

CERTIFICATE OF ANALYSIS

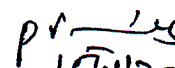
Product : Risperidone
Batch No. : RN0091025
Dispatch Qty.: 50.000 Kg
Reference : USP-NF2024

CAS No. : [106266-06-2]
Date of Mfg. : October- 2025
Retest Date : September -2030

Storage condition: Preserve in well closed containers and store room temperature.			
S.No	Test	Specification	Result
1.0	Description	White or Almost white powder	White powder
2.0	Solubility	Soluble in Methylene Chloride, Sparingly soluble in alcohol and practically insoluble in Water.	Complies
3.0	Identification		
3.1	By IR	IR absorption spectrum of the test sample should be concordant with spectrum obtained with Risperidone working standard.	Complies
3.2	By HPLC	The Retention time of the major peak in the chromatogram of the assay preparation corresponds to that in the chromatogram of the standard preparation, as obtained in the assay.	Complies
4.0	Residue on ignition (%w/w)	Not more than 0.1	0.06
5.0	Loss on drying (%w/w)	Not more than 0.5	0.18
6.0	Related substance by HPLC (in %)		
6.1	E-oxime	Not more than 0.20	Not detected
6.2	Z-oxime	Not more than 0.20	Not detected
6.3	9-hydroxyrisperidone	Not more than 0.20	0.02(Below quantitation limit:0.06)
6.4	Desfluoro risperidone	Not more than 0.10	0.01(Below quantitation limit:0.03)
6.5	Risperidone difluoroketone	Not more than 0.10	Not detected
6.6	5-fluororisperidone	Not more than 0.20	Not detected
6.7	Risperidone related compound G	Not more than 0.10	0.02(Below quantitation limit:0.03)
6.8	6-methylrisperidone	Not more than 0.20	Not detected
6.9	Any unknown impurity	Not more than 0.10	0.01
6.10	Total impurities	Not more than 0.30	0.04
7.0	Assay by HPLC (On dried basis) (%w/w)	Not less than 98.0 and not more than 102.0	99.5

Remarks: The product confirms as per the above specification.

Prepared by: 
Date: 15/11/2025

Checked by: 
Date: 15/11/2025

Approved by: 
Date: 15/11/2025

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Plant Address:
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CIN - U21001TS2024PTC189157

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