

Worst Case Residue Limits Calculations Matrix

Leucine

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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 (Pr2)

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

Previous API (A)	PDE (A)	Min Batch Size (B)	Min Daily Dosage (A)	Largest Daily Dose (B)	Shared Contact Surface Area	Toxicity Based SAL	General SAL	Dosage Based SAL	Worst SAL	Next Production ID (B)
Febuxo-stat	0.12	43.523	40	40	600	217.615	0.725	72.538	0.725	Pr2
Febuxo-stat	0.12	165	40	40	600	825	2.75	275	2.75	Pr4
Febuxo-stat	0.12	198	40	40	600	990	3.3	330	3.3	Pr3
Febuxo-stat	0.12	325	40	40	600	1625	5.417	541.667	5.417	Pr6

Shared Area Calculation for Pr1 and Pr2.

Equipment	Largest Surface Area
Scoop (DAPR009)	300
Scoop (DAWH001)	300
TOTAL	600

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

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Worst SAL: 2.083 mg/sqcm

Next Production: Febuxostat Tablets 40 mg 80 mg and 120 mg (Pr1)

Swab Limit: 5208.333 ppm Swab Area: 25 sqcm Swab Volume: 10 ml

Previous API (A)	PDE (A)	Min Batch Size (B)	Min Daily Dosage (A)	Largest Daily Dose (B)	Shared Contact Surface Area	Toxicity Based SAL	General SAL	Dosage Based SAL	Worst SAL	Next Production ID (B)
Dabi-gatran Etexilate	20	125	40	40	600	104166.667	2.083	208.333	2.083	Pr1
Dabi-gatran Etexilate	20	165	40	40	600	137500	2.75	275	2.75	Pr4
Dabi-gatran Etexilate	20	198	40	40	600	165000	3.3	330	3.3	Pr3
Dabi-gatran Etexilate	20	325	40	40	600	270833.333	5.417	541.667	5.417	Pr6

Shared Area Calculation for Pr2 and Pr1.

Equipment	Largest Surface Area
Scoop (DAPR009)	300
Scoop (DAWH001)	300
TOTAL	600

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

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Worst SAL: 0.0456 mg/sqcm

Next Production: Rosuvastatin Calcium Tablets 5 mg 10 mg 20 mg and 40 mg (Pr4)

Swab Limit: 114.124 ppm Swab Area: 25 sqcm Swab Volume: 10 ml

Rinse Limit: 11.412 ppm Rinse Area: 25 sqcm Rinse Volume: 100 ml

Previous API (A)	PDE (A)	Min Batch Size (B)	Min Daily Dosage (A)	Largest Daily Dose (B)	Shared Contact Surface Area	Toxicity Based SAL	General SAL	Dosage Based SAL	Worst SAL	Next Production ID (B)
Telmisartan	0.8	165	40	40	36145	91.299	0.0456	4.565	0.0456	Pr4
Telmisartan	0.8	325	40	40	8410	772.889	0.386	38.644	0.386	Pr5
Telmisartan	0.8	43.523	40	40	600	1450.767	0.725	72.538	0.725	Pr2
Telmisartan	0.8	125	40	40	600	4166.667	2.083	208.333	2.083	Pr1
Telmisartan	0.8	325	40	40	600	10833.333	5.417	541.667	5.417	Pr6

Shared Area Calculation for Pr3 and Pr4.

Equipment	Largest Surface Area
Scoop (DAPR009)	300
Scoop (DAWH001)	300
Compression Machine (39 stn) (DEPR022)	18725
Tablet deduster & metal detector (DEPR023)	8410
Tablet deduster & metal detector (DEPR024)	8410
TOTAL	36145

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

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Worst SAL: 0.0548 mg/sqcm

Next Production: Telmisartan Tablets 20 mg 40 mg and 80 mg (Pr3)

Rinse Limit: 13.695 ppm Rinse Area: 25 sqcm Rinse Volume: 100 ml

Previous API (A)	PDE (A)	Min Batch Size (B)	Min Daily Dosage (A)	Largest Daily Dose (B)	Shared Contact Surface Area	Toxicity Based SAL	General SAL	Dosage Based SAL	Worst SAL	Next Production ID (B)
Rosuvastatin	0.15	198	40	40	36145	20.542	0.0548	5.478	0.0548	Pr3
Rosuvastatin	0.15	325	40	40	8410	144.917	0.386	38.644	0.386	Pr5
Rosuvastatin	0.15	43.523	40	40	600	272.019	0.725	72.538	0.725	Pr2
Rosuvastatin	0.15	125	40	40	600	781.25	2.083	208.333	2.083	Pr1
Rosuvastatin	0.15	325	40	40	600	2031.25	5.417	541.667	5.417	Pr6

Shared Area Calculation for Pr4 and Pr3.

