



Macsen Laboratories

Manufacture Of Fine Chemicals & Pharmaceuticals

CERTIFICATE OF ANALYSIS

NAME OF PRODUCT - FLUORESCEIN SODIUM Ph.Eur.-9.0			
AMOUNT RECEIVED FOR ANALYSIS	25 Gm	CAS .NO	518 – 47 – 8
BATCH NO.	FS-030521	DATE OF RECEIPT	10.5.2021
DATE OF ANALYSIS	10.5.2021	ANALYTICAL REPORT NO	FS-030521
MFG.DT:	MAY.2021	EXP .DT:	APRIL.2024

SR.NO	CRITERIA	LIMIT/SPECIFICATION	TEST RESULTS
1.	APPEARANCE	Orange Red, Fine powder, Hygroscopic	Orange Red, Fine powder, Hygroscopic
2.	SOLUBILITY	Freely soluble in water, soluble in ethanol (96%), practically insoluble in hexane and in methylene chloride.	Freely soluble in water, soluble in ethanol (96%), practically insoluble in hexane and in methylene chloride.
3.	IDENTIFICATION	Must Comply Identification Test A to D	Complies A to D tests
4.	APPEARANCE OF SOLUTION S	Solution S is clear and orange – yellow with yellowish – green fluorescence.	Solution S is clear and orange – yellow with yellowish – green fluorescence.
5.	pH	In between 7.0 to 9.0	8.7
6.	RELATED SUBSTANCES(HPLC)	1. Impurity A – NMT 0.5 % 2. Impurity B – NMT 0.5% 3. Impurity C – NMT 0.5% 4. Other Impurity – NMT 0.1% Unspecified impurity (RT 11.410 Mint.) Unspecified impurity (RT 13.373 Mint.) Sum of impurities other than A,B,C – NMT 0.5%	Not detected Not detected 0.21% 0.015% 0.006% 0.021%
7.	CHLORIDES	Max. 0.25%	0.11%
8.	SULPHATES	Max. 1.0%	0.22%
9.	ZINC	Must pass Test	Passes Test
10.	LOSS ON DRYING (Drying at 105°C)	Max. 10.0%	8.74 %
11.	ASSAY (Dried Substance)	95.0 % to 103.0%	98.76 %

Additional tests:

12	Pyrogen free test	Must pass Test	Passes Test
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Residual Solvents :

13	Acetone	≤5000 PPM	< 5 PPM
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Microbiological quality:

SR.No	Criteria	Limit/Specification	Test Results
1.	TAMC	≤100 CFU/g	< 10 CFU/g
2.	TYMC	≤ 50 CFU/g	< 10 CFU/g
3.	Bile tolerant Gram-Bacteria	Absent/g	Absent
4.	Staphylococcus Aureus	Absent/g	Absent
5.	Pseudomonas Aeruginosa	Absent/g	Absent
6.	Escherichia Coli	Absent/g	Absent
7.	Salmonella	Absent/g	Absent

REPORT:- THE SAMPLE SUBMITTED FOR ANALYSIS COMPLIES WITH SPECIFICATIONS OF THE STANDARD .



ANALYTICAL CHEMIST

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NET Wt 1.00 KG FLUORESCHEIN SODIUM Ph.Eur -9.0 MFG LIC. RAJ-2186 Batch No. FS-030521 Mfg. Dt. May 2021 Exp. Dt. April 2024	
Mfg By : MACSEN LABORATORIES VILLAGE TITERDI, TEHSIL GIRVA, UDAIPUR – 313002 MADE IN INDIA	