

METAPHARMACEUTICAL



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

AZELIS ESPANA SAU
AIRPHARM
CALLE 22 DEL PARC LOGISTIC
08040 BARCELONA
ESPAGNE

N DE LOTE:

0220921

af 21/09/21

Manufacturing Plant

NOVACYL établissement Roussillon
RUE GASTON MONMOUSSEAU
38150 Roussillon
France

Page 1 / 2

Certificate of analysis

Print Date
25.AUG.2020
Purchase order Item/Date
PO217021506 / 09.JUL.2020
Delivery Item/Date
80576748 900001 / 14.OCT.2020
Order Item/Date
279486 000010 / 09.JUL.2020
Customer N°
6153
Truck number /Seal number
/

Material: Our / Your reference

128115 YMS-METHYL SALICYLATE PHARMA DR50KG/P450 / 109319

This product complies with the European Pharmacopeia and with the USP-NF current versions. The test of angular rotation is not carried out because Novacyl's Methyl Salicylate is of synthetic origin.

This batch of Methyl Salicylate was manufactured in accordance with EU GMP Volume 4 Part II (ICH Q7) and to the dossier CEP 1994-007 current version.

Residual solvents: Only methanol, a class 2 solvent is used as reagent. It is part of our specifications with a limit of 0.10% max, which is tighter than the ICHQ3C limit of 0.3% max

Batch: RMS2022611 / Manufacturing date: 13.AUG.2020 / Re-test date: 13.AUG.2025
Delivered quantity: 4 950.00 KG

Characteristic	Unit	Value	Lower limit	Upper Limit
Identity (Infrared)	-	IR - In specification -	-	-
Location of main assay peak(USP)	-	Complies	-	-
Ethanollic sol.-colour	-	-Liquid less coloured than Y7 -	-	-
Ethanollic sol.-turbidity	-	CLEAR LIQUID	-	-
Solubility in 70% alcohol	-	Complete and clear	-	-
Specific gravity at 20/20 PE		1,186	1,182	1,188
Specific gravity at 25/25 USP		1,182	1,180	1,185
Refractive index at 20°C		1,5360	1,5350	1,5380
Acidity	ml	< 0,01	-	0,40
Assay (HPLC) USP	%	100,60	98,00	102,00
Assay (Potentiometry) PE	%	99,8	99,0	101,0
Number of related substances>0,10 %	-	None	-	-
Salicylic acid (USP)	%	< 0,1	-	0,1
Dimethyl 4-hydroxyisophthalate (USP)	%	< 0,5	-	0,5
Total impurities	%	< 0,0	-	0,5
Phenol	ppm	< 50	-	50
Methanol (residual solvent)	%	< 0,05	-	0,10



METAPHARMACEUTICAL

Page 2 / 2

N DE LOTE:

0220921

af 21/09/2021.

Material : Our / Your reference

128115 YMS-METHYL SALICYLATE PHARMA DR50KG/P450 / 109319

Batch: RMS2022611 / Manufacturing date: 13.AUG.2020 / Re-test date: 13.AUG.2025

Delivered quantity : 4 950.00 KG

Batch released on : 24.AUG.2020

Person responsible for batch release: Christelle TALLARON