

METAPHARMACEUTICAL

N DE LOTE:

0090622



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

AZELIS TR KIMYA END. ÜR. #TH. #HR. TIC.
DİLOVASI OSB. MAH. D-5007 SK. NO:3 DİLOVASI
41455 KOCAELİ
TURQUIE

Manufacturing Plant

NOVACYL établissement Roussillon
RUE GASTON MONMOUSSEAU
38150 Roussillon
France

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Certificate of analysis

Print Date
06.APR.2022
Purchase order Item/Date
PO240008910 / 20.JAN.2022
Delivery Item/Date
80639767 900002 / 25.APR.2022
Order Item/Date
317552 000010 / 20.JAN.2022
Customer N°
7103
Truck number /Seal number
34ga3360/

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: RMS2204711 / Manufacturing date: 16.FEB.2022 / Re-test date: 16.FEB.2027
Delivered quantity: 1 350.00 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	%	99,00	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	23	-	50
Methanol (residual solvent)	%	< 0,05	-	0,10



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Batch: RMS2204711 / Manufacturing date: 16.FEB.2022 / Re-test date: 16.FEB.2027

Delivered quantity: 1 350.00 KG

Batch released on : 25.FEB.2022

Person responsible for batch release: Lucie FORESTIER