



Manufacturing Plant

NOVACYL établissement Roussillon
RUE GASTON MONMOUSSEAU
38150 Roussillon
France

Page 1 / 1

Certificate of analysis

Print Date
31.AUG.2022
Purchase order Item/Date
5000021924 / 13.JUL.2022
Delivery Item/Date
80655721 900001 / 01.SEP.2022
Order Item/Date
329563 000020 / 13.JUL.2022
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: RAS2218900 / Manufacturing date: 08.JUL.2022 / Re-test date: 08.JUL.2027
Delivered quantity: 5 000.00 KG

Characteristic	Unit	Value	Lower limit	Upper Limit
IR Spectrum - Identification (EP)	-	In specification	-	-
IR Spectrum - Identification (USP)	-	In specification	-	-
Clarity (EP)	-	In specification	-	-
Coloration (EP)	-	In specification	-	-
Assay (EP) - dry basis	%	99,9	99,0	100,5
Sulfates	%	0,0162	-	0,0200
Loss on drying (USP)	%	0,0	-	0,5
Chlorides (Cl-) (EP)	%	< 0,0100	-	0,0100
Melting point - Identification (EP)	°C	159	158	161
Sulphated ash/Residue on ignition USP/EP	%	0,04	-	0,05
4-hydroxybenzoic acid (USP)	%	0,04	-	0,10
4-hydroxyisophthalic acid (USP)	%	0,03	-	0,05
Phenol (USP)	%	< 0,00	-	0,01
Total associated acids	%	0,07	-	0,20
Total impurities (USP)	%	0,07	-	0,20
Any other individual impurity (USP)	%	0,00	-	0,05
Assay (USP) - dry basis	%	100,3	98,0	102,0
Retention time - Identification (USP)	-	In specification	-	-

Batch released on : 27.JUL.2022

Person responsible for batch release: Lucie FORESTIER

SALPH-PE/USP
7 - 13.JUN.2022

Property of Novacap, no modification is allowed

22-mar-23

