



DAPSONA (EUR. PH.)			
PRODUCT CODE: 002614		CAS Nº: 80-08-0	ANALYSIS Nº: 231/23
MANUFACTURER BATCH:	DAPS/22-23/002	CERTIFICATE ID:	39.488
SUPPLIER BATCH:	----	MANUFACTURING DATE:	01/10/2022
METAPH BATCH:	0140923	EXPIRY DATE:	30/09/2027

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	178.9 °C
Related substances		
Impurity B	=< 0.4 %	Not Detected
Impurity A	=< 0.3 %	Not Detected
Impurity C	=< 0.3 %	Not Detected
Unspecified impurities	=< 0.10 %	< 0.05 %
Total impurities	=< 1.0 %	< 0.05 %
Loss on drying	=< 1.5 %	0.2 %
Sulfated ash	=< 0.1 %	0.06 %
Assay	99.0 - 101.0 %	100.5 %

COMPLIES WITH

European Pharmacopoeia 11.0

REMARKS

Product fully analyzed within the EU, in compliance with the currents regulations "EudraLex - Volume 4 - Good Manufacturing Practice (GMP) guidelines" Part-II.

It shows polymorphism.

Dapsone is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006.

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

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.

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 weel-ventilated place.

Analysis date: 16/11/2023
Signature: Albert Sánchez López (QP)
Conclusion: Complies
Original certificate available upon request

Manufacturer: 40001000
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