

Worst Case Residue Limits Calculations Matrix

Leucine

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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)

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 |

1.2 Dabigatran Etxilate 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 |

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 |

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 |

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 |

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 |

Chapter 2

Cleaning Agent Limit Calculations

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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 |

2.2 Scoop (DAWH001)

some text here

Worst SAL: 510307.175 mg/sqcm

Next Production: Dabigatran Etxilate 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 |

2.3 IdenticalGroup1 (EGI1)

some text here

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 |