
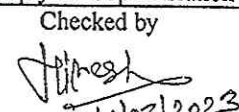
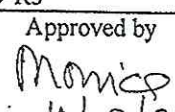
 14/09/2023
CERTIFICATE OF ANALYSIS

Product	Dapsone Ph. Eur.		
Synonyms	4,4'-sulfonyldianiline		
CAS No.	80-08-0	Batch No.	DAPS/22-23/002
A.R. No.	MR/API/FP/22/10/169	Manufacturing date	October 2022
Batch size	25.400 kg	Retest date	September 2027
Storage condition	Store protected from light.		
Date of analysis	19/11/2022		

Test	Specification	Results
Description	A white or slightly yellowish-white, crystalline powder	White crystalline powder
Solubility	Practically insoluble in water, freely soluble in acetone, sparingly soluble in ethanol (96%). It dissolves in dilute mineral acids.	Complies
Identification (By IR)	The IR spectrum of the substance being examined should be concordant with the reference spectrum of Dapsone CRS or working standard.	Conforms with standard
Loss on drying (At 105±2°C, for 3 h)	Not more than 1.5%	0.23%
Sulfated ash	Not more than 0.1%	0.07%
Assay (By Primary Aromatic Amino-Nitrogen)	99.0% to 101.0% (dried substance).	99.87%
Related Substances (By HPLC)		
(a) Impurity A	Not more than 0.3%	Not detected
(b) Impurity B	Not more than 0.4%	Below reporting threshold
(c) Impurity C	Not more than 0.3%	Not detected
(d) Unspecified Impurities	Not more than 0.10%	Below reporting threshold
(e) Total Impurities	Not more than 1.0%	Below reporting threshold
In House test		
Residual solvent (By GC)		
Methanol	Not more than 3000 ppm	Not detected
Additional test		
Particle size (Dry dispersion method)		
D ₉₀	Less than 350 microns	340 µm
D ₅₀	Less than 150 microns	109 µm
D ₁₀	Less than 30 microns	19.6 µm

Remark: The above material complies/~~does not comply~~ with specification No. QCD/APS/029-R3

Prepared by  10/03/2023	Checked by  10/03/2023	Approved by  10/03/23
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