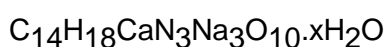




PRODUCT CODE: Z4C393

Diethylenetriaminepentaacetic Acid Calcium and Trisodium Salt x-hydrate (Ph. Eur.) low endotoxin IPEC grade



M.= 497,35 +xH₂O

CAS [12111-24-9]

EINECS 235-169-1

TARIC 2922 49 85 90

SYNONYMS: Calcium Trisodium Pentetate x-hydrate, DPTA Calcium and Trisodium Salt x-hydrate

PHYSICAL DATA: solid, White, Soluble in water. Hygroscopic •

BIBLIOGRAPHY: Sax 6624 • BRN 8182604 • Ph. Eur. 10.0 •

HAZARDOUS: LD L0 oral rat 10.000 mg/kg • LD50 oral rat 12.000 mg/kg •

OBSERVATIONS: Storage away from direct light. •

SPECIFICATIONS:

Assay (Compl.) (a.a.s.)	98,0-100,5 %
Identity :	
Identity according to Pharmacopoeia:	
Identity A	IR passes test
Identity B Calcium	passes test
Identity C Sodium	passes test
pH of 20% solution	8,0-9,5

Maximum limit of impurities

Appearance of solution	
Appearance Transparent < formazin I < 3 NTU	passes test
Appearance Colourless < B9	passes test
Chloride (Cl)	0,1%
Microbial Limits	
Bacterial endotoxins	0,1 IU/mg

Other Residual solvents (Ph.Eur.)	passes test
Methanol	0,3%
Impurity A - Nitrilotriacetic Acid (HPLC.)	0,1%
Impurity B - Diethyltriaminepentaacetic Acid	1,0%

Water (H2O)	9,0-15,0 %
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Ba	0,001 %
Fe	0,0020 %
K	0,05 %
Mg	0,05 %
Ni	0,0005 %
Sr	0,01 %
Zn	0,0005 %

Elemental impurities (ICH Q3D):

Class 1

Cd	0,5 ppm
Pb	5 ppm
As	1,5 ppm
Hg	1,5 ppm

Class 2A

Co	5 ppm
V	10 ppm
Ni	5 ppm

Class 2B

Au	10 ppm
Pd	10 ppm
Ir	10 ppm
Os	10 ppm
Rh	10 ppm
Ru	10 ppm
Ag	15 ppm
Pt	10 ppm

Class 3

Li	55 ppm
Sb	120 ppm
Ba	10 ppm
Mo	25 ppm
Cu	250 ppm
Sn	600 ppm
Cr	25 ppm