

CERTIFICATE OF ANALYSIS

FLUODROP B10 EUR/EN/US DOMES

A002861200

BATCH NO : 6X41
 Manufacturing Date : 01/05/2026
 Expiry Date : 05/2029

Part 2.E - Test on the finished product - April 2024

	METHODS	SPECIFICATIONS	RESULTATS
General controls			
Solution aspect	Visual inspection	Practically clear, orange-yellow. Practically free of particles	Complies
Deliverable volume	Internal method	0.40 ml	0.44 ml
pH determination	Ph. Eur. 2.2.3	7.0 - 9.0	7.9
Osmolality	Ph. Eur. 2.2.35	270 to 310 mosmol/kg	299 mosmol/kg
Sub-visible particles count $\geq$ 10 μ m	Ph. Eur. 2.9.53	$\leq$ 3000 per dose	<1
Sub-visible particles count $\geq$ 25 μ m	Ph. Eur. 2.9.53	$\leq$ 300 per dose	<1
Sterility	Ph. Eur. 2.6.1	Sterile	Complies
Identifications			
HPLC retention time	Ph. Eur. 2.2.29	RT test similar to RT reference	Positive
HPLC/Diode array detector	Ph. Eur. 2.2.29	Test spectrum similar to reference spectrum	Test spectrum similar to reference spectrum
Assay (for 100 ml)			
Fluorescein sodium	Ph. Eur. 2.2.29	4.75 - 5.25 mg/ml	4.97 mg/ml
Impurities			
Impurity B (Phthalic acid)	Ph. Eur. 2.2.29	$\leq$ 1.0%	<0.1 %
Impurity C	Ph. Eur. 2.2.29	$\leq$ 1.0%	<0.1 %
Individual unknown degradation product	Ph. Eur. 2.2.29	$\leq$ 1.0%	<0.1 %
Total of unknown degradation products	Ph. Eur. 2.2.29	$\leq$ 2.0%	<0.1 %

CONCLUSION :

Date : 2010712026

Emmanuelle GARY
 Pharmacien AQ Produits

By delegation of the Qualified Person