

NOVACYL SAS

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

SYNOPTIS INDUSTRIAL SP. Z O.O.
KRAKOWIAKÓW 65
02 255 WARSZAWA
POLOGNE

Certificate of analysis

Print Date
04.MAR.2022
Purchase order Item/Date
PO205013116-PO205015 / 17.FEB.2021
Delivery Item/Date
80640339 900003 / 18.MAR.2022
Order Item/Date
294294 000030 / 17.FEB.2021
Customer N°
7038
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: FRH2202911 / Manufacturing date: 29.JAN.2022 /Re-test date: 28.JAN.2025
Delivered quantity : 300.00 KG

Characteristic	Unit	Value	Lower limit	Upper Limit
IR Spectrum USP	-	In specification	-	-
Colored reaction USP	-	In specification	-	-
Ethanollic sol.-colour Ph. Eur.	-	Liquid less coloured than B9	-	-
Ethanollic sol.-turbidity Ph. Eur.	-	Clear	-	-
Loss on drying Ph. Eur.	%	0,04	-	0,50
Assay (on a dry basis) Ph. Eur.	%	100,0	99,5	101,0
Sulphated ash Ph. Eur. / USP	%	< 0,01	-	0,05
Anhydride of acetylsalicylic acid HPLC	%	< 0,03	-	0,15

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Acetylsalicylsalicylic acid	%	< 0,03	0,15
HPLC			
Salicylsalicylic acid	%	< 0,03	0,15
HPLC			
4-hydroxybenzoic acid	%	< 0,03	0,15
HPLC			
4-hydroxyisophthalic acid	%	< 0,03	0,15
HPLC			
Free salicylic acid	%	< 0,03	0,15
HPLC			
Unspecified impurities>0.05%	-	None	-
HPLC			
Sum of related substances	%	< 0,03	0,25
HPLC			
Retained on 180 mu sieve	%	95,0	60,0
FRITSCH			
Retained on 710 mu sieve	%	0,3	5,0
FRITSCH			

Batch released on : 11.FEB.2022

Person responsible for batch release: Cécile PAYET-MORICE

Authorized person of Quality Unit

10 MAR. 2022

Cécile PAYET - MORICE

