

**TETRACYCLINI HYDROCHLORIDUM 100 g**

Lot No.: 22G11-APR22203

Authorisation:	1890R05463	Date Of Analysis:	23/05/2022
Analytical Reference:	Ph. Eur. 10.7 [01/2017:0210] Corr. 10.0	Production Number:	140722-GS22068
CNK:	3592-201	Expiry Date:	12/2024

**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)	- 248
Related substances		
Impurity A	≤ 3.0%	2.3%
Impurity B	≤ 1.5%	0.7%
Impurity C	≤ 0.5%	0.3%
Impurity D	≤ 0.5%	Not detected
Loss on drying	≤ 2.0%	0.6%
Sulfated ash	≤ 0.5%	0.04%
ASSAY	SPECIFICATION	RESULT
LC-UV	95.0% to 102.0% (dried substance)	98.3%

CONCLUSION: COMPLIES

RESPONSIBLE PHARMACIST:

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2022.07.25  
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