

## **PRODUCT SPECIFICATION**

Product : **Oxytetracycline Dihydrate**  
**(Injectable Grade)**

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Characters : Appearance – yellow, crystalline powder.  
Solubility – very soluble in water.  
It dissolves in dilute acid and alkaline solutions.

Identification : A Thin-layer chromatogram - conform  
B Positive  
C Positive

pH : 4.5 – 7.5

Specific optical rotation : -203° ~ -216°

Absorbance (353 nm) : 290 – 310

Light absorbing impurities : 430 nm: NMT 0.25  
490 nm: NMT 0.20

Related substances : Impurity A: 4-epioxytetracycline NMT 0.5 %  
Impurity B: Tetracycline NMT 2.0 %  
Impurity C: other substances NMT 2.0 %

Heavy metals : NMT 50 ppm

Water : 6.0 – 9.0 %

Sulfated ash : NMT 0.5 %

Assay (HPLC) : 95.0 – 102.0 % (anhydrous)

Bacterial endotoxins : less than 0.4 IU/mg (internal)

MSDS : available upon request