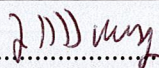
 ADVANEX	DOC No: AEU00056	TITLE: MDI WEIGH COUNT			Advanex Europe Ltd Head Office: Southwell Site Mill Park Way, Southwell Nottinghamshire, UK, NG25 0ET ☎: 00 44 (0) 1636 815555 ☎: 00 44 (0) 1636 817725 Bilborough Site ☎: 00 44 (0) 115 9293931 ☎: 00 44 (0) 115 9295773 Video Conference IP:80.176.189.113 www.advanexeurope.co.uk
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DOCUMENT APPROVAL

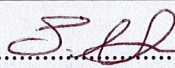
Author's Signature:

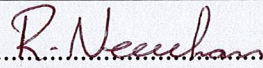
Your signature indicates that this document has been prepared in accordance with company standards or guidelines and adequately reflects the tasks and deliverables necessary.

Signature		Date	5 JUL 2017
Print Name	James Drury		
Title	Production Engineer		

Reviewer's Signature:

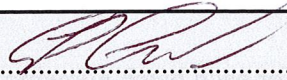
Your signature indicates that, you have reviewed this document and that it accurately and completely reflects the tasks and deliverables necessary.


Signature		Date	5 JULY 2017
Print Name	Steve Harris		
Title	Head of M&P manufacturing		

Signature		Date	6 July 2017
Print Name	Rob Newham		
Title	Operations Manager AEUS		

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	07 JULY 2017
Print Name	Gary Crawley		
Title	Quality 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 correct numbers of pharmaceutical products are packed.

2.0 SCOPE

- 2.1. This document will apply to the weigh count of any designate MDI (Measured Dose Inhaler) product by ADVANEX EUROPE Ltd.
- 2.2. All equipment and processes on the MDI 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. Works Order Instructions issued by the setter for each batch allowing full traceability for the batch.
- 5.2. Production Bin Identification Label (Document Number AEU00384).

6.0 PROCEDURE

6.1. Weigh Counting

- 6.1.1. **When to Weight Count.** Weigh counting into required bag quantities is completed at the end of each shift, before any required washing or cleaning operation.
- 6.1.2. **Component Control.** The weigh counting area must be totally clear of all product except for the batch being counted.


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Figure 1: Scales shown with sample weight.

- 6.1.3. **Setting the Scales.** The weigh counting scales are set by placing the relevant sample weight onto the stainless steel receptacle on the weigh count scales, type '1000' and press the "Sample" button, then remove the sample weight. As shown in Figure 1:
- 6.1.4. **Counting Components.** The batch of parts is counted into individual bag quantities as shown on the Works Order Instruction.
- 6.1.5. **Component Traceability.** The counted wire forms must remain with the Works Order Instructions while they await any secondary washing or cleaning process and subsequently final packing, each box used is to be identified using Production Bin Identification Label (Document Number AEU00384).
- 6.1.6. **Stratified Samples Collection.** If Stratified Samples are required as identified on the Works Order Instructions, then a sample of components will be taken at the end of each weigh count. These will be collated into a bag identified as 'STRATIFIED SAMPLES' and added to as necessary to make a bag quantity as defined on the Works Order Instructions to create the final bag of the production batch.
- 6.1.7. **Inspection of Components.** During the weigh counting operation the operator will visually check the parts for visual defects (deformity, gross discolouration etc.), any such discrepancy is recorded on the Works Order Instruction and the batch identified as non-conforming, segregated pending further investigation and the section leader must be informed.