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## **PRODUCT SPECIFICATION**

Product : **Oxytetracycline Hydrochloride**

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Appearance	:	yellow, crystalline powder, hygroscopic
Solubility	:	freely soluble in water, sparingly soluble in Ethanol (96 %). Solutions in water become turbid on Standing, owing to the precipitation of Oxytetracycline
Identification	:	A: thin-layer chromatography – complies B: reaction with sulphuric acid – complies C: reaction of chlorides – complies
pH	:	2.3 to 2.9
Specific optical rotation	:	-188° to -200°
Specific absorbance (353 nm)	:	270 to 290
Light-absorbing impurities (430 nm)	:	NMT 0.50
(490 nm)	:	NMT 0.20
Related substances	:	
Impurity A	:	NMT 0.5 %
Impurity B	:	NMT 2.0 %
Impurity C	:	NMT 2.0 %
Any other impurity	:	NMT 0.1 %
Total impurities D, E, F	:	NMT 2.0 %
Heavy metals	:	NMT 50 ppm
Water	:	NMT 2.0 %
Sulfated ash	:	NMT 0.5 %
Residual solvent	:	Methanol – NMT 3000 ppm
Assay (content of C <sub>22</sub> H <sub>25</sub> CIN <sub>2</sub> O <sub>9</sub> )	:	95.0 % to 102.0 % (anhydrous substance)

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MSDS : available upon request