
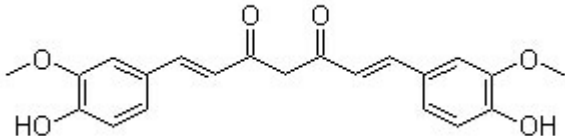



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|--|---|---------|------------|--------|
|  | Code of the specification | Version | Valid from | Page |
| | SOP-06-PA-067-SP01 | V03 | 2020-08-21 | 1 of 2 |
| | Specification of PBT-produced curcumin | | | |

1. General information/ specifications

| | |
|------------------------------|--|
| Material | |
| Material type | <input checked="" type="checkbox"/> Active substance <input checked="" type="checkbox"/> GMP <input type="checkbox"/> non GMP |
| Material Identification | <p>Name of the material: Curcumin IUPAC: 1,7-bis(4-hydroxy-3-methoxyphenyl)-hepta-1,6-diene-3,5-diones CAS No.: 458-37-7 Material No. (if applicable): Description (formula, molar mass, if applicable): C₂₁H₂₀O₆, 368.38 g/mol</p>  <p>Required quality: ≥ 92 % Curcumin-1</p> |
| Supplier/ manufacturer | Product of PharmBioTec |
| Storage/transport conditions | Storage RT Storage class 10-13 |
| Shelf life | Based on stability data |
| Re- Test Interval | Based on stability data |

2. Analytical data/ specifications

| Parameters | Method Instruction [SOP-06-MA, Document No.] | Setpoint or area |
|-----------------------------|---|--|
| Characterization | | |
| Solubility | n.a. | 100mg/ml in PEG 400 |
| Content / Activity | | |
| Curcuminoid content HPLC | SOP-06-MA-022 | ≥ 92 % Curcumin < 10 % Desmethoxycurcumin < 1 % Bisdesmethoxycurcumin |
| Identity | | |
| Identity by HPLC | SOP-06-MA-022 | Retention times comply with standards |
| melting range | Ph. Eur | 172 - 183°C |
| DC | SOP-06-MA-021 | Under UV light (365 nm) 2 orange bands of the sample are identical in colour and position to the reference |
| Purity | | |
| Purity by HPLC | SOP-06-MA-022 | ≤ 1.0 % Contamination A ≤ 0,1 % single unknown impurity ≤ 1,0 % total unknown contamination |

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|  | Code of the specification | Version | Valid from | Page |
| | SOP-06-PA-067-SP01 | V03 | 2020-08-21 | 2of 2 |
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| Parameters | Method Instruction [SOP-06-MA, Document No.] | Setpoint or area |
|---|---|---|
| Additional characterisations | | |
| Drying loss | SOP-06-MA-026 | Max. 2.0 % in 1g |
| Total ash | SOP-06-MA-013 | Max. 1.0 % in 2g |
| Heavy metals | External laboratory | Cobalt ≤ 10 ppm Lead ≤ 10 ppm Arsenic ≤ 30 ppm Mercury ≤ 6 ppm Cadmium ≤ 4 ppm Vanadium ≤ 20 ppm Nickel ≤ 40 ppm Lithium ≤ 500 ppm Antimony ≤ 180 ppm Copper ≤ 600 ppm |
| Aflatoxins | Ph. Eur. | meets the requirements |
| Pesticide residues | Ph. Eur. | meets the requirements |
| residual solvents | Ph. Eur. | < 5000 ppm acetone < 3000 ppm methanol |
| TAMC (total aerobic microbial count) | Ph. Eur. | Max. 10 ² KBE per g |
| TYMC (total combined yeasts and moulds) | Ph. Eur. | Max. 10 ¹ KBE per g |
| Detection of specific microorganisms: Salmonella sp. Escherichia coli | Ph. Eur. | Absent in 25 g in 1 g |
| Bacterial endotoxins | Ph. Eur. | 500 IU/g (= 25 IU/mL of a 1g/20 mL suspension) |