



NOVACYL SAS
21, Chemin de la Sauvegarde,
Ecully Parc CS 33167,
69134 ECULLY Cedex
FRANCE

NEOLOGISTICA SRL
LARGO U. BOCCIONI 1
21040 ORIGGIO (VA)
ITALIE

Manufacturing Plant

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NOVACYL établissement Saint-Fons
RUE PROSPER MONNET
69190 Saint Fons
France

Certificate of analysis

Print Date
06.DEC.2024
Purchase order Item/Date
PO201065488 / 31.OCT.2024
Delivery Item/Date
80706251 900002 / 27.JAN.2025
Order Item/Date
363953 000020 / 31.OCT.2024
Customer N°
4504
Truck number /Seal number
/

Material : Our / Your reference
12004 ACETYLSALICYLIC ACID 3020 DRUM 50 KG / 108702
NOVACYL PDS : ASA-3020-EP-1809-V3

This product complies with the specifications of the Aspirin USP monograph and Acetylsalicylic acid Ph. Eur. Monograph 0309, current editions.
Our Acetylsalicylic acid is periodically checked in microbiology by a qualified laboratory in accordance with the European Pharmacopeia.
This batch of Acetylsalicylic acid is manufactured in accordance with EUDRALEX Volume 4 Part II / ICH Q7 and with current files [R2-CEP 1993-007] and [US DMF 11373].
Residual solvents: Only acetic acid, a class III solvent, is used in the manufacture. It is covered by the Loss on drying test.

Batch: FRH2432211 / Manufacturing date: 17.NOV.2024 /Re-test date: 17.NOV.2027
Delivered quantity : 600.00 KG

Characteristic	Unit	Value	Lower limit	Upper Limit
IR Spectrum	-	In specification	-	-
USP				
Colored reaction	-	In specification	-	-
USP				
Coloration (EP)	-	Liquid less coloured than B9 -	-	-
Ph. Eur.				
Clarity (EP)	-	Clear	-	-
Ph. Eur.				
Loss on drying	%	0,00	-	0,50
Ph. Eur.				
Assay (on a dry basis)	%	100,1	99,5	101,0
Ph. Eur.				
Sulphated ash	%	0,03	-	0,05
Ph. Eur. / USP				
Anhydride of acetylsalicylic acid	%	< 0,01		0,15
HPLC				

R3020-EUR-2
6 - 23.SEP.2020

Property of Novacap, no modification is allowed

06/02/2025
AZELIS ITALIA S.r.l.
Via T. Gulli, 39
20147 MILANO

Material : Our / Your reference

12004 ACETYLSALICYLIC ACID 3020 DRUM 50 KG / 108702

NOVACYL PDS : ASA-3020-EP-1809-V3

Batch: FRH2432211 / Manufacturing date: 17.NOV.2024 / Re-test date: 17.NOV.2027

Delivered quantity : 600.00 KG

Acetylsalicylsalicylic acid	%	0,01	0,15
HPLC			
Salicylsalicylic acid	%	< 0,01	0,15
HPLC			
4-hydroxybenzoic acid	%	< 0,01	0,15
HPLC			
4-hydroxyisophtalic acid	%	< 0,01	0,15
HPLC			
Free salicylic acid	%	0,01	0,15
HPLC			
Unspecified impurities>0.05%	-	None	-
HPLC			
Sum of related substances	%	0,02	0,25
HPLC			
Retained on 180 mu sieve	%	93,9	60,0
FRITSCH			
Retained on 710 mu sieve	%	0,4	5,0
FRITSCH			

Batch released on : 02.DEC.2024

Person responsible for batch release: Cécile PAYET-MORICE

Authorized person of Quality Unit

12 DEC. 2024

Cécile PAYET - MORICE



R3020-EUR-2

6 - 23.SEP.2020

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06/21/2025
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