



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

Manufacturing Plant

Page 1 / 1

NOVACYL établissement Roussillon  
RUE GASTON MONMousseau  
38150 Roussillon  
France

### Certificate of analysis

Print Date  
20.NOV.2019  
Purchase order Item/Date  
4500424073 / 22.JUL.2019  
Delivery Item/Date  
80546130 900001 / 28.NOV.2019  
Order Item/Date  
256977 000010 / 22.JUL.2019  
Customer N°  
1076673  
Truck number /Seal number  
/

Material: Our /Your reference  
28869 YSA-SALICYLIC ACID PHARM PB\*25 KG/PAL 1T / 211193

This batch of salicylic acid was manufactured in accordance with ICHQ7 and Sudralax 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: RAS1931400 / Manufacturing date: 10.NOV.2019 /Re-test date: 09.NOV.2024  
Delivered quantity: 5 000.00 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)              | %    | 100,4                 | 99,0        | 100,5       |
| Assay USP (dry basis)             | %    | 100,3                 | 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             | %    | 0,04                  | -           | 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 : 20.NOV.2019  
Person responsible for batch release: Lucie FORESTIER

SALPH-PE/USP  
4 - 05.JAN.2019

Property of Novacyl, no modification is allowed