Olon Spa Stab. Segrate
Via B. Cellini 20
20054 Segrate (MI)

PEC: olon@pec.olonspa.it
Tel. HQ: +39 02 9523.1
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Olon S.p.A. - Sede Legale
Strada Rivoltana Km 6/7
20053 Rodano (MI)

Certificate of Analysis

Product name	**DICLOFENAC SODIUM Ph. Eur./BP/USP**		
		Manufacturing date	25/08/2021
Product Code	B01441	Re-test date	24/08/2026
Batch Number		Certificate Nr.	
Batch Size	556,000 KG		

Test	Specification	M.U.	Result
Description: White or slightly yellowish, slightly hygroscopic crystalline powder. Sparingly soluble in water, freely soluble in methanol; soluble in ethanol (96%); slightly soluble in acetone. Practically insoluble in chloroform and in ether. It melts at about 280°C, with decomposition.	Complies with the Test		Complies
Identification:	-		-
A) IR spectrum: Conforms to Diclofenac sodium RS.	Complies with the Test		Complies
B) Retention Time: The retention time of the Diclofenac peak in the chromatogram of the test solution corresponds to that of reference solution (b) as obtained in the test for related substances.	Complies with the Test		Complies
C) Reaction of sodium: Yields reaction (b) of sodium.	Complies with the Test		Complies
pH (1 % w/v aqueous solution)	7,0 - 8,5		7,9
Appearance of solution: A 50 mg/ml solution in methanol is as clear as the reference suspension 1 and its absorbance at 440 nm is not more than 0.050.	<= 0,050	Abs	0,005
Water (K. Fischer)	<= 0.5	%	0,12
Loss on drying	<= 0.5	%	0,28
Assay (Titrimetric, on dried substance)	99,0 - 101,0	%	100,5
Related Substances (HPLC):	-		-
- Impurity A	<= 0,10	%	< Disregard limit (0,05)
- Impurity F	<= 0,10	%	< Disregard limit (0,05)
- Any other impurity	<= 0,10	%	< Disregard limit (0,05)
- Total impurities	<= 0.4	%	< Disregard limit (0,05)
Residual Solvents (GC):	-		-

Edoardo Bassani QC Manager Approved September 13, 2021	Claudia Maurogiovanni Qualified Person Released September 13, 2021

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Test	Specification	M.U.	Result
- Ethyl acetate	<= 50	ppm	< LOD (3)
ADDITIONAL TESTS	-		-
Particle size (air jet sieve):	-		-
- <= 500 Microns	>= 90	%	100
- <= 250 Microns	>= 50	%	96

This material has been prepared following the current Good Manufacturing Practice (cGMP).
It has been tested according and conforms to the requirements of current Pharmacopoeias.

Edoardo Bassani QC Manager Approved September 13, 2021	Claudia Maurogiovanni Qualified Person Released September 13, 2021