

QUETIAPINI FUMARAS 25 g

Lot No.: 25A21-F250043

Authorisation:	1890R6169	Date Of Analysis:	13/12/2024
Analytical Reference:	Ph. Eur. [01/2017:2541]	Production Number:	040225-G240248
CNK:	4600-946	Expiry Date:	01/2027

ANALYTICAL TESTS

CHARACTERS	SPECIFICATION	RESULT
Appearance	White or almost white powder	Complies
IDENTIFICATION	SPECIFICATION	RESULT
Infrared absorption spectrophotometry	The spectrum complies with Quetiapine fumarate CRS	Complies
TESTS	SPECIFICATION	RESULT
Related substances		
Impurity G	$\leq 0.15\%$	$< 0.05\%$
Impurity N	$\leq 0.15\%$	$< 0.05\%$
Unspecified impurities	$\leq 0.10\%$ for each impurity	0.06%
Total	$\leq 0.5\%$	0.1%
Loss on drying	$\leq 0.5\%$	0.3%
Sulfated ash	$\leq 0.1\%$	0.1%
ASSAY	SPECIFICATION	RESULT
Potentiometric titration		
Quetiapine fumarate	99.0% to 101.0% (dried substance)	100.7%
Fumaric acid	12.5% to 13.8% (dried substance)	13.2%

Manufacturer identification code: S/GS/165

CONCLUSION: COMPLIES

RESPONSIBLE PHARMACIST: