



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

Manufacturing Plant

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NOVACYL Etablissement Roussillon
RUE GASTON MONMOUSSEAU
38150 Roussillon
France

Certificate of analysis

Print Date
19.OCT.2020
Purchase order Item/Date
4500448322 / 15.JUL.2020
Delivery Item/Date
80582909 900004 / 14.DEC.2020
Order Item/Date
281652 000010 / 18.AUG.2020
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 Euralex 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: RAS2027600 / Manufacturing date: 02.OCT.2020 / Re-test date: 02.OCT.2025
Delivered quantity: 2 000.00 KG

Characteristic	Unit	Value	Lower limit	Upper Limit
IR spectrum	-	Complies	-	-
Melting point	°C	159,7	158,0	161,0
Location of main assay peak (USP)	-	Complies	-	-
Loss on drying	%	0,1	-	0,5
Sulfates	%	0,0160	-	0,0200
Assay EP (dry basis)	%	100,3	99,0	100,5
Assay USP (dry basis)	%	99,4	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	%	0,02	-	0,05
4-hydroxybenzoic acid	%	0,04	-	0,10
4-hydroxyisophthalic acid	%	0,03	-	0,05
Phenol	%	< 0,01	-	0,01
Water impurities	%	< 0,11	-	0,20
No other relat. subst. > 0,05%	-	Complies	-	-

Batch released on : 15.OCT.2020

Person responsible for batch release: Lucie FORESTIER

SALPH-RE/USP

4 - 05.JAN.2018

44 8344/95

211103

Property of Novacap, no modification is allowed