



PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

ANALYTICAL SPECIFICATION FOR NICOTINAMIDE IP

Manufacturer Name :		Supplier Name :	
Manufacturer's Batch No.:		Manufacturer's Batch Size :	
Manufacturing Date :		Expiry Date :	
Quantity received :		Sample Quantity :	
Document No.:	Effective Date. :	Change Control No.: N/A	
Control No./A.R.No. :		Retest Date :	

Reference : IP 96 (Page No : 507-508)

Description : Colourless crystals or white, crystalline powder; odour faint and Characteristic; free from foreign particles.
Complies/Does Not Comply

Solubility : Freely Soluble in *water* and in *ethanol (95%)*(1 in 1-10), slightly soluble in chloroform and in *ether* (1 in 100-1000).
Complies/Does Not Comply

S.No.	Test	Reference	Result	Specification	Remark
1	Identification (A,E) or (B,C,D,E) A. Infra-red spectrum B. C.	IP		Note : Routinely Identifiacion A,E performed A. The infra-red absorption spectrum is concordant with the <i>reference spectrum</i> of nicotinamide. B. Pyridine is evolved on heating. C.Ammonia is evolved on boiling with dilute sodium hydroxide.	



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S. No.	Test	Reference	Result	Specification	Remark
1.	Identification (continued) D. Colour reaction E. Melting Point			D. A golden yellow colour develops. E. Between 128° and 131°	
2.	pH	IP		Between 6.0 and 7.5	
3	Clarity and colour of Solution	IP		Solution is clear and not more intensely coloured than <i>reference solution</i> BYS7.	
4	Chloride	IP		Not more than 250 ppm	
5	Sulphate	IP		Not more than 125 ppm	
6	Heavy metals	IP		Not more than 30 ppm	
7	Related Substances	IP		Any secondary spot in the chromatogram obtained with solution (1) is not more intense than with the spot in the chromatogram obtained with solution (2).	
8	Sulphated Ash	IP		Not more than 0.1 %	
9	Loss on drying	IP		Not more than 0.5 %	
10	Assay as C ₆ H ₆ N ₂ O (ondried basis)	IP		Not less than 99.0 % and not more than 101.0 %	

Raw Data Reference :

Analyst Name :

Analyst Name :

Analyst Name :

Analyst Hard Book No. :

Page No. :



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Results : Sample Conforms / Does Not Conform to Specification

Analyzed By : _____

Date : _____

Checked By : _____

Date : _____

Approved By : _____

Date : _____