

**683379****Lot: 821163****Tylosin tartrate**1. General Information

Formula	C <sub>50</sub> H <sub>83</sub> NO <sub>23</sub>	Expiry Date	01 Oct 2027
<b>Mol. Weight</b>	<b>1066.19 g/mol</b>	Store at	4°C (in the dark)
CAS-No.	74610-55-2		

2. Batch Analysis

Identity	confirmed by LC-MS		
<b>Overall Purity</b>	<b>92.63 % (g/g)</b>	<b>Expanded Uncertainty</b>	<b>1.00 % (g/g)</b>
Assay Purity (HPLC)	92.63 % (g/g)	Uncertainty	0.50 % (g/g)

Certified on 25 Sep 2023

by YingYing Gao  
RM ReleaseThe overall purity is calculated by:  $\text{Purity(\%)} = \text{Assay purity} \times (100 - \text{water content} - \text{impurities}) / 100$ 

The reported uncertainties are determined in accordance with ISO 17034 with a 95% confidence level ( $k=2$ ). The Uncertainty is based on the combined uncertainties, including uncertainties of characterization and stability testing. The expiry date is based on the current knowledge and holds only for proper storage conditions in the originally closed flask. If the substance is proven to be unstable under the given storage conditions, you will be contacted immediately. The warranty of this product is limited to the purchasing price of this product and to the first point of use.

Our standards are for laboratory use only and can be used as reference material for calibration of chromatographic systems or related analytical techniques. For handling instructions see the MSDS. A minimum sample of 2 mg is recommended. Deploying less material will increase the uncertainty by a factor 2 for half of sample and 4 for a quarter of sample. The material in the vial can be used multiple times, but it is strongly recommended that all external negative influences to the material are considered and ruled out (e.g. high temperatures, UV-radiation, moisture, oxygen). It is strongly recommended to open the vial at room temperature only and handle the material under inert gas if necessary. The integrity of the purity cannot be guaranteed if the substance is handled under unfavorable conditions.

The balances used are calibrated with weights traceable to the national standards (DKD).

The HPC Standards GmbH produces reference materials according to ISO 17034. For further information, check:

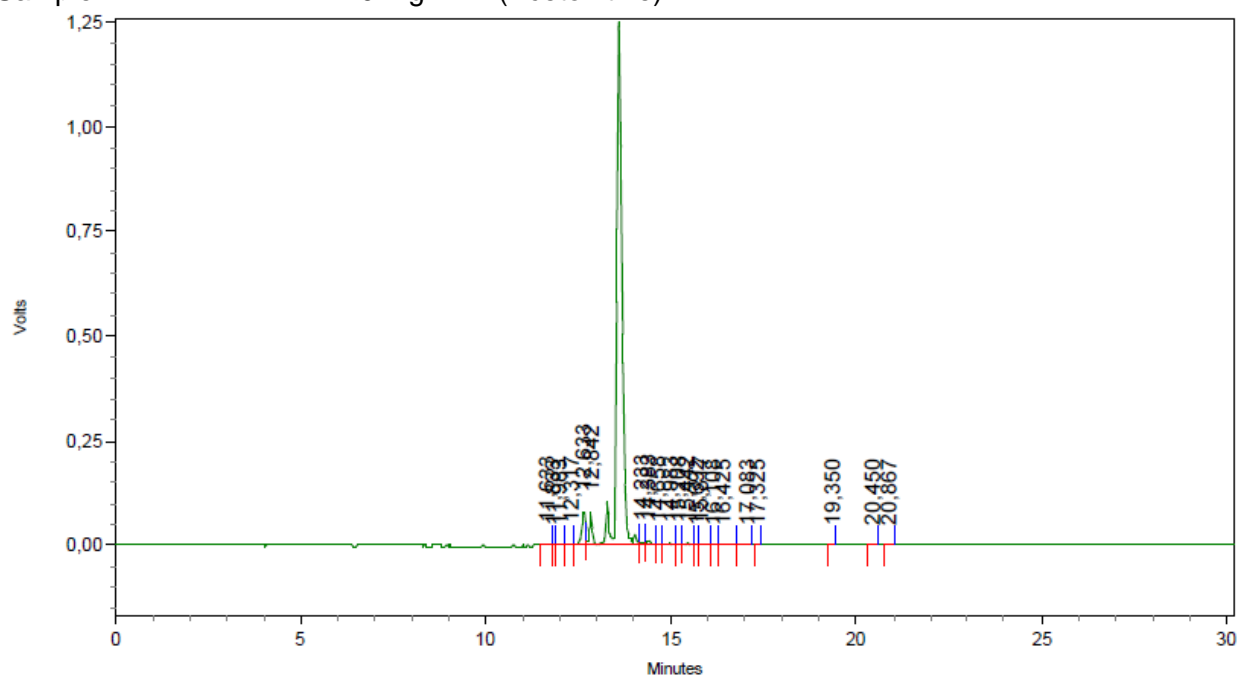


**HPLC-Method**

Article 683379  
Lot-No. 821163  
Column L=250mm, ID=4.6mm; Luna-Omega C18, 100A, 5µm  
Eluent A Acetonitrile  
Eluent B 0.1 % Phosphoric acid (Water)  
Gradient  

time	%A	%B
0min	0	100
22.5min	90	10
25min	90	10

  
Flow 1.0 ml min<sup>-1</sup>  
Detector UV-220nm  
Injection-Volume 5 µl  
Sample 2.0 mg ml<sup>-1</sup> (Acetonitrile)



Detector A - 1 (280nm)

Retention Time	Height	Area	Area Percent	
11,633	3128	21453	0,16	
11,833	200	745	0,01	
11,983	603	5681	0,04	
12,317	2089	25761	0,19	
12,633	81404	599731	4,50	
12,842	77852	12339308	92,57	<- Sum of Tylosin A, B, C and D
14,233	8018	63505	0,48	
14,383	10541	89103	0,67	
14,658	4132	39795	0,30	
14,983	4796	56785	0,43	
15,208	1512	12057	0,09	
15,442	5937	47622	0,36	
15,692	788	4976	0,04	
15,817	1426	9784	0,07	
16,108	130	1213	0,01	
16,425	271	3610	0,03	
17,083	287	3411	0,03	
17,325	180	1025	0,01	
19,350	191	1059	0,01	
20,450	238	1561	0,01	
20,867	254	1824	0,01	
Totals	203977	13330009	100,00	

Exemplary chromatogram of given method.

Version	Article	Lot	Reason for Change	Date
1	683379	821163	Initial Version	25 Sep 2023