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FRANCE

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XPO LOGISTICS - COURE
POLIGONO INDUSTRIAL DEL LLOBREGAT
08755 CASTELLBISBAL
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Manufacturing Plant

NOVACYL établissement Roussillon
RUE GASTON MONMOUSSEAU
38150 Roussillon
France

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Certificate of analysis

Print Date
21.DEC.2018
Purchase order Item/Date
PO217011193 / 10.SEP.2018
Delivery Item/Date
80508229 900001 / 02.JAN.2019
Order Item/Date
235903 000010 / 10.SEP.2018
Customer N°
2030387
Truck number /Seal number
/

Material: Our / Your reference

128115 YMS-METHYL SALICYLATE PHARMA DR50KG/P450 / 109319

This product complies with the European Pharmacopoeia 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: RMS1835211 / Manufacturing date: 18.DEC.2018 / Re-test date: 18.DEC.2023
Delivered quantity: 4 950.00 KG

Characteristic	Unit	Value	Lower limit	Upper Limit
Identification (Infrared)	-	IR - In specification -	-	-
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	%	100,3	98,0	102,0
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	34	-	50
Residual solvent (methanol)	%	0,001	-	0,100

SMSP-PHAUE-1

4 - 05.JAN.2018

Property of Novacap, no modification is allowed



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128115 YMS-METHYL SALICYLATE PHARMA DR50KG/P450 / 109319

Batch: RMS1835211 / Manufacturing date: 18.DEC.2018 / Re-test date: 18.DEC.2023

Delivered quantity : 4 950.00 KG

Batch released on : 21.DEC.2018

Person responsible for batch release: Lucie FORESTIER

SMSP-PHAUE-1

4 - 05.JAN.2018

Property of Novacap, no modification is allowed