

Specification

Product name:	Thiotepa, Tris(aziridin-1-yl)phosphine sulfide	EU
Formula:	C ₆ H ₁₂ N ₃ PS	
Heraeus Ident-No.:	89730026	
The product is in compliance with USP, BP and Heraeus Specification		

No.	Parameter	Specification	Method
1.	Characters		
a	Appearance	fine, white crystalline flakes	BP
2.	Identification		
a	IR spectrum	conforms to standard	BP
b	HPLC (retention time)	conforms to standard	USP
c	Identification test B	solution becomes turbid	BP
d	Identification test C	blue color is produced	BP
3.	Tests		
a	Melting range [°C]	52 - 57	USP / BP
b	Clarity in a 2.0 % [w/v] solution	solution is clear	BP
c	Particles in a 2 % solution [p/mL]	NMT 5 / ml > 0.1 mm	Ph. Eur.
4.	Related substances		
a	Chloro-adduct [area%]	NMT 0.15	BP
b	Hydroxythiotepa A + B [area%]	NMT 0.1	BP
c	Single greatest unknown impurity [area%]	NMT 0.10	BP
d	Total impurities [area%]	NMT 0.2	BP
5.	Water [wt.%]	NMT 0.5	USP / BP
6.	Chloroform [ppm]	NMT 60	Heraeus
7.	Dichloromethane [ppm]	NMT 350	Heraeus
8.	Pentane [ppm]	NMT 2300	Heraeus
9.	Assay [wt.%] (on anhydrous basis)	97.0 - 102.0	USP
10.	Assay [wt.%] (anhydrous substance)	97.0 - 102.0	BP
11.	Microbial bioburden		
a	TAMC: Total aerobic microbial count [CFU/g]	NMT 100	BP / USP
b	Escherichia coli	absent / 1g	Heraeus
c	Pseudomonas aeruginosa	absent / 1g	Heraeus
d	Salmonella	absent / 1g	Heraeus
e	Staphylococcus aureus	absent / 1g	Heraeus
f	TYMC: Total combined yeast and mould count [CFU/g]	NMT 50	BP / USP
g	Bacterial endotoxins [EU/mg]	NMT 0.33	BP / USP

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The product is in compliance with USP and Heraeus specification.		

No.	Parameter	Specification	Method
1.	Characters		
a	Appearance	fine, white crystalline flakes	USP / BP
2.	Identification		
a	IR spectrum	conforms to standard	USP
b	HPLC (retention time)	conforms to standard	USP
3.	Tests		
a	Melting range [°C]	52 - 57	USP
b	Solubility in water	3% solution is clear	Heraeus
4.	Related substances		
a	Thiotepa chloroethyl analog P,P-Bis(aziridin-1-yl)-N-(2-chloroethyl)phosphinothioic amide [wt.%]	NMT 0.15	USP
b	Any individual unspecified impurity [wt.%]	NMT 0.10	USP
c	Total unspecified impurities [wt.%]	NMT 0.20	USP
5.	Water [wt.%]	NMT 0.5	USP
6.	Chloroform [ppm]	NMT 60	Heraeus
7.	Dichloromethane [ppm]	NMT 350	Heraeus
8.	Pentane [ppm]	NMT 2300	Heraeus
9.	Assay [wt.%] (on anhydrous basis)	97.0 - 102.0	USP
10.	Microbial bioburden		
a	TAMC: Total aerobic microbial count [CFU/g]	NMT 100	USP / Ph. Eur.
b	Escherichia coli	absent / 1g	Heraeus
c	Pseudomonas aeruginosa	absent / 1g	Heraeus
d	Salmonella	absent / 1g	Heraeus
e	Staphylococcus aureus	absent / 1g	Heraeus
f	TYMC: Total combined yeast and mould count [CFU/g]	NMT 50	USP / Ph. Eur.
g	Bacterial endotoxins [EU/mg]	NMT 6.25	USP / Ph. Eur.