Specification

Product name:	Dacarbazine, 5-(3,3-Dimethyl-1-triazenyl)imidazole-4-carboxamide	Ph. Eur.
Formula:	$C_6H_{10}N_6O$	
Heraeus Ident-No.:	89730025	
The product is in compliance with Ph. Eur., and Heraeus specification.		

No.	Parameter	Specification	Method
1.	**Characters**		
a	Appearance	white or slightly yellowish, crystalline powder	Ph. Eur.
b	Solubility	slightly soluble in water and anhydrous ethanol; practically insoluble in methylene chloride	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 (1%)	clear and not more intensely coloured than reference solution BY_6	Ph. Eur.
4.	**Related substances**		
a	Impurity A: 2-Azahypoxanthine (AHX) [wt.%]	NMT 0.2	Ph. Eur.
b	Any unspecified impurity eluting after Impurity A [area%]	NMT 0.10	Ph. Eur.
c	Impurity B: 4-Aminoimidazole-5-carboxamide (AICA) [wt.%]	NMT 0.1	Ph. Eur.
d	Any unspecified impurity (HPLC-B) [area%]	NMT 0.10	Ph. Eur.
e	Total impurities (HPLC-B) [%]	NMT 0.5	Ph. Eur.
f	Any other impurity [area%]	NMT 0.10	Ph. Eur.
5.	**Impurity D**: Dimethylamine [wt.%]	NMT 0.05	Ph. Eur.
6.	**Water** [wt.%]	NMT 0.5	Ph. Eur.
7.	**Acetone** [ppm]	NMT 250	Heraeus
8.	**Sulphated ash** [wt.%]	NMT 0.1	Ph. Eur.
9.	**Assay** [wt.%] (anhydrous substance)	98.5 - 101.0	Ph. Eur.
10.	**Microbial bioburden**		
a	TAMC: Total aerobic microbial count [CFU/g]	NMT 100	Ph. Eur. / USP
b	Enterobacteria [CFU/g]	NMT 10	Heraeus
c	Escherichia coli	absent in 1 g	Heraeus

No.	Parameter	Specification	Method
d	Pseudomonas aeruginosa	absent in 1 g	Heraeus
e	Salmonella	absent in 1 g	Heraeus
f	Staphylococcus aureus	absent in 1 g	Heraeus
g	TYMC: Total combined yeast and mould count [CFU/g]	NMT 100	Ph. Eur. / USP
h	Bacterial endotoxins [EU/mg]	NMT 0.2	Ph. Eur. / USP

Specification

Product name:	Dacarbazine, 5-(3,3-Dimethyl-1-triazenyl)imidazole-4-carboxamide	US
Formula:	$C_6H_{10}N_6O$	
Heraeus Ident-No.:	89730025	
The product is in compliance with USP and Heraeus specification.		

No.	Parameter	Specification	Method
1.	**Characters**		
a	Appearance	white or slightly yellowish, crystalline powder	Heraeus
2.	**Identification**		
a	IR spectrum	conforms to standard	USP
3.	**Tests**		
a	Clarity & colour of 2% solution	clear, less intensive than reference solution BY_6	Heraeus
b	UV spectrum Absorbance maximum [nm] (0.0006% solution in 0.1 N HCl)	322-324	Heraeus
c	UV spectrum Shoulder [nm] (0.0006% solution in 0.1 N HCl)	274-276	Heraeus
d	UV spectrum Absorption [AU] (0.0006% solution in 0.1 N HCl at 323 nm)	0.61-0.67	Heraeus
e	Absorption [AU] (of 1% solution at 500 nm after 3 h in diffuse light)	NMT 0.070	Heraeus
4.	**Related substances**		
a	Impurity A: 2-Azahypoxanthine (AHX) [wt.%]	NMT 0.2	Ph. Eur.
b	Any unspecified impurity eluting after Impurity A [area%]	NMT 0.10	Ph. Eur.
c	Impurity B: 4-Aminoimidazole-5-carboxamide (AICA) [wt.%]	NMT 0.1	Ph. Eur.
d	Any unspecified impurity (HPLC-B) [area%]	NMT 0.10	Ph. Eur.
e	Total impurities (HPLC-B) [%]	NMT 0.5	Ph. Eur.
5.	**Impurity D**: Dimethylamine [wt.%]	NMT 0.05	Ph. Eur.
6.	**Water** [wt.%]	NMT 0.5	Heraeus
7.	**Acetone** [ppm]	NMT 250	Heraeus
8.	**Sulphated ash** [wt.%]	NMT 0.1	USP
9.	**Assay** [wt.%] (anhydrous substance)	98.5 - 101.0	Ph. Eur.

No.	Parameter	Specification	Method
10.	**Microbial bioburden**		
a	TAMC: Total aerobic microbial count [CFU/g]	NMT 100	Ph. Eur. / USP
b	Enterobacteria [CFU/g]	NMT 10	Heraeus
c	Escherichia coli	absent in 1 g	Heraeus
d	Pseudomonas aeruginosa	absent in 1 g	Heraeus
e	Salmonella	absent in 1 g	Heraeus
f	Staphylococcus aureus	absent in 1 g	Heraeus
g	TYMC: Total combined yeast and mould count [CFU/g]	NMT 100	Ph. Eur. / USP
h	Bacterial endotoxins [EU/mg]	NMT 0.2	Ph. Eur. / USP