

QUALITY CONTROL DEPARTMENT

PHENYTOINUM NATRICUM
ANALYSIS REPORT: 21D15-APR22051

AUTHORISATION	1890R05434	DATE OF ANALYSIS	22/03/2021
LOT NUMBER	21D15-APR22051	EXPIRY DATE	06/2023
PRODUCTION NUMBER	080222-GS21018	ANALYTICAL REFERENCE	PH. EUR. 10.0 [01/2019:0521]

ANALYTICAL TESTS

CHARACTERS	SPECIFICATION	RESULT
Appearance	White or almost white, very hygroscopic, crystalline powder	Complies
IDENTIFICATION	SPECIFICATION	RESULT
Identification A	The spectrum complies with the spectrum obtained with phenytoin sodium CRS	Complies
Identification C	Reaction (b) of sodium	Complies
TESTS	SPECIFICATION	RESULT
Appearance of solution	Clear and not more intensely coloured than reference solution BY ₆	Complies
Related substances		
Impurity E	≤ 0.3 %	< 0.05 %
Impurity C	≤ 0.2 %	< 0.05 %
Impurity D	≤ 0.15 %	0.06 %
Unspecified impurities	≤ 0.10 %	< 0.05 %
Total	≤ 0.5 %	0.06 %
Free phenytoin	≤ 1.0 mL of 0.1 M NaOH is required to change the colour of the indicator to pink	Complies
Water	≤ 3.0 %	0.9 %
ASSAY	SPECIFICATION	RESULT
HPLC	98.0 % to 102.0 % (anhydrous substance)	100.3 %

CONCLUSION: COMPLIES

RESPONSIBLE PHARMACIST:


Maxime Brits

DATE: 03 MAR. 2022