

LOTE: RAS1717500

 **novacyl**
novacap group
NOVACYL SAS
29 AVENUE JOANNES MASSET
69009 - LYON
FRANCE

Manufacturing Plant

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NOVACYL établissement Roussillon
RUE GASTON MONMOUSSEAU
38150 Roussillon
France

Certificate of analysis

Print Date
18.JUL.2017
Purchase order Item/Date
4500367817 / 19.MAY.2017
Delivery Item/Date
80448352 900003 / 31.JUL.2017
Order Item/Date
205945 000010 / 19.MAY.2017
Customer N°
1076673
Truck number /Seal number
/

Material: Our / Your reference

28869 YSA-SALICYLIC ACID PHARM PB*25 KG/PAL 1T / 211103

This batch of salicylic acid was manufactured in accordance with ICHQ7 and Eudralex Volume 4 Part 2 GMP requirements. It complies with the requirements of current version of Ph.Eur. and USP and with the current revision of R2-CEP-1993-008.
Residual solvents: No class 1, 2 or 3 solvents are used in the salicylic acid process. Therefore, there are no residual solvents likely to be present.

Batch: RAS1717500 / Manufacturing date: 24.JUN.2017 /Re-test date: 24.JUN.2022
Delivered quantity: 3 000.00 KG

Characteristic	Unit	Value	Lower limit	Upper Limit
IR spectrum	-	Complies	-	-
Melting point	°C	158,8	158,0	161,0
Location of main assay peak(USP)	-	Complies	-	-
Loss on drying	%	0,1	-	0,5
Sulfates	%	0,0130	-	0,0200
Assay BP (dry basis)	%	100,1	99,0	100,5
Assay USP (dry basis)	%	100,5	98,0	102,0
Clarity of ethanolic solution.	-	Complies	-	-
Coloration of ethanolic solution.	haz	< 10	-	10
Heavy Metals	%	< 0,0010	-	0,0020
Chlorides (Cl-)	%	< 0,0100	-	0,0100
Residual solvents (none)	-	Guaranteed conformity	-	-
Sulphated ash/Residue on ignition	%	0,01	-	0,05
4-hydroxybenzoic acid	%	0,03	-	0,10
4-hydroxyisophthalic acid	%	0,03	-	0,05
Phenol	%	< 0,01	-	0,01
Total impurities	%	< 0,11	-	0,20
No other relat. subst.>0,05%	-	Complies	-	-

Batch released on : 18.JUL.2017

Person responsible for batch release: Lucie FORESTIER



SALPH-PE/USP

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