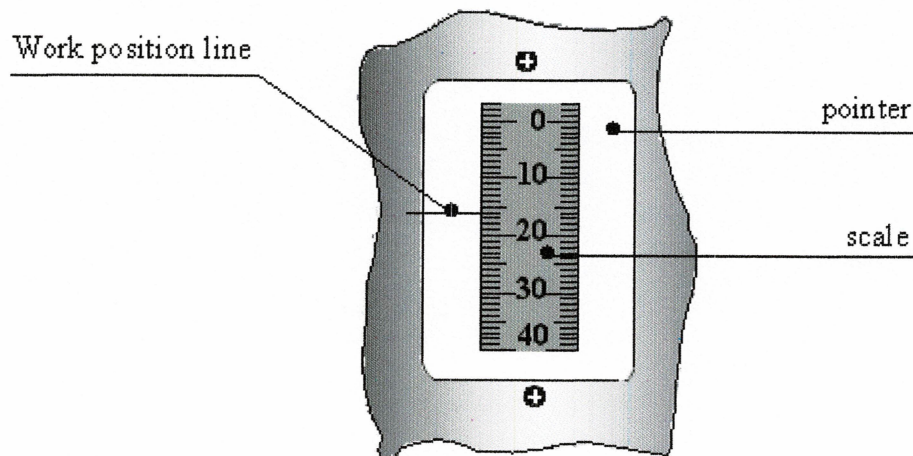


Fig. 20 Scale

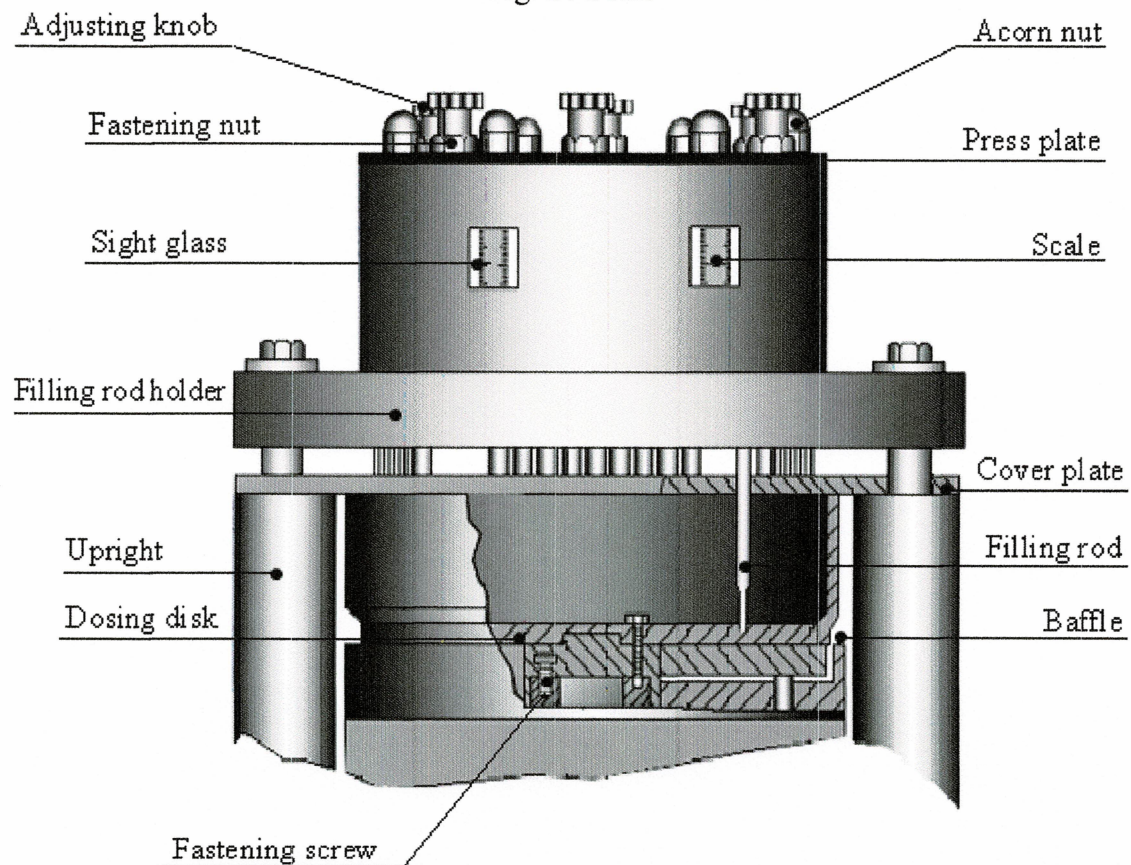


Fig. 21 Adjustment of Filling Rod Height

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Adjustment of Powder Height Sensor (refer to Fig. 22)

Sensor is applied to control the height of powder in the powder-storing ring. The signal emitted by sensor controls the start and stop of feeding motor. Therefore, the height of sensor decides the amount of powder in powder tank. Appropriately adjust the height of sensor according to powder specification and its flowability to obtain precise filling volume. To adjust the height of sensor, loosen the fastening screw on the sensor and raise or lower the sensor. After adjustment, fasten the screw. The screw in the upper part of sensor may control sensitivity. The distance between sensor and powder is 2~8mm.

