



**Maximum limit of impurities**

Appearance	passes test
Appearance of solution	passes test
Residue on ignition (as SO <sub>4</sub> )	0,2 %
Related Substances (HPLC)	
Guanine	0,3 %
Inosine	0,2 %
Any individual no specified	0,25 %
Total	1,0 %
2-Propanol (G.C.)	5000 ppm
Residual solvents (Ph.Eur/USP)	passes test
Microbial Limits	
Bacterial endotoxins	0,5 IU/mg
Total combined yeast and moulds (TYMC)	100 cfu/g
Total Aerobic Microbial Count (TAMC)	100 cfu/g
Water (H <sub>2</sub> O)	5 %
Heavy metals (as Pb)	0,001 %

## Elemental impurities (ICH Q3D):

Class 1	
Cd	0.5 ppm
Pb	0.5 ppm
As	1.5 ppm
Hg	1.5 ppm
Class 2A	
Co	5 ppm
V	10 ppm
Ni	20 ppm
Class 3	
Li	55 ppm
Sb	120 ppm
Cu	250 ppm