METAPHARMACEUTICAL IND SL
Josep Plà, 163, 2n 5a / Tel. 933 089 976 / info@metapharmaceutical.com

DAPSONA (EUR. PH.)

PRODUCT CODE: 002614	CAS Nº: 80-08-0	ANALYSIS Nº: 167/25	
MANUFACTURER BATCH:	DAPS/24-25/002	CERTIFICATE ID:	46.833
SUPPLIER BATCH:	----	MANUFACTURING DATE:	01/06/2024
METAPH BATCH:	0020625	RETEST DATE:	30/05/2029

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 (*)
Melting point	175 - 181 ºC	177.1 ºC
Identification	Complies	Complies
Related substances		
Impurity B	=< 0.4 %	Not Detected
Impurity A	=< 0.3 %	Not Detected
Impurity C	=< 0.3 %	Not Detected
Unspecified impurities	=< 0.10 %	0.06 % (RT = 21.77 min)
Total impurities	=< 1.0 %	0.06 %
Loss on drying	=< 1.5 %	0.08 %
Sulfated ash	=< 0.1 %	0.08 %
Assay	99.0 - 101.0 %	100.7 %

COMPLIES WITH

European Pharmacopoeia 11.4

REMARKS

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

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

All data controlled by Metapharmaceutical Industrial SL.
(*) 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: 14/10/2025
Signature: Albert Sánchez López (QP)
Conclusion: Complies
Original certificate available upon request

Manufacturer: 40001000
MEDILUX LABORATORIES PVT. LTD.
Plot N. 98-99, Sector-1, Industrial Area
Distr. Dhar, Madhya Pradesh
454775 Pithampur