

QUALITY DIVISION
CERTIFICATE OF ANALYSIS

NAME OF THE PRODUCT : FUROSEMIDE BP			
BATCH No. :	23047H1ARIIX	BATCH SIZE :	649.90 Kgs
MFG. DATE :	Nov. 2023	A. R. No. :	IBDA - 241639
EXP. DATE :	Oct. 2028	DATE :	21/05/2024
SPECIFICATION No. / REV. No. : TS/API/H/BP/ 4.0			
CUSTOMER NAME / ITEM CODE : PT TATARASA PRIMATAMA			

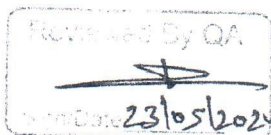
TESTS	SPECIFICATIONS	RESULTS
CHARACTERS	Appearance : A white or almost white, crystalline powder. Solubility : Practically insoluble in water, soluble in acetone, sparingly soluble in Ethanol (96%), practically insoluble in methylene chloride. It dissolves in dilute solutions of alkali hydroxides.	Almost white crystalline powder Conforms
IDENTIFICATION	Infrared absorption spectra of sample and standard are concordant.	Conforms <i>terlampir</i>
APPEARANCE OF SOLUTION	The specified solution is clear and not more intensely coloured than reference solution BY ₅ .	Conforms
RELATED SUBSTANCES (By HPLC)	Impurity A : NMT 0.10% Impurity B : NMT 0.10% Impurity C : NMT 0.20% Impurity D : NMT 0.15% Impurity E : NMT 0.10% Any Unspecified Impurity : NMT 0.10% Sum of Impurity : NMT 0.50%	BQL BDL 0.08% BQL BDL BQL 0.08%
CHLORIDES	NMT 200 ppm	< 200 ppm
SULPHATES	NMT 300 ppm	< 300 ppm
LOSS ON DRYING (at 105°C)	NMT 0.5% w/w	0.18% w/w
SULPHATED ASH	NMT 0.1% w/w	0.07% w/w
ASSAY	98.5% - 101.0% w/w of C ₁₂ H ₁₁ ClN ₂ O ₅ S (on dried basis)	100.1% w/w (odb)
BACTERIAL ENDOTOXIN TEST	NMT 3.6 EU/mg	< 0.25 EU/mg

REMARKS : The above sample **CONFORMS** as per above Specifications.

Note : BDL - Below Detection Limit
BQL - Below Quantitation Limit

PREPARED BY

DATE : 21/05/2024



MANAGER QUALITY CONTROL

DATE : 22/05/24

Butuh penyesuaian terlampir

STANDARISASI CERTIFICATE OF ANALYSIS BAHAN BAKU

No	Nama Bahan	Manufaktur	Referensi pada CoA Manufaktur saat ini	Referensi pada CoA yang diusulkan	Penyesuaian Parameter			Nomor SPBB	Keterangan
					Parameter yang Dihilangkan	Parameter yang Ditambah	Parameter yang direvisi		
1	Furosemide	Ipca Lab	BP	USP 47/FI VI	Appearance Of Solution	Logam Berat ≤ 20 ppm	Pemerian disesuaikan dengan USP 47	RD 02-SBA/138.01	Penyesuaian CoA dari Manufaktur
							Kelarutan disesuaikan dengan USP 47		
					Identifikasi nanoran	Identifikasi disesuaikan dengan USP 47	LOD ≤ 1 % (Usp 47) Cemaran organik disesuaikan dengan U		
							Kadar 98 % - 102%		Update SPBB dan Penyesuaian CoA dari Manufaktur

Diperiksa Oleh

Disetujui Oleh,


25/10/24
Koordinator QC


09/09/24
Koordinator TS


25/10/24
Koordinator QA


25/10/24
Manager QA