

Specification Sheet for Tretinoin	
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Specification sheet for Tretinoin

This section shows the specification of Tretinoin. Material which is released meets all the requirements outlined in Table 1.

Table 1 - Specification of Tretinoin

Test	Requirement	Analytical method
<u>Specification stated on the Certificate of Analysis</u>		
Appearance	Yellow or light orange crystalline powder	Qualitative visual examination
Identification - IR	The IR spectrum of sample is identical with that of reference spectrum of Tretinoin	Ph.Eur.
Assay (calculated on dried basis)	98.0 - 102.0 %	
Loss on drying	nmt. 0.5 %	
Sulfated ash	nmt. 0.1 %	
Heavy metals	nmt. 20 ppm	
Melting point	182.0° C ±2° C	
Related substances Impurity A Unspecified impurities Total impurities	 nmt. 0.5 % nmt. 0.2 % nmt. 1.0 %	
Residual solvents Acetaldehyde Ethyl acetate	 nmt. 15 ppm nmt. 5000 ppm	In-house GC-headspace method
Microbiology TAMC TYMC Staphylococcus aureus Pseudomonas aeruginosa	 nmt. 100 CFU/g nmt. 100 CFU/g absent absent	Ph.Eur.