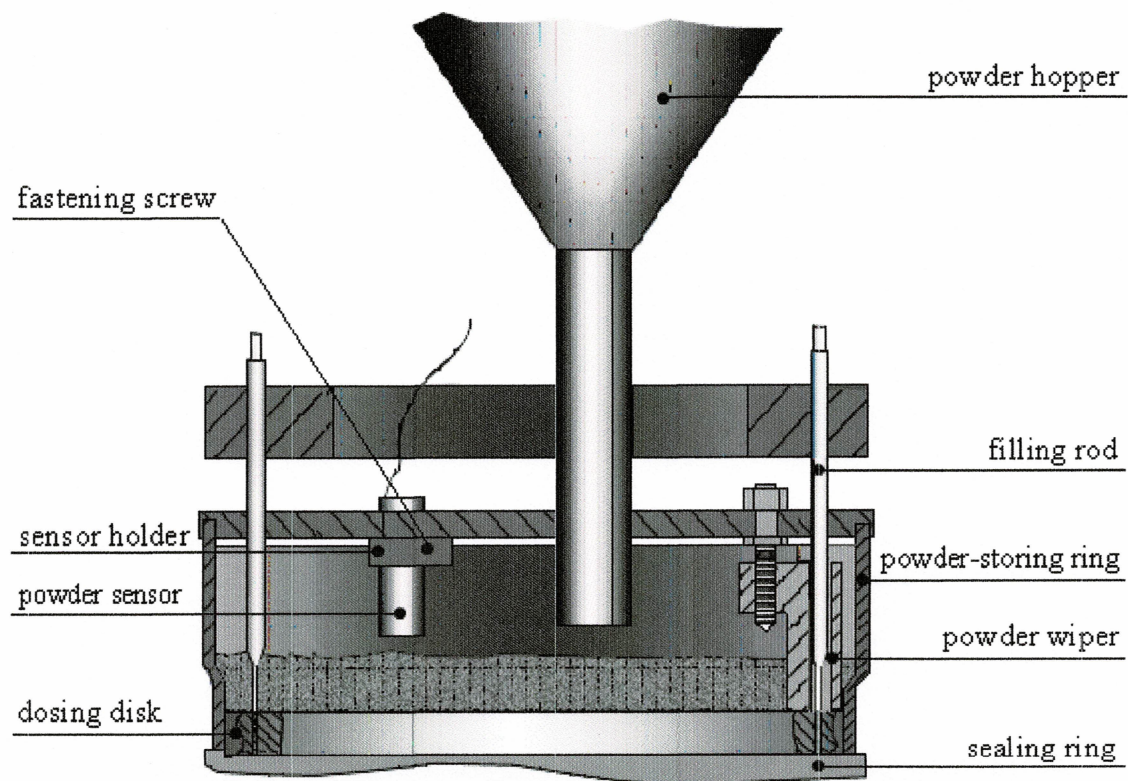


Fig. 22 Adjustment of Powder Height Sensor

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Adjustment of Defect Capsule Rejection (refer to Fig. 23, 24)

At station 6, absorption entrance and the pushrod reciprocating vertically can reject unseparated or other defect capsules in the upper die assembly. When capsule size is changed, this part should be adjusted appropriately. To adjust the height of absorption entrance, loosen fastening screw and adjust absorption to suitable position, then tighten fastening screw. The height of absorption entrance cannot be too low, or it will absorb the separated cap on the upper die assembly hole.

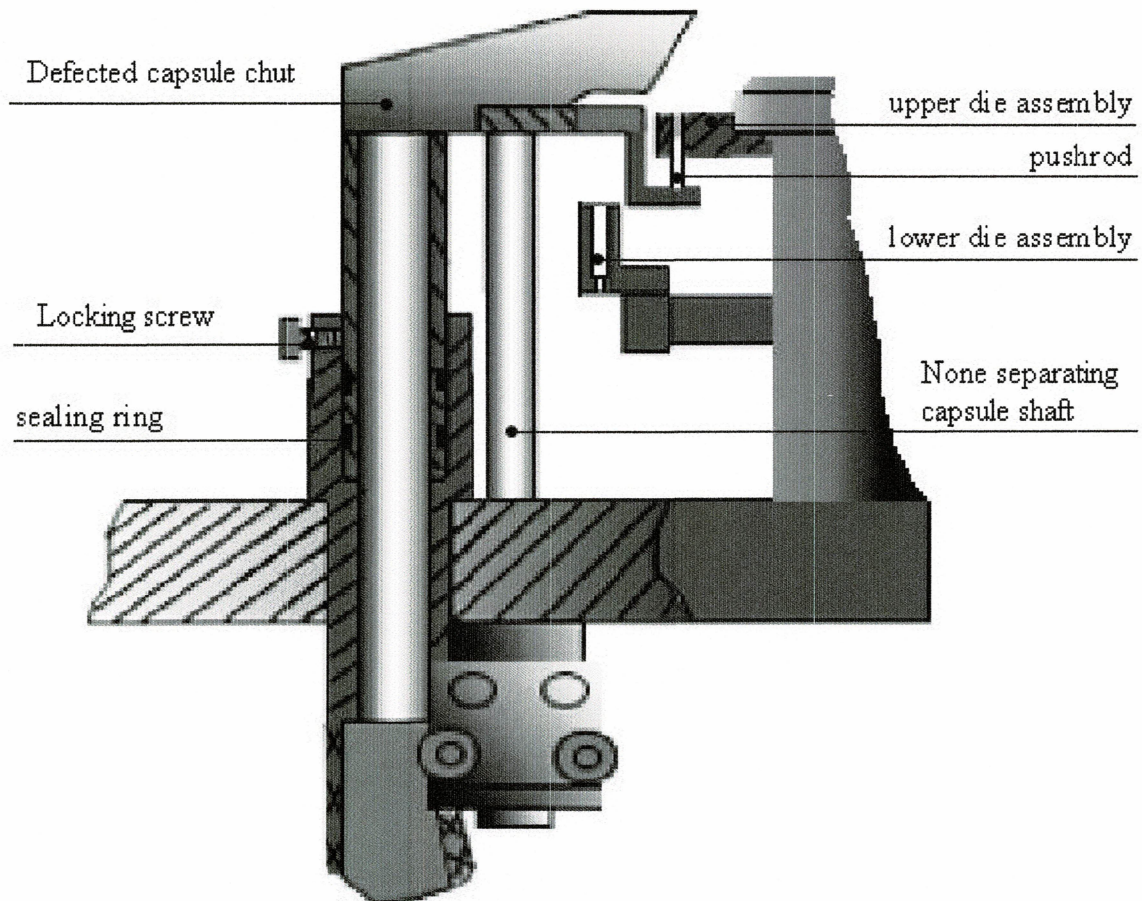


Fig. 23 Mechanism of Defect Capsule Rejection

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To adjust regulating pushrod height, loosen fastening nuts on knuckle bearings on both ends of regulating rod under workbench, rotate regulating rod to adjust pushrod height. Put unsplit capsule in the hole of upper die assembly at Station5 and Station 6, move main motor shaft with hand crank to raise and lower the regulating rod, see to it that defect capsules are successfully absorbed, finally tighten nut. The adjustment of pushrod must be careful to avoid collision between upper and lower die assemblies when pushrod runs vertically.

