

## **PRODUCT SPECIFICATION**

Product	:	<b><u>Doxycycline Hyclate</u></b>
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Appearance	:	yellow crystalline powder
Identification	:	A) HPLC test – corresponds B) Sulphuric Acid yellow colour reaction – corresponds C) Chloride's reaction – corresponds
pH	:	2.0 to 3.0
Specific optical rotation	:	-105° to -120°, calculated on the anhydrous, Ethanol-free substance
Specific absorbance	:	300-335 at 349 nm, calculated on the anhydrous, ethanol-free substance
Light-absorbing impurities	:	NMT 0.07 at 490 nm, calculated on the anhydrous, Ethanol-free substance
Related substances (%)	:	
Metacycline	:	NMT 2.0 %
6-Epidoxycycline	:	NMT 2.0 %
Oxytetracycline	:	NMT 0.5 %
4-Epidoxycycline	:	NMT 0.5 %
4,6-Epidoxycycline	:	NMT 0.5 %
Impurity F	:	NMT 0.5 %
Any other impurities	:	NMT 0.5 %
Ethanol	:	4.3 to 6.0 %
Heavy metals (ppm)	:	less than 50 ppm
Water	:	1.4 to 2.8 %
Sulphated ash	:	NMT 0.4 %
Assay	:	95.0 – 102.0 % of C <sub>22</sub> H <sub>25</sub> CIN <sub>2</sub> O <sub>8</sub> , calculated on the Anhydrous, ethanol-free substance
MSDS	:	available upon request