Chemische Werke Hommel GmbH & Co. KG

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Specification

Concerning Product:				
Article number	58617WPEG			
Trade name / designation / denomination	Adenosin, pharma			
CAS number	58-61-7			
Other names / synonyms	•2-(6-aminopurin-9-yl)-5-(hydroxymethyl)oxolane-3,4-diol; •9- beta-D-ribofuranosyladenine; •adenosine;			
EC number	200-389-9 607-743-5			
Customs tariff number / CN code / TARIC	29349990			
Molecular weight [g / mol]	267.24132			
Formula	$C_{10}H_{13}N_5O_4$			

Parameter	Test Method	Specification	Unit			
Organoleptic test						
Appearance of solution	c = 3.3 %, w/v, in H 2 O	colourless				
Appearance		white crystalline powder, odourless				
Physical parameter						
Acidity/Alkalinity		blue-violet colour (with nmt 0.3 ml of 0.01 M NaOH) yellow colour (with nmt 0.1 ml of 0.01 M HCl)				
Loss on drying		@ 105°C, 2h: ≤ 0,5	%			
Specific Optical Rotation	(acc. to Ph.Eur.): (c = 2,5 %, in 1 M HCl)	45,0 – 49,0	o			
Specific Optical Rotation	(acc. to USP): (c = 2 %, in 5 % NaOH)	68,0 – 72,0	o			
Melting range		233,0 – 238,0	°C			
Solubility		practically insoluble in acetone, methylene chloride, alcohol and ether, slightly soluble in water at 20 °C, soluble in boiling water, freely soluble in diluted acids				
Identity						
Assay	HPLC	≥ 99,5	%			

Assay	from titration (HCIO 4)	on dry basis 99,0 – 101,0	%
Identification	IR Spectrum	complies	
Impurities			
Ammonium		≤ 4	ppm
Residue on ignition		≤ 0,1	%
Heavy Metals (as Pb)		≤ 10	ppm
Sulphates (SO ₄)		≤ 200	ppm
Related substances		Adenine ≤ 0,1	% [w/w]
Related substances	TLC	each single \leq 1,0	% [w/w]
Related substances		Guanosine ≤ 0,1	% [w/w]
Related substances		in sum: ≤ 0,5	% [w/w]
Related substances		Inosine $\leq 0,1$	% [w/w]
Related substances		Unspecified impurities $\leq 0,1$	% [w/w]
Related substances		Uridine ≤ 0,1	% [w/w]
Elemental Impurities			
Chlorides (Cl)		≤ 70	ppm
Microbiological data			
Escherichia Coli.		neg. in 1 g	CFU/g
Endotoxintest (LAL)		≤ 20,0	EU/100 mg
Pseudomonas aeruginosa		neg. in 1 g	
Salmonella		neg. in 10 g	
Staphylococcus Aureus		neg. in 1 g	
Total Plate Count		(TAMC): ≤ 100	CFU/g
Yeast and Mould		(TYMC): ≤ 100	CFU/g

Supplemental information:

Storage conditions: stable at RT when stored in tightly closed containers, protected from light and humidity

Complies with monographie: EP, USP,

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Waltrop, 08. Feb. 2022

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