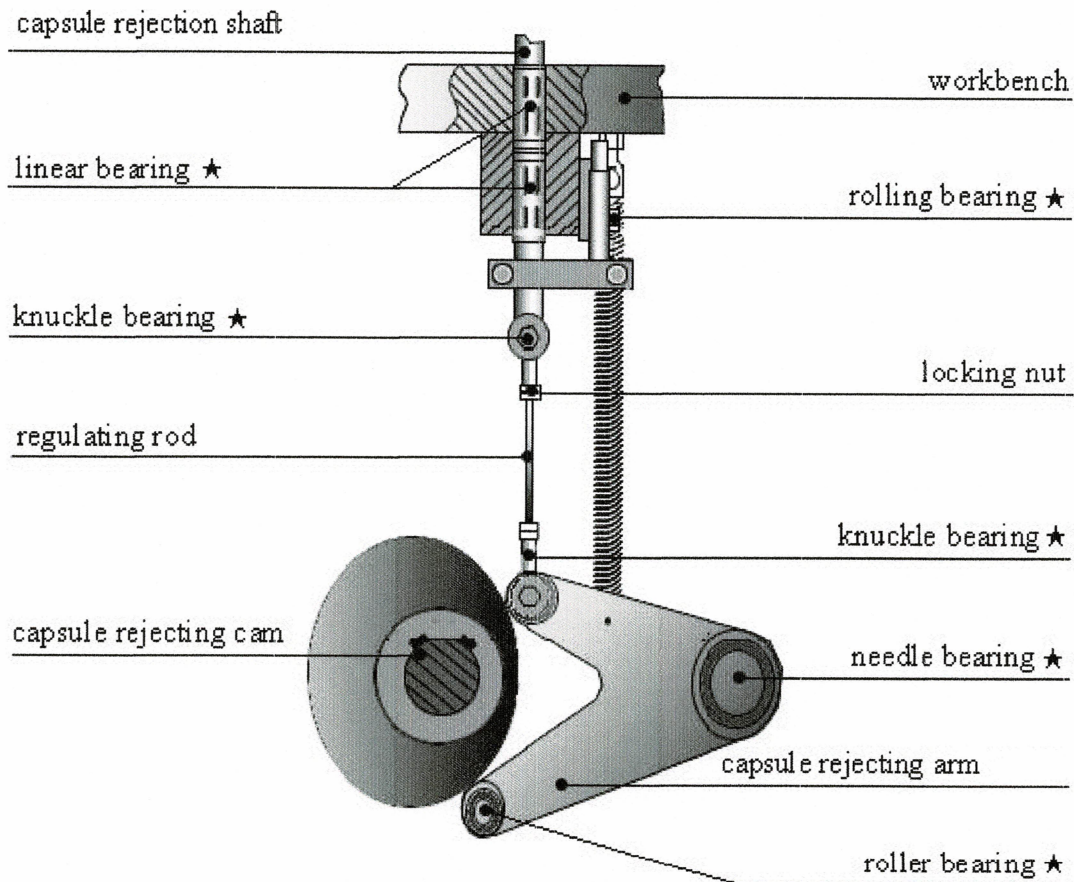


Fig. 24 Driving mechanism for defect capsule rejection

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Adjustment of Capsule Joining (refer to Fig.25, 26, 27)

Adjustment of length of capsule joined shall be made according to the different sizes and lengths or when replacing capsule. The clearance between capsule locking plate and the upper die assembly should be preferably 0.8~1 mm. The clearance can be adjusted by adjusting hand wheel. To adjust, loosen two screws, rotate the hand wheel until the clearance is right, and fasten the screws. To adjust the height of pushrod, place the joined capsule in the segment, adjust the length on the regulating rod to the position that is require to lock the capsule, the locking pin should make contact with the lower part of capsule not. If joining capsule is not normal in the course of locking, e.g., the capsule is too long to join or too short to maintain regular shape, re-adjustment shall be made carefully. After the adjustment, fasten the nut.

