



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

AZELIS DEUTSCHLAND PHARMA GMBH
ZUM SIEGBLICK 37
53757 SANKT AUGUSTIN
ALLEMAGNE

Manufacturing Plant

NOVACYL établissement Roussillon
RUE GASTON MONMOUSSEAU
38150 Roussillon
France

Page 1 / 2

Lte: 0090720

Certificate of analysis

Print Date
16.OCT.2019
Purchase order Item/Date
PO212002271 / 06.AUG.2019
Delivery Item/Date
80542457 900001 / 25.OCT.2019
Order Item/Date
257742 000010 / 06.AUG.2019
Customer N°
6110
Truck number /Seal number
/

Material : Our / Your reference
128115 YMS-METHYL SALICYLATE PHARMA DR50KG/P450 /

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: RMS1927511 / Manufacturing date: 02.OCT.2019 /Re-test date: 01.OCT.2024
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	0,02	-	0,40
Assay (HPLC) USP	%	100,40	98,00	102,00
Assay (Potentiometry) PE	%	99,7	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	< 50	-	50
Methanol (residual solvent)	%	< 0,05	-	0,10

Material : Our / Your reference

128115 YMS-METHYL SALICYLATE PHARMA DR50KG/P450 /

Batch: RMS1927511 / Manufacturing date: 02.OCT.2019 / Re-test date: 01.OCT.2024

Delivered quantity : 4 950.00 KG

Batch released on : 16.OCT.2019

Person responsible for batch release: Lucie FORESTIER

SMSP-PHAUE-1

5 - 28.JUN.2019

Property of Novacap, no modification is allowed