# Worst Case Residue Limits Calculations Matrix

Leucine

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#### **Document Information**

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#### 0.1 Actives Limit Calculations

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#### 0.1.1 Febuxostat Tablets 40 mg 80 mg and 120 mg (Pr1)

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Worst SAL: 0.725 mg/sqcm

Next Production: Dabigatran Etexilate Capsules 75 mg 110 mg and 150 mg  $(\Pr 2)$ 

Next PSwab Limit: 1813.458 ppm Swab Area: 25 sqcm Swab Volume: 10 ml

Previous API(A)	Next Production	ID (B)
1	Pr2	Pr2
2	Pr3	Pr3
3	Pr4	Pr4

Equipment Largest Surface Area

Scoop (DAPR009) 300

#### 0.1.2 Dabigatran Etexilate Capsules 75 mg 110 mg and 150 mg (Pr2)

some text here

Worst SAL: 0.725 mg/sqcm

Next Production: Dabigatran Etexilate Capsules 75 mg 110 mg and 150 mg  $(\mathrm{Pr}2)$ 

Next PSwab Limit: 1813.458 ppm Swab Area: 25 sqcm Swab Volume: 10 ml

Previous $API(A)$	Next Production	ID (B
1	Pr2	Pr2
2	Pr3	Pr3
3	Pr4	Pr4

Equipment Largest Surface Area

Scoop (DAPR009) 300

#### 0.1.3 Telmisartan Tablets 20 mg 40 mg and 80 mg (Pr3)

some text here

Worst SAL: 0.725 mg/sqcm

Next Production: Dabigatran Etexilate Capsules 75 mg 110 mg and 150 mg (Pr2)

Next PSwab Limit: 1813.458 ppm Swab Area: 25 sqcm Swab Volume: 10 ml

Previous API(A)	Next Production	ID (B)
1	Pr2	Pr2
2	Pr3	Pr3
3	Pr4	Pr4

Scoop (DAPR009) 300

#### 0.1.4 Rosuvastatin Calcium Tablets 5 mg 10 mg 20 mg and 40 mg (Pr4)

some text here

Worst SAL: 0.725 mg/sqcm

Next Production: Dabigatran Etexilate Capsules 75 mg 110 mg and 150 mg (Pr2) Next PSwab Limit: 1813.458 ppm Swab Area: 25 sqcm Swab Volume: 10 ml

Previous API(A)	Next Production	ID (B
1	Pr2	Pr2
2	Pr3	Pr3
3	Pr4	Pr4

Equipment Largest Surface Area

Scoop (DAPR009) 300

#### 0.1.5 Pregabalin Capsules 25 mg 50 mg 75 mg 100 mg 150 mg 200 mg 225 mg and 300 mg (Pr5)

some text here

Worst SAL: 0.725 mg/sqcm

Next Production: Dabigatran Etexilate Capsules 75 mg 110 mg and 150 mg (Pr2) Next PSwab Limit: 1813.458 ppm Swab Area: 25 sqcm Swab Volume: 10 ml

Previous API(A)	Next Production	ID (B)
1	Pr2	Pr2
2	Pr3	Pr3
3	$\Pr$ 4	Pr4

Scoop (DAPR009) 300

## 0.1.6 Test Product (Pr6)

some text here

Worst SAL: 0.725 mg/sqcm

Next Production: Dabigatran Etexilate Capsules 75 mg 110 mg and 150 mg (Pr2)

Next PSwab Limit: 1813.458 ppm Swab Area: 25 sqcm Swab Volume: 10 ml

Previous API(A)	Next Production	ID (B
1	Pr2	Pr2
2	Pr3	Pr3
3	$\Pr$ 4	Pr4

Equipment Largest Surface Area

Scoop (DAPR009) 300

## 0.2 Cleaning Agent Limit Calculations

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#### 0.2.1 Febuxostat Tablets 40 mg 80 mg and 120 mg (Pr1)

some text here

Worst SAL: 0.725 mg/sqcm

Next Production: Dabigatran Etexilate Capsules 75 mg 110 mg and 150 mg (Pr2) Next PSwab Limit: 1813.458 ppm Swab Area: 25 sqcm Swab Volume: 10 ml

Previous API(A)	Next Production	ID (B
1	Pr2	Pr2
2	Pr3	Pr3
3	Pr4	Pr4

Equipment Largest Surface Area

Scoop (DAPR009) 300

#### 0.2.2 Dabigatran Etexilate Capsules 75 mg 110 mg and 150 mg (Pr2)

some text here

Worst SAL: 0.725 mg/sqcm

Next Production: Dabigatran Etexilate Capsules 75 mg 110 mg and 150 mg (Pr2)

Next PSwab Limit: 1813.458 ppm Swab Area: 25 sqcm Swab Volume: 10 ml

Previous API(A)	Next Production	ID(B)
1	Pr1	Pr1
2	Pr2	Pr2
3	Pr3	Pr3

Scoop (DAPR009) 300

#### 0.2.3 Telmisartan Tablets 20 mg 40 mg and 80 mg (Pr3)

some text here

Worst SAL: 0.725 mg/sqcm

Next Production: Dabigatran Etexilate Capsules 75 mg 110 mg and 150 mg (Pr2) Next PSwab Limit: 1813.458 ppm Swab Area: 25 sqcm Swab Volume: 10 ml

Previous API(A)	Next Production	ID (B
1	Pr2	Pr2
2	Pr3	Pr3
3	Pr4	Pr4

Equipment Largest Surface Area

Scoop (DAPR009) 300

## 0.2.4 Rosuvastatin Calcium Tablets 5 mg 10 mg 20 mg and 40 mg (Pr4)

some text here

Worst SAL: 0.725 mg/sqcm

Next Production: Dabigatran Etexilate Capsules 75 mg 110 mg and 150 mg (Pr2) Next PSwab Limit: 1813.458 ppm Swab Area: 25 sqcm Swab Volume: 10 ml

Previous API(A)	Next Production	ID (B)
1	Pr2	Pr2
2	Pr3	Pr3
3	Pr4	Pr4

Scoop (DAPR009) 300

#### 0.2.5 Pregabalin Capsules 25 mg 50 mg 75 mg 100 mg 150 mg 200 mg 225 mg and 300 mg (Pr5)

some text here

Worst SAL: 0.725 mg/sqcm

Next Production: Dabigatran Etexilate Capsules 75 mg 110 mg and 150 mg (Pr2) Next PSwab Limit: 1813.458 ppm Swab Area: 25 sqcm Swab Volume: 10 ml

Previous API(A)	Next Production	ID (B
1	Pr2	Pr2
2	Pr3	Pr3
3	Pr4	Pr4

Equipment Largest Surface Area

Scoop (DAPR009) 300

## 0.2.6 Test Product (Pr6)

some text here

Worst SAL: 0.725 mg/sqcm

Next Production: Dabigatran Etexilate Capsules 75 mg 110 mg and 150 mg (Pr2)

Next PSwab Limit: 1813.458 ppm Swab Area: 25 sqcm Swab Volume: 10 ml

Previous API(A)	Next Production	ID (B
1	Pr2	Pr2
2	Pr3	Pr3
3	Pr4	Pr4

Equipment Largest Surface Area

Scoop (DAPR009) 300

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