

Worst Case Residue Limits Calculations Matrix

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Chapter 1

Actives Limit Calculations

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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 (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
4	Pr4	Pr4

Shared Area Calculation for Pr1 and Pr2

Equipment	Largest Surface Area
Scoop (DAPR009)	300
Scoop (DAWH001)	300

1.2 Dabigatran Etxilate Capsules 75 mg 110 mg and 150 mg (Pr2)

some text here

Worst SAL: 0.725 mg/sqcm

Next Production: Dabigatran Etxilate 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
4	Pr4	Pr4

Shared Area Calculation for Pr1 and Pr2

Equipment	Largest Surface Area
Scoop (DAPR009)	300
Scoop (DAWH001)	300

1.3 Telmisartan Tablets 20 mg 40 mg and 80 mg (Pr3)

some text here

Worst SAL: 0.725 mg/sqcm

Next Production: Dabigatran Etxilate 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
4	Pr4	Pr4

Shared Area Calculation for Pr1 and Pr2

Equipment	Largest Surface Area
Scoop (DAPR009)	300
Scoop (DAWH001)	300

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	Pr1	Pr1
2	Pr2	Pr2
3	Pr3	Pr3
4	Pr4	Pr4

Shared Area Calculation for Pr1 and Pr2

Equipment	Largest Surface Area
Scoop (DAPR009)	300
Scoop (DAWH001)	300

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	Pr1	Pr1
2	Pr2	Pr2
3	Pr3	Pr3
4	Pr4	Pr4

Shared Area Calculation for Pr1 and Pr2

Equipment	Largest Surface Area
Scoop (DAPR009)	300
Scoop (DAWH001)	300

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	Pr1	Pr1
2	Pr2	Pr2
3	Pr3	Pr3
4	Pr4	Pr4

Shared Area Calculation for Pr1 and Pr2

Equipment	Largest Surface Area
Scoop (DAPR009)	300
Scoop (DAWH001)	300

Chapter 2

Cleaning Agent Limit Calculations

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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	Pr1	Pr1
2	Pr2	Pr2
3	Pr3	Pr3
4	Pr4	Pr4

Shared Area Calculation for Pr1 and Pr2

Equipment	Largest Surface Area
Scoop (DAPR009)	300
Scoop (DAWH001)	300

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)
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Shared Area Calculation for Pr1 and Pr2

Equipment	Largest Surface Area
Scoop (DAPR009)	300
Scoop (DAWH001)	300

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

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Shared Area Calculation for Pr1 and Pr2

Equipment	Largest Surface Area
Scoop (DAPR009)	300
Scoop (DAWH001)	300

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

some text here

Worst SAL: 0.725 mg/sqcm

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Shared Area Calculation for Pr1 and Pr2

Equipment	Largest Surface Area
Scoop (DAPR009)	300
Scoop (DAWH001)	300

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 Etxilate Capsules 75 mg 110 mg and 150 mg (Pr2)

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3	Pr3	Pr3
4	Pr4	Pr4

Shared Area Calculation for Pr1 and Pr2

Equipment	Largest Surface Area
Scoop (DAPR009)	300
Scoop (DAWH001)	300

2.6 Test Product (Pr6)

some text here

Worst SAL: 0.725 mg/sqcm

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Equipment	Largest Surface Area
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Scoop (DAWH001)	300