



ANALYSIS CERTIFICATE

Site Code	Analysis No.	Product Description			
2612	12262	URSODEOXYCHOLIC ACID (Ursodiol) USP Curr.Ed.			
Batch	Quantity	Manufacturing date	Retest date	Manufacturing site	
2020120544	kg 100	December 2020	December 2025	Via Novi 78, I-15060 Basaluzzo (AL), Italy	
Customer			Customer Annotations		
SUAN FARMA Inc. - Fair Lawn (USA)					

Test	Requirement	Results	U.M.
Description	White or almost white crystalline powder	White or almost white crystalline powder	
Loss on drying	<=0.5	0.1	%
Melting range	200 - 205	202	°C
Specific optical rotation	+57.0 - +62.0	+60.5	° o.d.b.
Assay	99.0 - 101.0 Acidimetric - 98.5 - 101.5 HPLC USP method	99.7 Acidimetric - 99.4 HPLC USP method	% o.d.b.
Residue on ignition	<=0.1	0.04	%
Lithocholic acid (TLC)	<=0.05	<0.05	%
Chenodeoxycholic acid (HPLC)	<=1.0 (Ph.Eur.Curr.Ed. method)	0.27	%
Other impurities each (HPLC)	<=0.10 (Ph.Eur.Curr.Ed. method)	<0.10	%
Total sum of all impurities (HPLC)	<=1.5 (Ph.Eur.Curr.Ed. method)	0.33	%
Identification	Positive (IR)	Positive (IR)	
Residual solvents	Complies with "Guidelines for Residual Solvents" (CPMP/ICH/283/95) Class 3	Complies with "Guidelines for Residual Solvents" (CPMP/ICH/283/95) Class 3	ppm
Particle size	D(v,0.5) 2-8; D(v,0.9) <=30	D(v,0.5) 6.95; D(v,0.9): 16.9	µm
Solubility	Freely soluble in alcohol and glacial acetic acid; sparingly soluble in chloroform; slightly soluble in ether; practically insoluble in water (from USP curr.ed.,description and solubility/reference tables)	Freely soluble in alcohol and glacial acetic acid; sparingly soluble in chloroform; slightly soluble in ether; practically insoluble in water (from USP curr.ed.,description and solubility/reference tables)	

Date of issue	Chemical Lab.	Biological Lab.	Opinion
09/12/2020	Picetti Edoardo		Complies to Specifications Ed.1 issued on 16/10/2020

Laboratory Manager	Quality Control Manager	QP Release