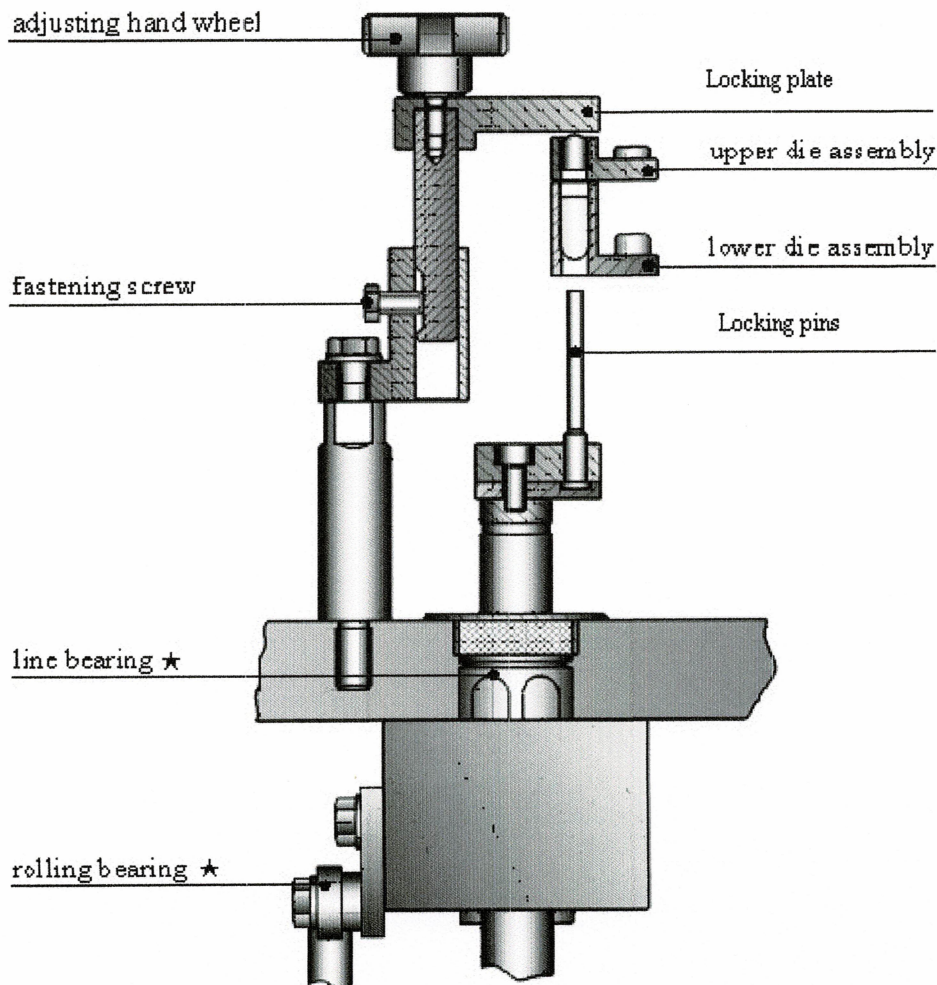


Fig. 25 Mechanism of Capsule locking

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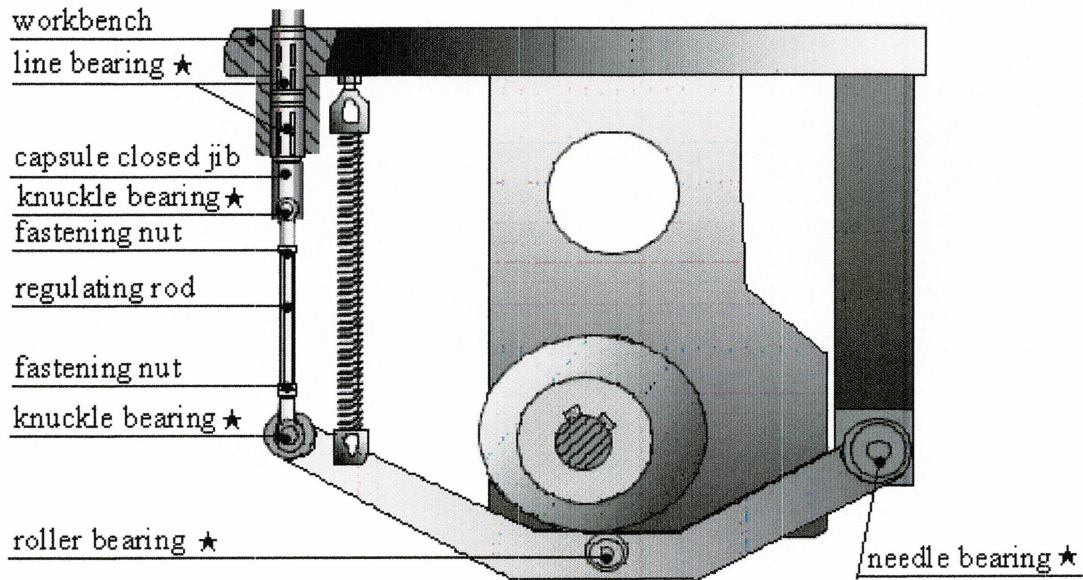


Fig. 26 Driving Mechanism for locking Capsule

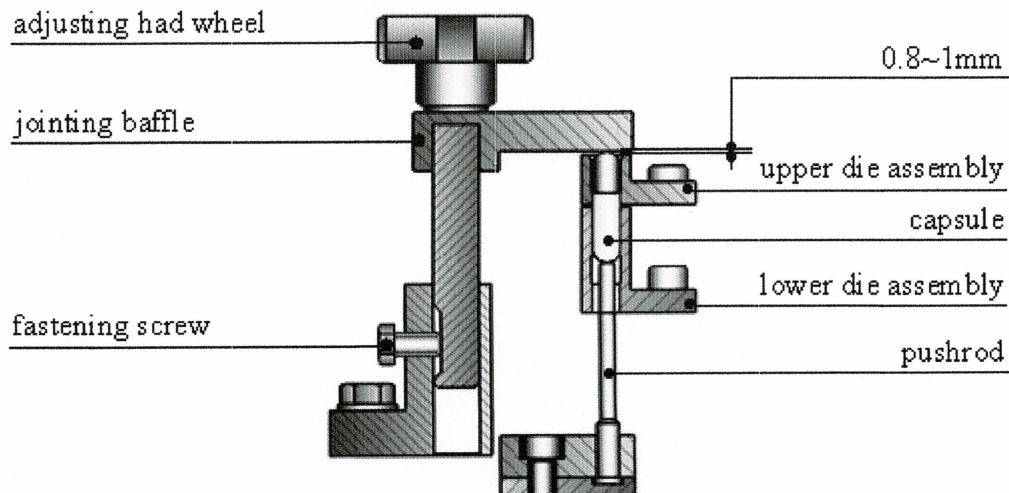


Fig. 27 Clearance between locking plate and Capsule

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Adjustment of Leading-Out Unit for Finished Product (refer to Fig.28, 29)

Adjustment of lead-out unit for finished product consists of joined capsule guide plate and pushrod adjustment. Joined capsule guide plate has guide grooves with the same distance as die assembly holes. Loosen fastening nut on guide plate on both sides; adjust the angle and height of guide plate so that guide grooves can align with the joined capsule that is driven out. The standard is to lead out joined capsules smoothly. Finally fasten the nut.

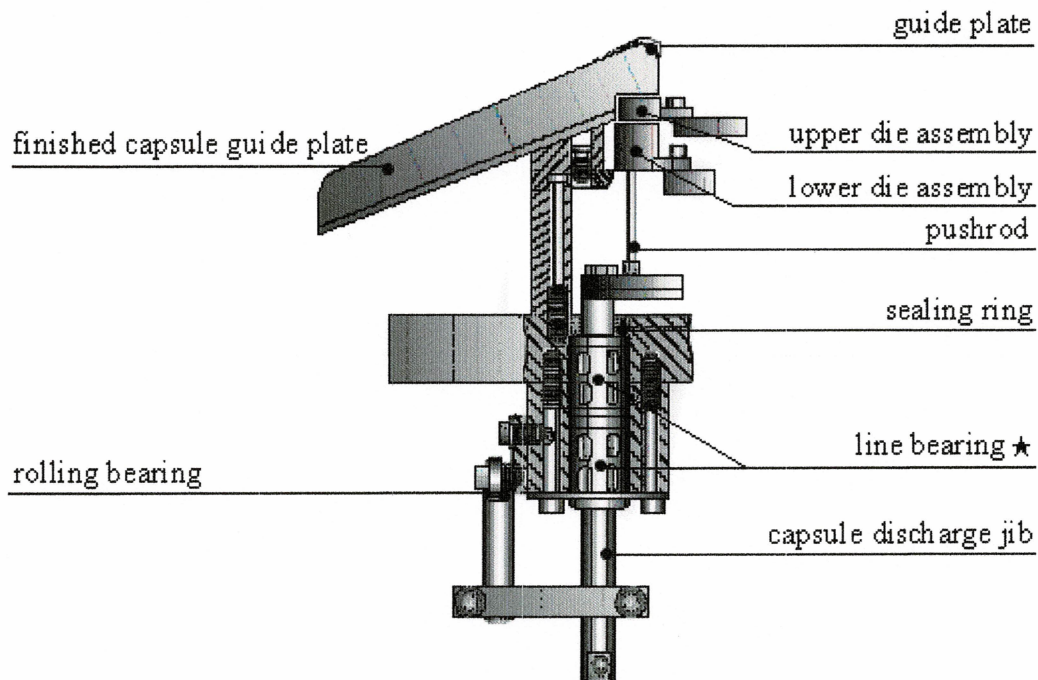


Fig. 28 Leading-out Unit for Joined Capsule

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The method of adjusting joined capsule crown rod is the same as adjusting joining crown rod. As illustrated in Fig. 26 and explained in Section 5.2.10, you may adjust pushrod to decide pushrod height so as to eject capsules when pushrod arrives at the highest position. When pushrod arrives at the lowest position, the upper surface shall be lower than the lower surface of lower die assembly.

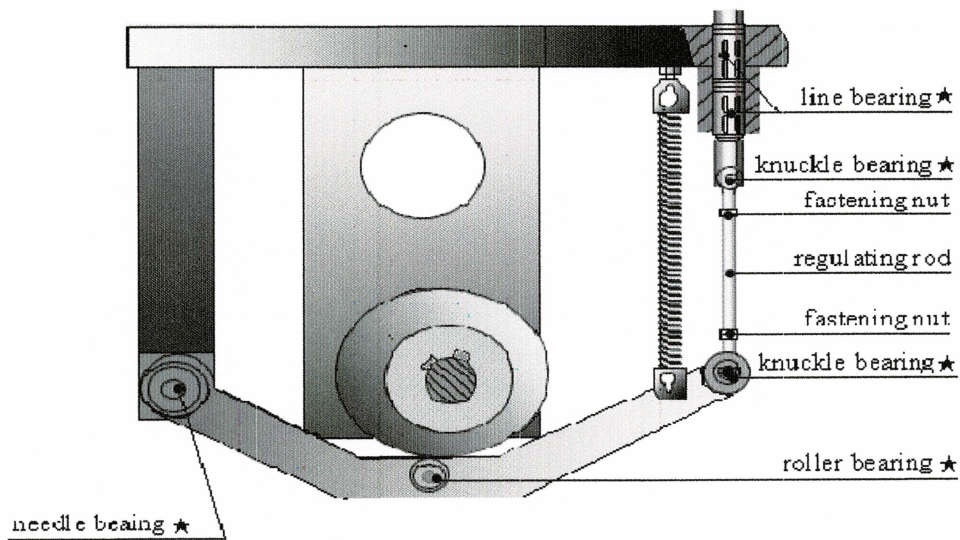


Fig. 29 Driving Mechanism for Leading-out Unit for Joined Capsule

Attachment 1 – Machine Manual: Illustrations and Instructions

Adjustment of Torque Overload Protection Device (refer to Fig. 30)

Torque overload protection device is installed in the output end of main motor reducer. It can protect the machine in case of overload, and should not slip under normal load. Since slippery may occur in long-term operation, the round nut of torque overload insurance device should be tightened to guarantee both the normal operation and protective function.

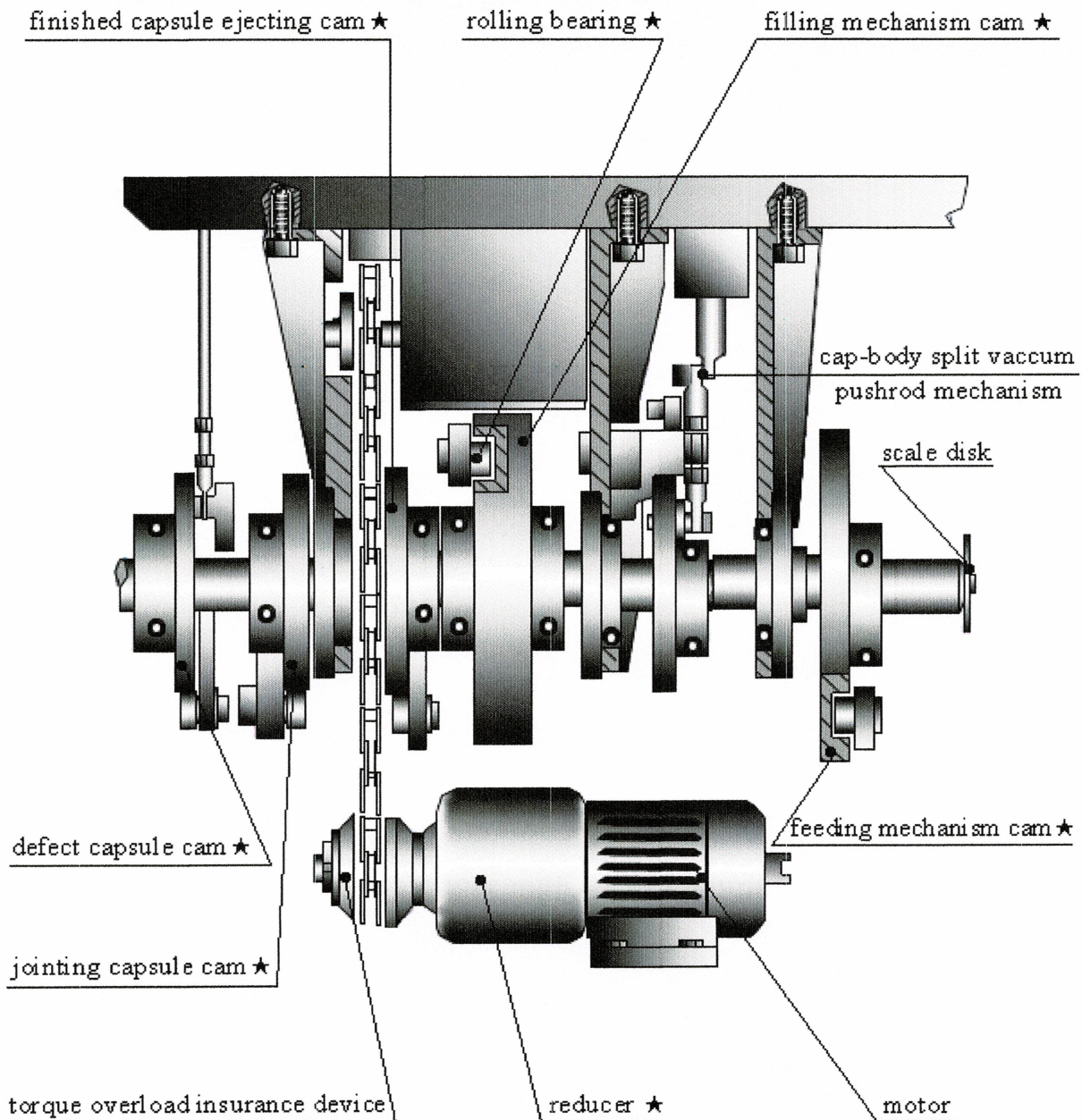


Fig. 30 Transmission Device

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Adjustment of Driving Chain (refer to Fig. 31)

If you find the chain is too loose, you can adjust the chain by moving jockey pulley but neither let the chain go off any chain pulley nor unlock the chain, otherwise the movement order of the whole mechanism will be disturbed.

Check the chain once a week. Tighten and lubricate the chain if necessary.

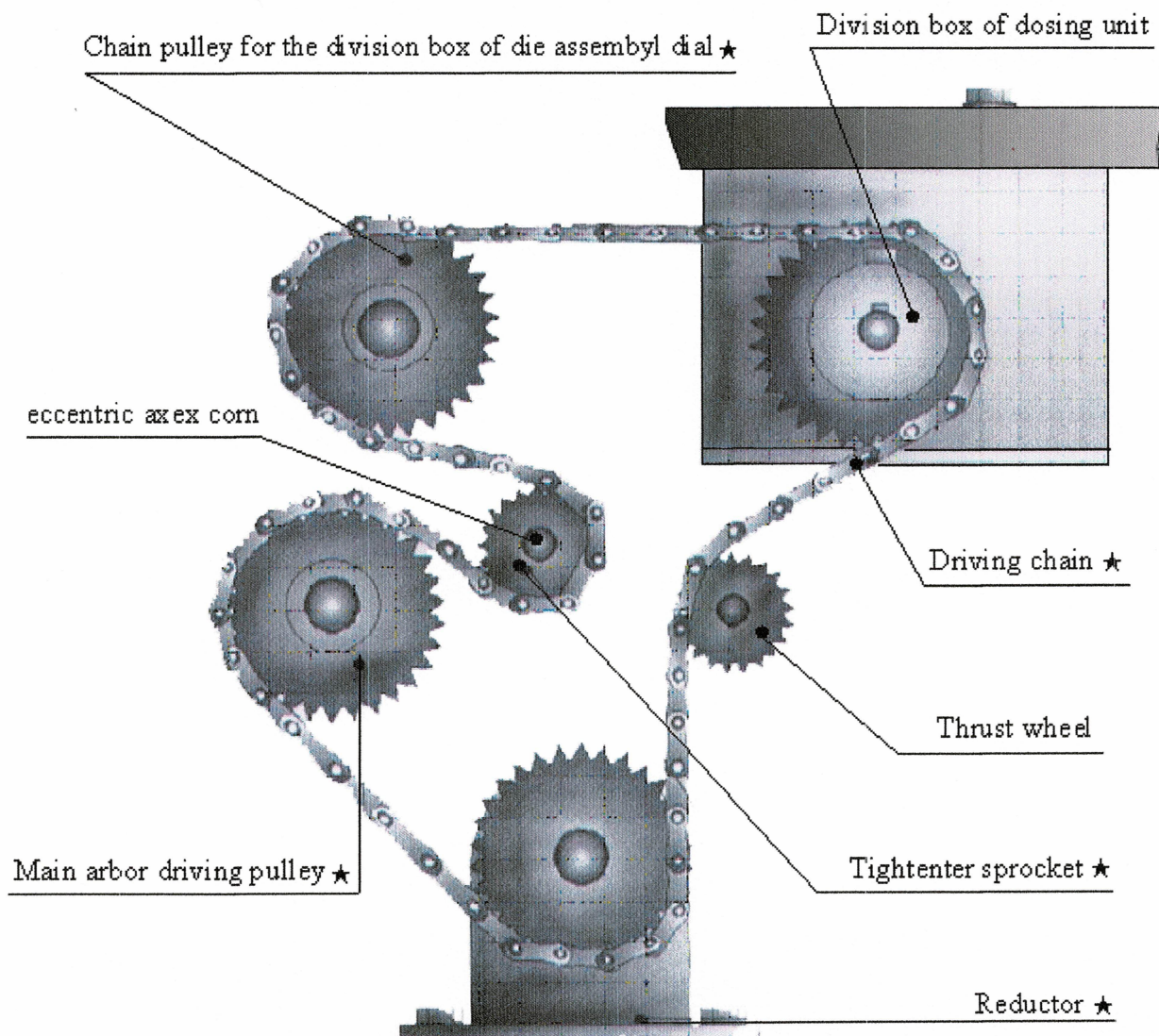


Fig. 31 Schematic Diagram of Driving Chain

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Maintenance and Cleaning of the Machine

In long operation of the machine, regularly clean the parts that contact powder directly. Also clean these parts when replacing another kind of medicine powder or shut down for a long time (general more than three months).

Deal with greasy dirt at driving parts in the lower part of the machine every operation for 500 hours, and check wear and tear, confirm no abnormal station, then running again after adding lubricant.

Clean the filter of vacuum system once times every operation for 200 hours. (Refer to Fig. 32)

Lubrication

Coating the working surface of cam with grease once time every operation for 50 hours (lithium base grease 2#).

Lubricate the joint bearings of all connecting rod under the working bench once time every operation for 50 hours (machine oil over 90#).

Lubricate all kinds of bearings once time every operation for 50 hours, roller bearing and sliding bearing lubricate machine oil over 90#, line bearing lubricate lithium base grease 0#. According to the actual operation situation of the necessary shorten the time to lubricate or clean.

Check and lubricate the driving chain for tightness every operation for 50 hours (lithium base grease 2#).

Check the main driving reducer for oil volume once every operation for 250 hours, and fill oil in time. Replace lubrication every operation for 3000 hours or half year, which arrive at first as limit. (Model A: lithium base grease 0#. Model B: industrial closed type Ep gear oil with viscosity 460~680, and original oil is Shell Omala 220, we suggest adopt the same brand as much as possible.)

Standard Operating Procedure Encapsulation Machine Model NJP-2000 and NJP-3200	SOP No B-507	Rev 5	Page 28 of 28
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Attachment 1 – Machine Manual: Illustrations and Instructions

Check Powder-feeding reducer for oil volume once every operation for 250 hours, and fill oil in time. Replace lubrication every operation for 1000 hours or 4 months, which arrive at first as limit. (Man-made worm gear oil with viscosity 550~680, or TIVEL

AOIL Sc 320 of Shell, or GL YGOYLE 30 of Mobil.)

Replace lubrication for two index boxes initial operation for 1000 hours or 4 months (first arriver as limit), then replace once every operation for 3000 hours or 1 year (first arriver as limit). (Industrial closed type Ep gear oil with viscosity 320~460, and original oil is Mobil Gear 632, we suggest adopt the same brand as much as possible.)

Remove cover plate of revolving platform every operation for 50 hours, lubricate once T-type shaft and each moving points in guide rod brass sleeve and sliding bearing and roller bearing (machine oil over 90#), line bearing (lithium base grease 0#). Uninstall T-type shaft and sealing ring for complete cleaning every operation for 1000 hours, check wear and tear, confirm no abnormal station and lubricate, then running again.

Note: capsule filling machine adopt cam system to drive pendulum bar for most mechanical movement of the machine. All positions of cams are precisely adjusted in manufacturing factory. To prevent any possible collision of different parts inside machine, please do not adjust any cam or other parts of driving system. Necessary adjustment should be by technician form manufacturer or under instructions of professional technician.