



NOVACYL SAS
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69009 - LYON
FRANCE

AZELIS DEUTSCHLAND PHARMA GMBH
STANDORT KREFELD
WEESERWEG 23
47804 KREFELD
ALLEMAGNE

Manufacturing Plant

NOVACYL établissement Roussillon
RUE GASTON MONMOUSSEAU
38150 Roussillon
France

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Certificate of analysis

Print Date
17.AUG.2017
Purchase order Item/Date
PO212000671 / 14.AUG.2017
Delivery Item/Date
80451161 900004 / 28.AUG.2017
Order Item/Date
211003 000010 / 14.AUG.2017
Customer N°
1071081
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: RMS1720111 / Manufacturing date: 20.JUL.2017 /Re-test date: 20.JUL.2022
Delivered quantity : 2 250.00 KG

Characteristic	Unit	Value	Lower limit	Upper Limit
Identification (Infrared)	-	Guaranteed conformity	-	-
identif.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°C		1,184	1,180	1,186
Specific gravity at 25°C		1,182	1,180	1,185
Refractive index at 20°C		1,536	1,535	1,538
Free acidity in NaOH 0.1N for 5 g	ml	< 0,01	-	0,40
Heavy metals	ppm	< 10	-	10
Assay (HPLC) USP	%	98,7	98,0	100,5
Assay (GC) PE	%	100,0	99,0	100,5
Number of related substances>0,10 %	-	None	-	-
Salicylic acid	%	< 0,1	-	0,1
Dimethyl 4-hydroxyisophthalate	%	< 0,5	-	0,5
Total impurities	%	< 0,030	-	1,000
Phenol	ppm	32	-	50
Residual solvent(methanol)	%	< 0,001	-	0,100

Material : Our / Your reference

128115 YMS-METHYL SALICYLATE PHARMA DR50KG/P450 /

Batch: RMS1720111 / Manufacturing date: 20.JUL.2017 / Re-test date: 20.JUL.2022

Delivered quantity : 2 250.00 KG

Batch released on : 09.AUG.2017

Person responsible for batch release: Lucie FORESTIER

SMSP-PHAUE-1

3 - 01.MAR.2016



Die Angaben auf dem Analysenzertifikat entbinden
den Käufer nicht von der Durchführung einer
vollständigen analytischen Wareneingangskontrolle.
The results on the Certificate of Analysis do not
absolve the buyer from a full analytical control.
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