

Geldig van 27 DEC 2018
tot 27 DEC 2021

QUALITY CONTROL DEPARTMENT

FLUORESCEINUM NATRICUM

ANALYSIS REPORT: 21I01-APR21204

AUTHORISATION	1890R06072	DATE OF ANALYSIS	09 AUG 2021
LOT NUMBER	21I01-APR21204	EXPIRY DATE	04/2024
PRODUCTION NUMBER	041021-GS21052	ANALYTICAL REFERENCE	PH. EUR. 10.5 [01/2008:1213] CORR. 6.0

ANALYTICAL TESTS

CHARACTERS	SPECIFICATION	RESULT
Appearance	Orange-red, fine powder, hygroscopic	Complies
IDENTIFICATION	SPECIFICATION	RESULT
Identification B	The spectrum complies with the spectrum obtained with fluorescein sodium CRS	Complies
Identification D	It gives reaction (a) of sodium	Complies
TESTS	SPECIFICATION	RESULT
Appearance of solution	Clear and orange-yellow with yellowish-green fluorescence	Complies
pH	7.0 to 9.0	8.0
Related substances		
Impurity A	$\leq 0.5\%$	$< 0.05\%$
Impurity B	$\leq 0.5\%$	$< 0.05\%$
Impurity C	$\leq 0.5\%$	0.07%
Unspecified impurities	$\leq 0.10\%$	1) 0.10% 2) 0.05%
Sum of impurities other than A, B and C	$\leq 0.5\%$	0.15%
Chlorides	$\leq 0.25\%$	Complies
Sulfates	$\leq 1.0\%$	Complies
Zinc	No turbidity or precipitate	Complies
Loss on drying	$\leq 10.0\%$	9.9%
ASSAY	SPECIFICATION	RESULT
Liquid chromatography	95.0% to 103.0% (dried substance)	95.0%

CONCLUSION: COMPLIES

RESPONSIBLE PHARMACIST:

[NAME]

DATE:

15 OCT 2021.