Equipment	Largest Surface Area
Scoop (DAPR009)	300
Scoop (DAWH001)	300
Compression Machine (39 stn) (DEPR022)	18725
Tablet deduster & metal detector (DEPR023)	8410
Tablet deduster & metal detector (DEPR024)	8410
TOTAL	36145

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

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Worst SAL: 0.196 mg/sqcm

Next Production: Rosuvastatin Calcium Tablets 5 mg 10 mg 20 mg and 40 mg (Pr4)

Swab Limit: 490.488 ppm Swab Area: 25 sqcm Swab Volume: 10 ml

Rinse Limit: 49.049 ppm Rinse Area: 25 sqcm Rinse Volume: 100 ml

Previous API (A)	PDE (A)	Min Batch Size (B)	Min Daily Dosage (A)	Largest Daily Dose (B)	Shared Contact Surface Area	Toxicity Based SAL	General SAL	Dosage Based SAL	Worst SAL	Next Production ID (B)
Prega-balin	0.5	165	40	40	8410	245.244	0.196	19.62	0.196	Pr4
Prega-balin	0.5	198	40	40	8410	294.293	0.235	23.543	0.235	Pr3

Shared Area Calculation for Pr5 and Pr4.

Equipment	Largest Surface Area
Tablet deduster & metal detector (DEPR024)	8410
TOTAL	8410

0.1.6 Test Product (Pr6)

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Worst SAL: 0.725 mg/sqcm

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

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

Previous API (A)	PDE (A)	Min Batch Size (B)	Min Daily Dosage (A)	Largest Daily Dose (B)	Shared Contact Surface Area	Toxicity Based SAL	General SAL	Dosage Based SAL	Worst SAL	Next Production ID (B)
Prega-balin	0.5	43.523	40	40	600	906.729	0.725	72.538	0.725	Pr2
Prega-balin	0.5	125	40	40	600	2604.167	2.083	208.333	2.083	Pr1
Prega-balin	0.5	165	40	40	600	3437.5	2.75	275	2.75	Pr4
Prega-balin	0.5	198	40	40	600	4125	3.3	330	3.3	Pr3

Shared Area Calculation for Pr6 and Pr2.

Equipment	Largest Surface Area
Scoop (DAPR009)	300
Scoop (DAWH001)	300
TOTAL	600

0.2 Cleaning Agent Limit Calculations

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0.2.1 Scoop (DAPR009)

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Worst SAL: 510307.175 mg/sqcm

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

Swab Limit: 1275767937.5 ppm Swab Area: 25 sqcm Swab Volume: 10 ml

Rinse Limit: 127576793.75 ppm Rinse Area: 25 sqcm Rinse Volume: 100 ml

Cleaning Agent (A)	Next Production ID (B)	PDE (A)	Largest Daily Dose (B)	Min Batch Size (B)	Shared Contact Surface Area	Worst SAL
Methanol	Pr2	281.4	40	43.523	600	510307.175
Methanol	Pr1	281.4	40	125	600	1465625
Methanol	Pr4	281.4	40	165	600	1934625
Methanol	Pr3	281.4	40	198	600	2321550
Methanol	Pr6	281.4	40	325	600	3810625

Shared Area Calculation for Methanol and Pr2.

Equipment	Largest Surface Area
Scoop (DAPR009)	300
Scoop (DAWH001)	300
TOTAL	600

0.2.2 Scoop (DAWH001)

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Worst SAL: 510307.175 mg/sqcm

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

Swab Limit: 1275767937.5 ppm Swab Area: 25 sqcm Swab Volume: 10 ml

Rinse Limit: 127576793.75 ppm Rinse Area: 25 sqcm Rinse Volume: 100 ml

Cleaning Agent (A)	Next Production ID (B)	PDE (A)	Largest Daily Dose (B)	Min Batch Size (B)	Shared Contact Surface Area	Worst SAL
Methanol	Pr2	281.4	40	43.523	600	510307.175
Methanol	Pr1	281.4	40	125	600	1465625
Methanol	Pr4	281.4	40	165	600	1934625
Methanol	Pr3	281.4	40	198	600	2321550
Methanol	Pr6	281.4	40	325	600	3810625

Shared Area Calculation for Methanol and Pr2.

Equipment	Largest Surface Area
Scoop (DAPR009)	300
Scoop (DAWH001)	300
TOTAL	600

0.2.3 IdenticalGroup1 (EGI1)

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Worst SAL: 57159.375 mg/sqcm

Next Production: Pregabalin Capsules 25 mg 50 mg 75 mg 100 mg 150 mg 200 mg 225 mg and 300 mg (Pr5)

Cleaning Agent (A)	Next Production ID (B)	PDE (A)	Largest Daily Dose (B)	Min Batch Size (B)	Shared Contact Surface Area	Worst SAL
Methanol	Pr5	281.4	40	325	40000	57159.375

Shared Area Calculation for Methanol and Pr5.

Equipment	Largest Surface Area
IdenticalGroup1 (EGI1)	40000
TOTAL	40000