

Worst Case Residue Limits Calculations Matrix

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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)

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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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 (Pr2)

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

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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

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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

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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

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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

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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 Etxilate 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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0.2.2 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

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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 Etxilate 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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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

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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

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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

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