

| DAPSONA (EUR. PH.) | | | |
|---------------------------|---------|---------------------|---------------------|
| PRODUCT CODE: 002614 | | CAS Nº: 80-08-0 | ANALYSIS Nº: 221/22 |
| MANUFACTURER BATCH: | 21/006 | CERTIFICATE ID: | 36.178 |
| SUPPLIER BATCH: | 219918 | MANUFACTURING DATE: | 01/02/2021 |
| METAPH BATCH: | 0051022 | EXPIRY DATE: | 01/01/2026 |

| ATTRIBUTES | SHOULD BE | IS |
|------------------------------|---|--------------------------|
| Appearance | White or slightly yellowish-white, crystalline powder | White crystalline powder |
| Solubility | Pratically insoluble in water, freely soluble in acetone, sparingly soluble in ethanol (96 %). It dissolves in dilute mineral acids | Complies (*) |
| Identification A | Complies | Complies |
| Identification B | Complies | Complies |
| Identification C | Complies | Complies |
| Melting point | 175 - 181 °C | 177 °C |
| Related substances | | |
| Impurity B | =< 0.4 % | < 0.40 % |
| Impurity A | =< 0.3 % | < 0.30 % |
| Impurity C | =< 0.3 % | < 0.30 % |
| Unspecified impurities | =< 0.10 % | < 0.10 % |
| Total impurities | =< 1.0 % | < 1.0 % |
| Loss on drying | =< 1.5 % | 0.05 % |
| Sulfated ash | =< 0.1 % | 0.07 % |
| Assay | 99.0 - 101.0 % | 100.8 % |
| Residual solvents [In-house] | | (*) (**) |
| Methanol | =< 2000 ppm | < LoD |
| Mono Chloro Benzene | =< 360 ppm | < LoD |
| Benzene | =< 2 ppm | < LoD |

COMPLIES WITH

European Pharmacopoeia 10.6

REMARKS

Dapsone is subjected to the requirements of the ICH Q3D "Elemental Impurities".

Absence of N-nitrosamines impurities has been ensured after a risk evaluation according to ICH Q9, ICH M7 and in accordance with guidelines EMA/428592/2019 Rev 2 and EMA/189634/2019.

(*) Data adapted from the certificate of analysis of the manufacturer.

(**) According to the requirements of guides EMA/CHMP/ICH/82260/2006.

Certificates of residual solvents, allergens, non-GMO and BSE-TSE, among others, are available upon request.

All methods of analysis are validated by official pharmacopoeias or are validated by internal methods of the manufacturer, which can be obtained at specific request. The above information does not exempt from the obligation to identify the product before use.

STORAGE

Keep the containers tightly closed. Store in a dry, cool and well-ventilated place.

Analysis date: 20/10/2022
 Signature: Ferran Gonzalez de Rivera Rier
 Conclusion: Complies
 Original certificate available upon request

Manufacturer: 40000614
 ATUL LTD.
 At & Post Atul
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 GUJARAT(India)

