

Specification

Product name:	Cisplatin, cis-Diamminedichloroplatinum(II)	Ph. Eur.
Formula:	cis-[PtCl ₂ (NH ₃) ₂]	
Heraeus Ident-No.:	89730021	
The product is in compliance with Ph.Eur. and Heraeus specification.		

No.	Parameter	Specification	Method
1.	Characters		
a	Appearance	yellow powder, or yellow or orange-yellow crystals	Ph. Eur.
b	Solubility	slightly soluble in water, sparingly soluble in dimethylformamide, practically insoluble in ethanol (96%)	Ph. Eur.
2.	Identification		
a	IR spectrum	conforms to standard	Ph. Eur.
b	TLC	conforms to standard	Ph. Eur.
3.	Tests		
a	Appearance of solution S1	solution S1 is clear and not more intensely coloured than reference solution GY ₅	Ph. Eur.
b	Appearance of solution S2	solution S2 is clear	Ph. Eur.
c	pH of solution S1	4.5 - 6.0	Ph. Eur.
4.	Related substances acc. Ph. Eur.		
a	Impurity A: Transplatin [wt.%]	NMT 0.15	Ph. Eur.
b	Impurity B: Trichloroammineplatinate [wt.%]	NMT 0.15	Ph. Eur.
c	Any unspecified impurity [area%]	NMT 0.10	Ph. Eur.
d	Sum of impurities others than A and B [area%]	NMT 0.5	Ph. Eur.
e	Total impurities [%]	NMT 0.6	Ph. Eur.
5.	Platinum [wt.%]	64.9 - 65.2	Heraeus
6.	Silver [ppm]	NMT 20	Ph. Eur.
7.	Water [wt.%]	NMT 0.1	Ph. Eur./USP
8.	UV purity ratio (E301/E246)	NLT 4.5	USP
9.	Assay [wt.%]	97.0 - 102.0	Ph. Eur.
10.	Microbial bioburden		
a	TAMC: Total aerobic microbial count [CFU/g]	NMT 10	Ph. Eur./USP
b	TYMC: Total combined yeast and mould count [CFU/g]	NMT 100	Ph. Eur./USP
c	Bacterial endotoxins [EU/mg]	NMT 0.2	Ph. Eur./USP

Specification

Product name:	Cisplatin, cis-Diamminedichloroplatinum(II)	US
Formula:	cis-[PtCl ₂ (NH ₃) ₂]	
Heraeus Ident-No.:	89730021	
The product is in compliance with USP and Heraeus specification.		

No.	Parameter	Specification	Method
1.	Characters		
a	Appearance	yellow to orange crystalline powder	Heraeus
2.	Identification		
a	IR spectrum	conforms to standard	USP
b	HPLC (retention time)	conforms to standard	USP
3.	Tests		
a	Crystallinity	meets the requirements	USP
4.	Related substances acc. USP		
a	Trichloroammineplatinate [wt.%]	NMT 0.1	USP
b	Transplatin [wt.%]	NMT 0.1	USP
5.	Platinum [wt.%]	64.42 - 65.22	Heraeus
6.	Silver [ppm]	NMT 20	Ph. Eur.
7.	Water [wt.%]	NMT 0.1	USP
8.	UV purity ratio (E301/E246)	NLT 4.5	USP
9.	Particle size [µm]	100% NMT 500	Heraeus
10.	Assay [wt.%] (on anhydrous basis)	98.0 - 102.0	USP
11.	Microbial bioburden		
a	TAMC: Total aerobic microbial count [CFU/g]	NMT 10	Ph. Eur. / USP
b	TYMC: Total combined yeast and mould count [CFU/g]	NMT 100	Ph. Eur. / USP
c	Bacterial endotoxins [EU/mg]	NMT 0.2	Ph. Eur. / USP