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**RELEASE STATEMENT  
BULK TABLETS FOR PACKAGING AT NEWBRIDGE**

**Batch No:** *CJ3863*

**Product Name:** *Loette/Alesse (100/20)*

**Item No:** *H000003104*

**Quantity:** *379.2kg*

**Date of Manufacture:** *07/10/2019*

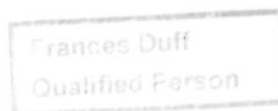
**QAR Number:** *N/A*

This batch complies with specifications and is manufactured in accordance with the EU guide to GMP for medicinal products and the requirements laid down in the Marketing Authorisation.

Signed: *Frances Duff*  
**Qualified Person.**

Date: *13/01/20*

**Printed Name:**



***Suitable for packaging at Newbridge for: Canada, Korea, Hong Kong, Austria, Australia, Belgium, Czech Republic, Denmark, Netherlands, Norway, Spain, Italy, Malaysia***

FORM-24902

Refer to SOP-24569

Rev: 2.0



## Certificate of Analysis

**Confidential**

Pfizer - Newbridge  
PLABWNB

**Product Description:** Alesse (Loette) 20/100

**Product (Version):** H000003104 (25)

**Formulation:** 68E

**Batch:** CJ3863

**Date Manufactured:** 07/10/2019

**Retest Date:** 30<sup>th</sup> April 2020

**Monograph / Version:** LAB-8542 / 7.0

**Master Manufacturing No./ Bulk Specification:** 68E

**Market:** CANADA

13/01/20

### Process Stage

#### **BULK**

<u>Analysis</u>	<u>Component</u>	<u>Specification</u>	<u>Result</u>	<u>Method/Revision</u>
Description	Description	Round pink biconvex tablet with W engraved on one side and "912" engraved on the other.	Conforms	LAB-8542 - 7.0
Assay	% Ethinylestradiol	90.0 - 110.0 %	99.2 %	LAB-7456 - 3.0
Assay	Ethinylestradiol ug/Tab	18.0 - 22.0 µg/tablet	19.8 µg/tablet	LAB-7456 - 3.0
Assay	% Levonorgestrel	90.0 - 110.0 %	99.8 %	LAB-7456 - 3.0
Assay	Levonorgestrel ug/Tab	90.0 - 110.0 µg/tablet	99.8 µg/tablet	LAB-7456 - 3.0
Average Weight	Average Weight	For Information only	70.8 mg	LAB-7267 - 3.0
CU Stage 1	Acceptance Value: Ethinylestradiol	<=15.0	2.6	LAB-7456 - 3.0
CU Stage 1	# Units Outside 85.0-115.0% EE	<1	0	LAB-7456 - 3.0
CU Stage 1	# Units Outside 75.0-125.0% EE	=0	0	LAB-7456 - 3.0
CU Stage 1	Acceptance Value: Levonorgestrel	<=15.0	3.0	LAB-7456 - 3.0
CU Stage 1	# Units Outside 85.0-115.0% LE	<1	0	LAB-7456 - 3.0
CU Stage 1	# Units Outside 75.0-125.0% LE	=0	0	LAB-7456 - 3.0
CU Stage 1	Content Uniformity Summary	Conforms as per Ph.Eur & USP	Conforms	LAB-7456 - 3.0
Deg. (Part B)	6-alpha-hydroxyethinylestradiol	<=0.4 µg/tablet	0.0 µg/tablet	LAB-7414 - 9.0
Deg. (Part B)	6-keto Ethinylestradiol	<=0.4 µg/tablet	0.0 µg/tablet	LAB-7414 - 9.0
Deg. (Part B)	Any single unknown degradant (LE)	<=0.2 µg/tablet	0.0 µg/tablet	LAB-7414 - 9.0
Deg. (Part B)	Any single other EE related degradant	<=0.2 µg/tablet	0.0 µg/tablet	LAB-7414 - 9.0

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Cont'd..

### Process Stage

#### **BULK**

<u>Analysis</u>	<u>Component</u>	<u>Specification</u>	<u>Result</u>	<u>Method/Revision</u>
Deg. (Part B)	Any single known LE related degradant	<=1.0 µg/tablet	0.0 µg/tablet	LAB-7414 - 9.0
Dissolution(Canada %Ethinylestradiol Values )		NLT 80% (Q) in 30 minutes	L1: 101 101 100 99 101 100 %	LAB-10577 - 4.0
Dissolution(Canada %Levonorgestrel Values )		NLT 80% (Q) in 30 minutes	L1: 98 97 95 96 97 95 %	LAB-10577 - 4.0
Identification	Ferric Oxide	Positive for Ferric Oxide	Conforms	LAB-7435 - 1.0
Identification	Titanium Dioxide	Positive for Titanium Dioxide	Conforms	LAB-7435 - 1.0
Identification (UV)	Identification (UV)	Positive for Ethinylestradiol and Levonorgestrel. The UV Spectrum for Ethinylestradiol and Levonorgestrel in the sample and standard chromatogram must compare in each case.	Conforms	LAB-7456 - 3.0
Identity - HPLC	Identity	Positive for Ethinylestradiol and Levonorgestrel. The retention times of the standard and sample chromatogram from Assay are compared. The retention times for Ethinylestradiol and Levonorgestrel should be similar in each case.	Conforms	LAB-7456 - 3.0
Identity;Chiral HPLC	Identity	Positive for Levonorgestrel	Conforms	LAB-7446 - 2.0
Microbiology	Total Aerobic Microbe Count (TAMC)	<=1000 CFU/g	<10 CFU/g	LAB-9836 - 15.0
Microbiology	Total Yeast and Mould Count (TYMC)	<=100 CFU/g	<10 CFU/g	LAB-9803 - 13.0
Microbiology	Bile Tolerant Gram-Negative Bacteria	NMT 100 CFU/G	Conforms	LAB-9804 - 10.0
Microbiology	Escherichia coli	No Escherichia coli in 1g	Conforms	LAB-9813 - 15.0
Microbiology	Salmonella	No Salmonella in 10.0g	Conforms	LAB-9817 - 11.0
Physical Inspection	Physical Inspection	Complies with test.	Conforms	LAB-7268 - 3.0

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Product (Version): H000003104 (25)

Product Description: Alesse (Loette) 20/100

Cont'd..

### Final Disposition

Disposition Type: Release / Approve

Disposition By: Frances Duff [DUFFF]

Title: Qualified Person

Disposition On: 13/01/2020 15:43:54

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**From:** David Roche  
**Date:** 08/11/19  
**Re:** Loette/Alesse(100/20)  
**Batch No:** CJ3863  
**Material No:** H000003104

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I can confirm that the Master Batch Records used in the manufacture of the above batch were as follows:

**Blending**

OC Active Dispensing (For All Formulations Except 28A 28B) MBR-20444 -Version 10.0  
OC Product Part 1 Blending (PK 3 Only) 68E MBR-19958 Version 5.0

**Compression**

OC Part 2 Compression, 68E MBR-19990 Version 5.0

**Coating**

OC Part 4 Coating, 68E MBR-20044 Version 6.0

**Sorting**

OC Part 5 Sorting, 68E MBR-20097 Version 6.0

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David Roche  
QA Specialist