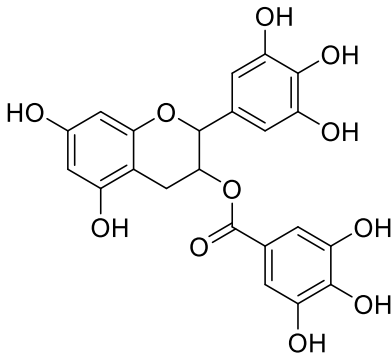

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	Specification for (-)-epigallocatechin gallate			

General information/ specifications

Material	
Material type	<input checked="" type="checkbox"/> Active GMP <input checked="" type="checkbox"/> <input type="checkbox"/> non GMP
Material identification	<p>Name of the material: <i>(-)-epigallocatechin gallate</i> IUPAC: [(2<i>R</i>,3<i>R</i>)-5,7-dihydroxy-2-(3,4,5-trihydroxyphenyl)-3,4-dihydro-2<i>H</i>-chromen-3-yl] 3,4,5-trihydroxybenzoate CAS No.: 989-51-5 Material no. (if applicable): Description (formula, molar mass etc. if applicable):</p>  <p>$C_{22}H_{18}O_{11}$, 458.38 g/mol</p> <p>Required quality: $\geq 97\%$</p>
Supplier/ Manufacturer	Product of PharmBioTec
Bearing/ Conditions of transport	Storage at -20 °C, storage class 10-13
Shelf life	<i>Based on stability data</i>
Re-test interval	<i>Based on stability data</i>

1. Analytical data/ specifications

Parameter	Method statement [SOP-06-MA, Document No.]	Set point or range
Content / Activity		
HPLC	According to USP 42, NF37, page 5009	$\geq 97\%$ (calculated as anhydrous substance)
Identity		
IR	Comparison with spectrum of the standard	corresponds to
Purity		
Purity by means of HPLC	According to USP 42, NF37, page 5009	max. 1 % Gallic acid (calculated as anhydrous substance)

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Parameter	Method statement [SOP-06-MA, Document No.]	Set point or range
Purity by means of HPLC	According to USP 42, NF37, page 5010	max. 0.1 % caffeine (calculated as anhydrous substance)
Additional characterisation		
Water content	SOP-06-MA-038 (EW: 0.5g)	max. 6 %
TAMC (total aerobic microbial count)	Ph. Eur.	max. ¹⁰² CFU per g
TYMC (total combined yeasts and moulds)	Ph. Eur.	max. ¹⁰¹ CFU per g
Detection of specific microorganisms: Salmonella, Escherichia coli, P. aeruginosa, S. aureus	Ph. Eur.	Absent in 10 g Absent in 1g Absent in 1g Absent in 1g
Pesticide residues	Ph. Eur.	Meets the requirements
Endotoxins	Ph. Eur.	60 IU/g
Aflatoxins	Ph. Eur.	Absent
Residual solvent	Ph. Eur.	< 5000 ppm acetone < 600 ppm DCM
Sulphated ash	SOP-06-MA-012 (1g at 600°C)	0,5 %
Heavy metals	External laboratory LS	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