

# MINOCYCLINI HYDROCHLORIDUM DIHYDRICUM 25 g

Lot No.: 24L23-F250121

Authorisation:	1890R05506	Date Of Analysis:	16/10/2024
Analytical Reference:	Ph.Eur. [01/2021 :1030]	Production Number:	210325-G240169
CNK:	3490646	Expiry Date:	03/2027

## ANALYTICAL TESTS

CHARACTERS	SPECIFICATION	RESULT
Appearance	Yellow, hygroscopic, crystalline powder	Complies
IDENTIFICATION	SPECIFICATION	RESULT
Identification A	Spectrum complies with the spectrum obtained with minocycline hydrochloride CRS	Complies
Identification C	Reaction (a) of chlorides	Complies
TESTS	SPECIFICATION	RESULT
Appearance of solution	Solution is clear and the absorbance at 450 nm $\leq 0.23$	Complies
pH	3.5 to 4.5	4.0
Light-absorbing impurities	Absorbance at 560 nm $\leq 0.06$	Complies
Related substances		
Impurity A	$\leq 1.2\%$	1.2%
Impurity B	$\leq 0.8\%$	< 0.05%
Impurity C	$\leq 0.6\%$	0.1%
Impurity E	$\leq 0.6\%$	0.1%
Impurity F	$\leq 0.5\%$	0.2%
Impurity G	$\leq 0.5\%$	0.1%
Impurity H	$\leq 0.3\%$	< 0.05%
Any other impurity	$\leq 0.15\%$	0.12%
Total	$\leq 3.5\%$	2.1%
Water	5.0% to 8.0%	6.7%
Sulfated ash	$\leq 0.5\%$	0.1%
ASSAY	SPECIFICATION	RESULT
LC-UV	94.5% to 102.0% (anhydrous substance)	97.2%

Manufacturer identification code: S/GS/034

CONCLUSION: COMPLIES

RESPONSIBLE PHARMACIST: