

# 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.  
DILOVASI OSB. MAH. D-5007 SK. NO:3 DILOVASI  
41455 KOCAELI  
TURQUIE

Manufacturing Plant

NOVACYL établissement Roussillon  
RUE GASTON MONMOUSSEAU  
38150 Roussillon  
France

Page 1 / 2

## 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-hydroxyisophtalate (USP) | %    | < 0,5                           | -           | 0,5         |
| Total impurities                    | %    | < 0,0                           | -           | 0,5         |
| Phenol                              | ppm  | 23                              | -           | 50          |
| Methanol (residual solvent)         | %    | < 0,05                          | -           | 0,10        |



Material: Our / Your reference

128115 YMS-METHYL SALICYLATE PHARMA DR50KG/P450 / 109319

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