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May, 2024

## Assessment of Elemental Impurities in Citric Acid

| Element | Class | Potentially present? | | Intentionally added? | | Tested lot by lot? | | Analytical method used (e.g., ICP-MS, ICP-OES…) with Limit of Detection if available | Content measured or range (µg/g) | Limit from material specification, if available | Comments : i.e. frequency of testing/ test performed in-house or externally |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Yes | No | Yes | No | Yes | No | | | | |
| **Cd** | **1** | X | | | X | **Skip-lot** | | **AAS** | 0.0012 | * 0.5 ppm | In-house |
| **Pb** | **1** | X | | | X | **Skip-lot** | | **AAS** | 0.0012 | 0.5 ppm | In-house |
| **As** | **1** | X | | | X | **Skip-lot** | | **AAS** | 0.0292 | 1.0 ppm | In-house |
| **Hg** | **1** | X | | | X | **Skip-lot** | | **AAS** | 0.0006 | 1.0 ppm | In-house |
| **Co** | **2A** | X | | | X | **Annually** | | **ICP** | <0.46 | * 5 ppm | Out-side |
| **V** | **2A** | X | | | X | **Annually** | | **ICP** | <1.176 | * 10 ppm | Out-side |
| **Ni** | **2A** | X | | | X | **Annually** | | **ICP** | <1.49 | * 20 ppm | Out-side |
| **Tl** | **2B** | | X | | | | X | NA | NA | NA | NA |
| **Au** | **2B** | | X | | | | X | NA | NA | NA | NA |
| **Pd** | **2B** | | X | | | | X | NA | NA | NA | NA |
| **Ir** | **2B** | | X | | | | X | NA | NA | NA | NA |
| **Os** | **2B** | | X | | | | X | NA | NA | NA | NA |
| **Rh** | **2B** | | X | | | | X | NA | NA | NA | NA |
| **Ru** | **2B** | | X | | | | X | NA | NA | NA | NA |
| **Se** | **2B** | | X | | | | X | NA | NA | NA | NA |
| **Ag** | **2B** | | X | | | | X | NA | NA | NA | NA |
| **Pt** | **2B** | | X | | | | X | NA | NA | NA | NA |
| **Li** | **3** | | | | X | Annually | | **ICP** | <0,050 | 55 ppm | Out-side |
| **Sb** | **3** | | | | X | Annually | | **ICP** | <0,0005 | * 120 ppm | Out-side |
| **Ba** | **3** | | | | X | Annually | | **ICP** | <0,030 | * 140 ppm | Out-side |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| **Mo** | **3** | | | | X | Annually | | **ICP** | <0,015 | * 300 ppm | Out-side |
| **Cu** | **3** | | | | X | Annually | | **ICP** | <0,002 | * 300 ppm | Out-side |
| **Sn** | **3** | | | | X | Annually | | **ICP** | 0,410 | * 600 ppm | Out-side |
| **Cr** | **3** | | | | X | Annually | | **ICP** | <0,0005 | * 1100 ppm | Out-side |

* Meet <USP 40 – Ch. 232> permitted concentration of Elemental Impurities for Individual Component Option

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