

METAPHARMACEUTICAL



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

N DE LOTE:

0190525

Al'audie
16/05/2025

Manufacturing Plant

NOVACYL établissement Roussillon
RUE GASTON MONMOUSSEAU
38150 Roussillon
France

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Certificate of analysis

Print Date
15.MAY.2024
Purchase order Item/Date
PO217041985 / 09.FEB.2024
Delivery Item/Date
80699113 900001 / 28.MAY.2024
Order Item/Date
356797 000010 / 09.FEB.2024
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: RMS2410611 / Manufacturing date: 15.APR.2024 /Re-test date: 15.APR.2029
Delivered quantity : 3 600.00 KG

Characteristic	Unit	Value	Lower limit	Upper Limit
Unspecified impurities (EP)	%	< 0,05	-	0,10
Total impurities (EP)	%	< 0,1	-	0,5
Phenol (EP)	ppm	32	-	50
Salicylic acid (USP)	%	< 0,1	-	0,1
Dimethyl 4-hydroxyisophthalate (USP)	%	< 0,5	-	0,5
Assay (USP)	%	100,7	98,0	102,0
Methanol (EP)	%	< 0,05	-	0,10
Retention time - Identification (USP)	-	Complies	-	-
Solubility in ethanol 70% (USP)	-	Complies	-	-
Coloration (EP)	-	Complies	-	-
Clarity (EP)	-	Complies	-	-
Assay (EP)	%	99,5	99,0	101,0
Relative density 20/20 (EP)		1,186	1,182	1,188
Specific gravity at 25/25 (USP)		1,183	1,180	1,185
Acidity (EP)	ml	0,10	-	0,40
Refractive index (EP)		1,537	1,535	1,538
IR Spectrum - Identification (EP/USP)	-	Guaranteed conformity-	-	-

SMSP-PHAUE-1
8 - 26.JUN.2023

Property of Novacap, no modification is allowed

Forestier L.
[Signature]



Material : Our / Your reference

128115 YMS-METHYL SALICYLATE PHARMA DR50KG/P450 / 109319

Batch: RMS2410611 / Manufacturing date: 15.APR.2024 / Re-test date: 15.APR.2029

Delivered quantity : 3 600.00 KG

Batch released on : 15.MAY.2024

Person responsible for batch release: Elodie BOUCHER

FORESTIER L.