

**DAPSONA (EUR. PH.)**

PRODUCT CODE: 002614	CAS Nº: 80-08-0	ANALYSIS Nº: 180/21
MANUFACTURER BATCH: 20/007	CERTIFICATE ID: 32.257	
SUPPLIER BATCH: 21B17-F05-377123	MANUFACTURING DATE: 01/09/2020	
METAPH BATCH: 0070721	RETEST DATE: 28/08/2025	

ATTRIBUTES	SHOULD BE	IS
Appearance	White or slightly yellowish-white, crystalline powder	White crystalline powder
Solubility	Very slightly soluble in water, freely soluble in acetone, sparingly soluble in alcohol. It dissolves in dilute mineral acids	Complies (*)
Identification A	Complies	Complies
Identification B	Complies	Complies
Identification C	Complies	Complies
Melting point	175 - 181 °C	180 °C
Related substances	Complies	Complies
Loss on drying	=< 1.5 %	0.06 %
Sulfated ash	=< 0.1 %	0.05 % (*)
Assay	99.0 - 101.0 %	99.8 %
Residual solvents [In-house]		(*) (**)
Methanol	=< 2000 ppm	< LoD
Mono Chloro Benzene	=< 360 ppm	< LoD
Benzene	=< 2 ppm	< LoD

COMPLIES WITH

European Pharmacopoeia 10.0

REMARKS

Producte completely analyzed inside the EU.

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: 27/07/2021

Signature: Ferran Gonzalez de Rivera Rier

Conclusion: Complies

Original certificate available upon request

Manufacturer: 40000614

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