

MINOCYCLINI HYDROCHLORIDUM DIHYDRICUM 5 g

Lot No.: 24L23-F250122

Authorisation:	1890R05506	Date Of Analysis:	16/10/2024
Analytical Reference:	Ph.Eur. [01/2021 :1030]	Production Number:	240325-G240169
CNK:	3490653	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 ≤ 0.23	Complies
pH	3.5 to 4.5	4.0
Light-absorbing impurities	Absorbance at 560 nm ≤ 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: