
	DOC No: AEU00053	TITLE: PARTICULATE SEPARATION OF SLIPPING CLUTCH SPRINGS			Advanex Europe Ltd Head Office: Southwell Site Mill Park Way, Southwell Nottinghamshire, UK, NG25 0ET ☎: 00 44 (0) 1636 815555 ☎: 00 44 (0) 1636 817725 Bilborough Site ☎: 00 44 (0) 115 9293931 ☎: 00 44 (0) 115 9295773 Video Conference IP: 80.176.189.113 www.advanexeurope.co.uk general@advanexeurope.co.uk
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DOCUMENT APPROVAL


Author's Signature:

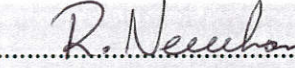
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Signature		Date	20-MAR-2015
Print Name	James Drury		
Title	Production Engineer		

Reviewer's Signature:

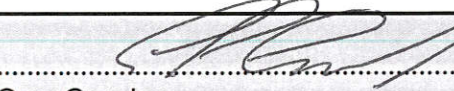
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Signature		Date	20-MAR-15
Print Name	Steve Harris		
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Quality Assurance/Compliance Approver's Signature:

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		Date	20-Mar-15
Print Name	Gary Crawley		
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1.0 PURPOSE

- 1.1. The purpose of the document is to define the SOP (Standard Operating Procedure) to be followed by ADVANEX EUROPE Ltd, in order to ensure that the particulate separation process applied to Slipping Clutch Springs is completed in a controlled and consistent manner.

2.0 SCOPE

- 2.1. This SOP applies to all Slipping Clutch Springs.
- 2.2. All equipment and processes on the MDI (Measured Dose Inhalers) section have been formally qualified and validated. All personnel working on the MDI section are responsible for ensuring that no changes are made to the process without full change control as defined in SOP/PH001 (Document Number AEU00226).

3.0 TERMS, DEFINITIONS & ABBREVIATIONS

- 3.1. None applicable.

4.0 HEALTH, SAFETY & ENVIRONMENTAL

- 4.1. GMP (Good Manufacturing Practice) guidelines apply (Document Number AEU00389).
- 4.2. Within the factory area safety footwear is mandatory.
- 4.3. Within the factory area safety glasses must be worn at all times.

5.0 ASSOCIATED DOCUMENTS

- 5.1. MDI Weight Count (Document Number AEU00056).
- 5.2. Works Order Instructions: Allowing full traceability for the batch.


6.0 PROCEDURE

6.1. General Instructions.

- 6.1.1. All Slipping Clutch springs will be weigh counted into 25,000 pcs with the exception of the final bag which will be 20,000 and a 5,000 Stratified Sample bag.

6.2. Sieving Process.

- 6.2.1. The bag quantities are to be tipped into the centre of the mesh screen.

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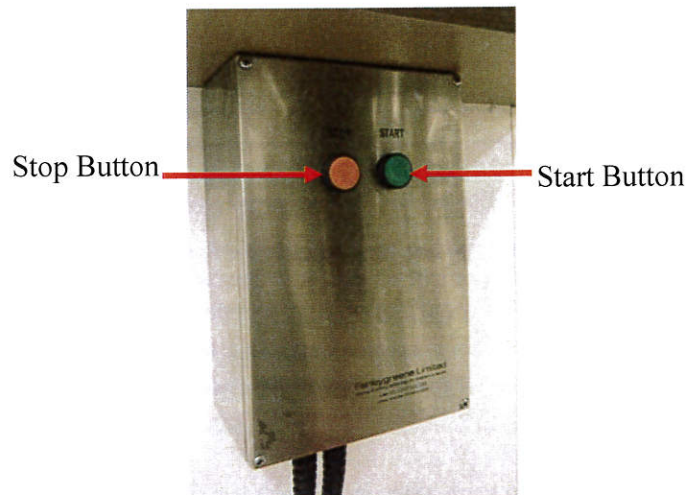


Figure 1: Separation unit control panel.

- 6.2.2. The separation unit is activated using the control panel shown in Figure 1: and allowed to run for the set duration.
- 6.2.3. When the machine stops, the operator will unclasp the top unit and lift it from the main machine.
- 6.2.4. The components are to be poured from the top unit into a stainless steel bowl to assist in the precise weigh counting measurement.
- 6.3. Weigh Counting.**
- 6.3.1. Set up scales as per SOP MDI Weight Count (Document Number AEU00056).
- 6.3.2. The components will be poured from the stainless steel bowl to measurement receptacle on the scales.
- 6.3.3. The springs will be weigh counted into bag quantities of 5,000, then poured from the measurement receptacle, using the funnel, into clean polythene bags for washing.
- 6.3.4. This is repeated for each bag of springs until completion of the batch.
- 6.4. Cleandown.**
- 6.4.1. Before re-assembly of the top unit, after the batch quantity has been processed, the mesh will be cleaned using compressed air ensuring that safety glasses are worn while using the compressed air.
- 6.4.2. The cleaning operation will take place not less than 5metres from the MDI production area.
- 6.4.3. The operator will clean the mesh by blowing air from the underside.
- 6.4.4. The stainless steel bowl and receptacle will also be cleaned between batches by use of a lint free clean cloth.

