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Manufacturing Plant

NOVACYL établissement Roussillon
RUE GASTON MONMOUSSEAU
38150 Roussillon
France

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Certificate of analysis

Print Date
27.JUL.2018
Purchase order Item/Date
PO201006752 / 04.JUN.2018
Delivery Item/Date
80490969 900002 / 10.SEP.2018
Order Item/Date
229780 000010 / 04.JUN.2018
Customer N°
4504
Truck number /Seal number
/

Material : Our / Your reference
28869 YSA-SALICYLIC ACID PHARM PB*25 KG/PAL 1T / 109406

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: RAS1819400 / Manufacturing date: 13.JUL.2018 / Re-test date: 13.JUL.2023
Delivered quantity: 4 000.00 KG

Characteristic	Unit	Value	Lower limit	Upper limit
IR spectrum	-	Complies	-	-
Melting point	°C	158,9	158,0	161,0
Location of main assay peak(USP)	-	Complies	-	-
Loss on drying	%	0,1	-	0,5
Sulfates	%	0,0150	-	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	%	0,04	-	0,05
4-hydroxybenzoic acid	%	0,04	-	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 : 23.JUL.2018
Person responsible for batch release: Lucie FORESTIER

SALPH-PE/USP
4 - 05.JAN.2018

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