

TETRACYCLINI HYDROCHLORIDUM 100g

Lot No.: 24G26-F250082

Authorisation:	1890R05463	Date Of Analysis:	22/05/2024
Analytical Reference:	Ph. Eur. [01/2017:0210]	Production Number:	030325-G240143
CNK:	3592-201	Expiry Date:	09/2027

ANALYTICAL TESTS

CHARACTERS	SPECIFICATION	RESULT
Appearance	Yellow, crystalline powder	Complies
IDENTIFICATION	SPECIFICATION	RESULT
Identification A	Chromatogram complies	Complies
Identification B	Colour reaction complies	Complies
Identification C	Reaction (a) of chlorides	Complies
TESTS	SPECIFICATION	RESULT
pH	1.8 to 2.8	2.5
Specific optical rotation	-240 to -255 (dried substance)	-244.7
Related substances		
Impurity A	≤ 3.0 %	2.1 %
Impurity B	≤ 1.5 %	0.5 %
Impurity C	≤ 0.5 %	0.3 %
Impurity D	≤ 0.5 %	< 0.1 %
Loss on drying	≤ 2.0 %	0.5 %
Sulfated ash	≤ 0.5 %	< 0.1 %
Bacterial endotoxins	≤ 0.5 IU/mg	0.02 IU/mg
ASSAY	SPECIFICATION	RESULT
LC-UV	95.0% – 102.0% (dried substance)	98.4 %

Manufacturer identification code: S/GS/024

CONCLUSION: COMPLIES

RESPONSIBLE PHARMACIST: