

DOXYCYCLINI HYCLAS 50 g

Lot No.: 23D17-APR23132

Autorisation :	1890R06230	Date Of Analysis :	23/03/2023
Analytical Reference :	Ph. Eur. 11.0 [01/2017 :0272] corr. 10.0	Production Number :	250423-GS23018
CNK :	4698-817	Expiry Date :	05/2026

ANALYTICAL TESTS

CHARACTERS	SPECIFICATION	RESULT
Appearance	Yellow, hygroscopic, crystalline powder	Complies
IDENTIFICATION	SPECIFICATION	RESULT
Identification A	Chromatogram complies	Complies
Identification B	A yellow colour develops	Complies
Identification C	It gives reaction (a) of chlorides	Complies
TESTS	SPECIFICATION	RESULT
pH	2.0 to 3.0	2.4
Absorbance	Maximum 0.07 at 490 nm (anhydrous and ethanol-free substance)	0.03
Related substances		
Impurity A	≤ 2.0%	1.5%
Impurity F	≤ 1.2%	1.1%
Impurity B	≤ 0.5%	< 0.05%
Impurity C	≤ 0.2%	0.1%
Unspecified impurities	≤ 0.10%	< 0.05%
Total	≤ 3.0%	2.7%
Ethanol	4.3% to 6.0%	4.4%
Water	1.4% to 2.8%	2.0%
Sulfated ash	≤ 0.4%	0.03%
ASSAY	SPECIFICATION	RESULT
LC	95.0% to 102.0% (anhydrous and ethanol-free substance)	98.1%

Manufacturer identification code: S/GS/187

CONCLUSION: COMPLIES

RESPONSIBLE PHARMACIST: