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FRANCE

AZELIS DEUTSCHLAND GMBH
TOR A PHARMA-LAGER
ZUM SIEGBLICK 37
53757 SANKT AUGUSTIN-BUISDORF
ALLEMAGNE

Manufacturing Plant

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NOVACYL établissement Roussillon
RUE GASTON MONMOUSSEAU
38150 Roussillon
France

Certificate of analysis

Print Date
07.MAR.2023
Purchase order Item/Date
PO211040366 / 19.DEC.2022
Delivery Item/Date
80674209 900001 / 23.MAR.2023
Order Item/Date
339406 000010 / 19.DEC.2022
Customer N°
6110
Truck number /Seal number
/

Material : Our / Your reference
28869 YSA-SALICYLIC ACID PHARM PB*25 KG/PAL 1T /

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: RAS2305600 / Manufacturing date: 25.FEB.2023 / Re-test date: 25.FEB.2028
Delivered quantity: 4 000.00 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	%	100,4	99,0	100,5
Sulfates	%	< 0,0200	-	0,0200
Loss on drying (USP)	%	0,0	-	0,5
Chlorides (Cl-) (EP)	%	< 0,0100	-	0,0100
Melting point - Identification (EP)	°C	160	158	161
Sulphated ash/Residue on ignition USP/EP	%	0,00	-	0,05
4-hydroxybenzoic acid (USP)	%	0,03	-	0,10
4-hydroxyisophthalic acid (USP)	%	0,03	-	0,05
Phenol (USP)	%	< 0,00	-	0,01
Total associated acids	%	0,06	-	0,20
Total impurities (USP)	%	0,06	-	0,20
Any other individual impurity (USP)	%	0,00	-	0,05
Assay (USP) - dry basis	%	99,3	98,0	102,0
Retention time - Identification (USP)	-	In specification	-	-

Batch released on : 07.MAR.2023
Person responsible for batch release: Lucie FORESTIER

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

Property of Novacap, no modification is allowed