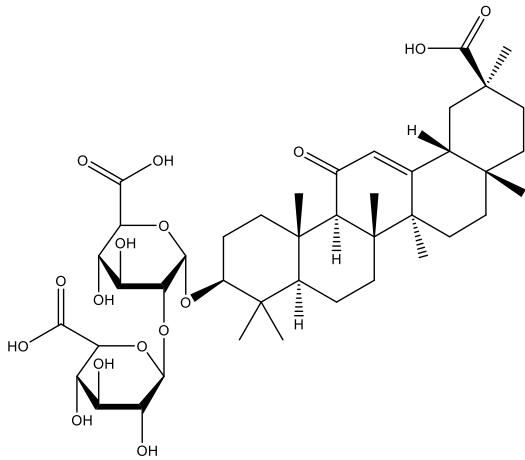

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	Specification of PBT-produced glycyrrhizic acid			

1. General information/ specifications

Material	
Material type	<input checked="" type="checkbox"/> Product (active pharmaceutical ingredient)
Material identification	<p>Name of the material: <i>Glycyrrhizic acid</i> Material no. (if applicable): Description (formula, molar mass etc. if applicable):</p>  <p>$C_{42}H_{62}O_{16}$, 822.94 g/mol Required quality: $\geq 90.0 - 102.0$ %.</p>
Supplier/ Manufacturer	Product of PharmBioTec
Storage/transport conditions	Storage at RT Storage class 10-13
Shelf life	Based on stability data
Re-test interval	Based on stability data

2. Analytical data/ specifications

Parameter	Method statement [SOP-06-MA, Document No.]	Set point or range
Content / Activity		
HPLC	[SOP-06-MA-037] as sum of 18-- and 18- β epimer (dried substance)	90,0 – 102,0 %
Identity		
Comparison HPLC retention time	Comparison with reference substance glycyrrhizic acid [SOP-06-MA-037]	positive
IR	[SOP-06-MA-003] Comparison with spectrum of reference substance	positive
Purity		

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Parameter	Method statement [SOP-06-MA, Document No.]	Set point or range
Purity by means of HPLC	According to Ph. Eur. 01/2008:1772 [SOP-06-MA-037]	18--Epimer ≤ 10 % Impurity A: ≤ 5 % Each additional VU: ≤ 2 % Sum of all other VU's: ≤ 7 %
Additional characterisation		
Appearance	According to Ph. Eur. 01/2008:1772 According to Ph. Eur. 2.2.1 According to Ph. Eur. 2.2.2 0.2g in 20ml ethanol (20% v/v)	White to off-white powder clear solution, not more strongly coloured than BY-7
Spec. rotation	SOP-06-MA-018] Measurement on a solution of (c=15 mg/ml in ethanol)	+58° to + 63° (dried substance)
Heavy metals	According to validated method from LS	Cobalt ≤ 25 ppm
		Lead ≤ 25 ppm
		Arsenic ≤ 75 ppm
		Mercury ≤ 15 ppm
		Cadmium ≤ 10 ppm
		Vanadium ≤ 50 ppm
		Nickel ≤ 100 ppm
		Lithium ≤ 1250 ppm
Sulphated ash	[SOP-06-MA-012]	Antimony ≤ 450 ppm
		Copper ≤ 1500 ppm
Sulphated ash	[SOP-06-MA-012]	≤ 0,2%
Water content	[SOP-06-MA-038]	≤ 10%
Residual solvent	Ph. Eur. 2.4.24	≤ 5000 ppm ethanol ≤ 5000 ppm acetone
TAMC (total aerobic microbial count) extern	Ph. Eur. 2.6.12	≤ ¹⁰² CFU per g
TYMC (total combined yeasts and moulds) extern	Ph. Eur. 2.6.12	≤ ¹⁰¹ CFU per g
Detection of specific microorganisms: Salmonella sp., Escherichia coli, Pseudomonas aeruginosa, Staph. aureus	Ph. Eur. 2.6.13	Absent in 1 g Salmonella absent in 10 g
Pesticide residues	Ph. Eur. 2.8.13	Meets the requirements
Bacterial endotoxins	Ph. Eur. 2.6.14	≤ 60 IU/g
Aflatoxins	Ph. Eur. 2.8.18	Meets the requirements