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DOCUMENT APPROVAL

Author's Signature:

Your signature indicates that this document has been prepared in accordance with company standards or guidelines and adequately reflects the tasks and deliverables necessary.

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Title

Your signature indicates that, you have reviewed this document and that it accurately and completely reflects the tasks and deliverables necessary.

Signature Print Name Title	Mark Sinfield Head of Production	Date	31.Jan. 2019
Signature	R. Needlan	Date	31-Jan 2019

Quality Assurance/Compliance Approver's Signature:

Dual Site Operations Manager

Rob Newham

Your signature indicates that this document complies with company standards or guidelines; and that the documentation and information contained herein complies with applicable regulatory, corporate, divisional/departmental requirements, and current Good Manufacturing Practices.

Signature	Flan/	Date	31 Jan 2019
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Title	Quality Assurance & Systems Manager		

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1.0 PURPOSE

1.1. The purpose of the document is to define the SOP (Standard Operating Procedures) to be followed by ADVANEX EUROPE Ltd, in order to ensure that the part number NND00030379-100 is set in a systematic and uniform manner.

2.0 SCOPE

- 2.1. This document applies to the setting of tooling on the Finzer W48K machine to make the component correct to drawing
- 2.2. All equipment and processes have been formally qualified and validated. All personnel working on the Pharmaceutical section are responsible for ensuring that no changes are made to the process without full change control.

3.0 TERMS, DEFINITIONS & ABBREVIATIONS

4.0 HEALTH, SAFETY & ENVIRONMENTAL

- 4.1. Within the factory area safety footwear is mandatory.
- 4.2. Within the factory area safety glasses must be worn.
- 4.3. Ear defenders must be worn in the designated areas of the factory.
- 4.4. Basket and bin weights must not exceed 12kg
- 4.5. Guards and interlocks need to be in place when the machine is in operation.

5.0 ASSOCIATED DOCUMENTS

- 5.1. START UP PROCEDURE FINZER (W48K) Document Number AEU00877
- 5.2. MEASUREMENT PROCEDURE NND00030379-100 (Document Number AEU00878)
- 5.3. Operator Booking Procedure (Document Number AEU00469).
- 5.4. Works Order Instructions: Allowing full traceability for the batch.

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6.0 PROCEDURE

6.1. Machine set up position.

• Wind the machine over by hand until the keyway in the back of the machine is in the position shown in figure 1.

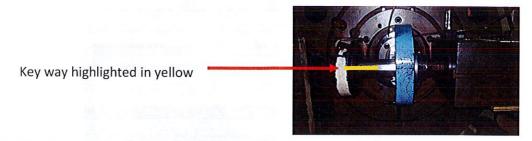


Figure 1: Key way position shown in the back of the machine

6.2. Setting Press Unit into Position

• Set the press unit using the setting block. Fit the setting block onto the face of the machine. Loosen the bolts at the three anchor points (two on the top and one at the bottom) and slide the press unit over to touch the setting block. Lock the three bolts to secure the press in the correct position.

6.3. Slide Unit Positions

• Place the tooling on the face plate of the machine. In position as shown in figure 2.

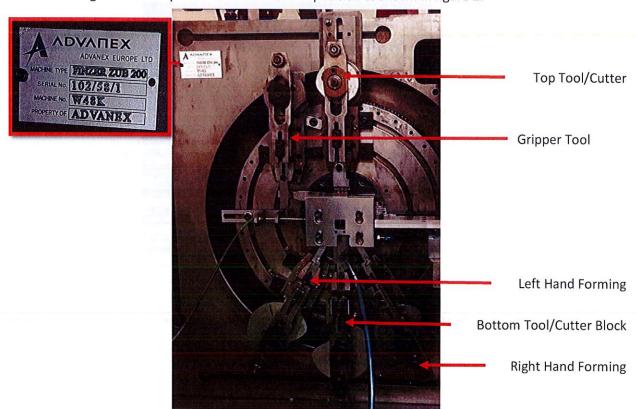


Figure 2: Slide Unit Positions and machine Identification

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6.4. Setting the timing positions on the slide units and back cam

• Place the slide units on making sure to have the cam timing position on the inside as shown in figure 3.

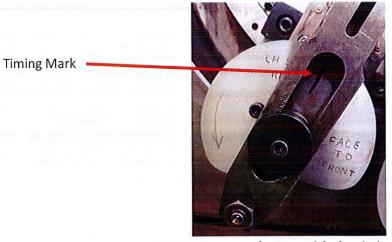


Figure 3: Image of a cam with the timing point position

• Put the back cam on using the correct key way slot that has been clearly marked. The cam is placed on the shaft so that the bearing goes into it from the right-hand side as shown in figure 4.

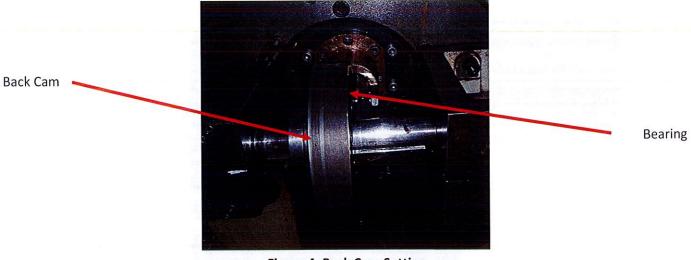
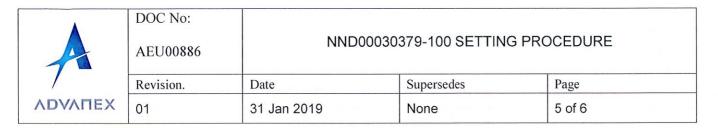


Figure 4: Back Cam Setting

6.5. Setting the die-set

- Put the Die set onto the press table, the die set tee-bolt will locate into the press slide. Fix the die set onto the press table using the two fixing clamps as shown in figure 5.
- Adjustment of BDC is determined by the die set setting block



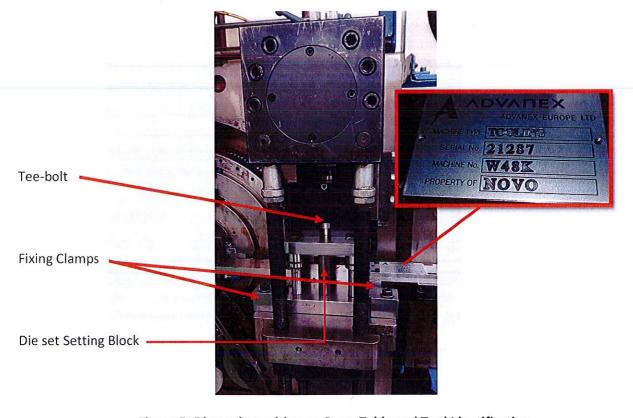


Figure 5: Die set in position on Press Table and Tool Identification

6.6. Feed Settings

- Set the feed scale setting to exactly 14.5mm, figure 6.
- Wind the machine over so the feed unit is as far over to the left as it will go.
- Turn the left-hand feed adjustment screw in until the feed stop just touches the feed unit.
- Wind the machine over fully to the right.
- Turn the right-hand adjustment screw in until the feed stop touches the feed stop.
- Wind the machine into a neutral position and turn both feed stops in 3 full rotations.
- Now tighten the locking screw.



Figure 6: Circled is the scale for setting the feed eccentric

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• Set the feed length to exactly 20.25mm as shown in figure 7. Use slip gauges to help. If making any adjustments to the feed stops, do them equally so that it stays balanced.

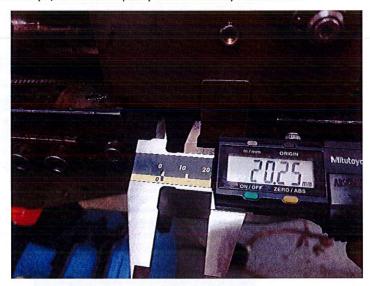


Figure 7: Checking the measurement of the feed length set

6.7. Material settings

• Use the straightening rollers to make the material straight, then make the material go up hill slightly as shown in figure 8. This helps with the production of the part. When the dimples are put into the strip it straightens the material again.

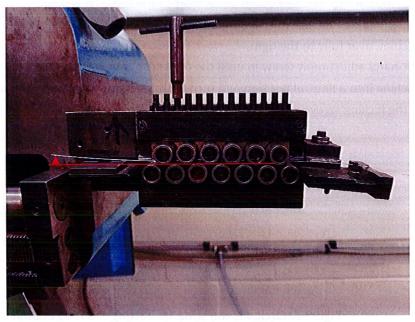


Figure 8: Example of how much the material should go up hill