

METAPHARMACEUTICAL

Manufacturing Plant

N DE LOTE:

0150424

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

NOVACYL établissement Roussillon
RUE GASTON MONMOUSSEAU
38150 Roussillon
France

af 16/04/2024

AZELIS ESPANA SAU
AIRPHARM
NUMERO 6-14
CALLE 22 DEL PARC LOGISTIC
08040 BARCELONA
ESPAGNE

Certificate of analysis

Print Date
10.AUG.2023
Purchase order Item/Date
PO217038120 / 24.MAY.2023
Delivery Item/Date
80689425 900001 / 04.OCT.2023
Order Item/Date
348814 000010 / 24.MAY.2023
Customer N°
6153
Truck number /Seal number
/

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: RMS2309611 / Manufacturing date: 06.APR.2023 /Re-test date: 05.APR.2028
Delivered quantity : 4 500.00 KG

Characteristic	Unit	Value	Lower limit	Upper Limit
Unspecified impurities (EP)	%	< 0,05	-	0,10
Total impurities (EP)	%	< 0,1	-	0,5
Phenol (EP)	ppm	38	-	50
Salicylic acid (USP)	%	< 0,1	-	0,1
Dimethyl 4-hydroxyisophthalate (USP)	%	< 0,5	-	0,5
Assay (USP)	%	99,8	98,0	102,0
Methanol (EP)	%	< 0,05	-	0,10
Retention time - Identification (USP)	-	In specification	-	-
Solubility in ethanol 70% (USP)	-	In specification	-	-
Coloration (EP)	-	In specification	-	-
Clarity (EP)	-	In specification	-	-
Assay (EP)	%	99,5	99,0	101,0
Relative density 20/20 (EP)		1,186	1,182	1,188
Specific gravity at 25/25 (USP)		1,183	1,180	1,185
Acidity (EP)	ml	0,10	-	0,40
Refractive index (EP)		1,537	1,535	1,538
IR Spectrum - Identification (EP/USP)	-	Guaranteed conformity-	-	-

Material : Our / Your reference

128115 YMS-METHYL SALICYLATE PHARMA DR50KG/P450 / 109319

Batch: RMS2309611 / Manufacturing date: 06.APR.2023 / Re-test date: 05.APR.2028

Delivered quantity : 4 500.00 KG

Batch released on : 16.MAY.2023

Person responsible for batch release: Amandine WEINSBERG

po WEINSBERG 16 MAY 2023

